Review of Medicines and Medical Devices Regulation

Discussion Paper

Emeritus Professor Lloyd Sansom AO
Mr Will Delaat AM
Professor John Horvath AO
Purpose of this discussion paper

This paper is being released to promote discussion and to assist the Panel undertaking the Review of Medicines and Medical Devices Regulation (the Panel) to form a view about whether there is a shared understanding amongst stakeholders of the issues and options for the future in respect of the regulation of medicines and medical devices in Australia. The Panel has made best efforts to ensure that the discussion paper reflects current regulatory practice and issues. However the discussion paper draws on historic documents and stakeholder submissions on particular issues and this may impact the currency of some of the content. The Panel welcomes corrections of fact as well as input on issues and options. This discussion paper, along with your responses, will form important input to the Panel’s report.

The discussion paper summarises concerns that have been expressed by stakeholders in the past about the regulation of medicines and medical devices and some of the options put forward by stakeholders to address these concerns. These have been drawn from previous reports, from a summary of stakeholder views and options for change provided to the Panel by the Therapeutic Goods Administration (TGA), and from a review of stakeholder submissions to a range of fora, including the Australian Government National Commission of Audit and consultations on Regulatory Impact Statements conducted by the TGA from time to time. As such, the issues, concerns, and possible options for the future outlined in each chapter do not necessarily represent the views of the Panel.

The paper is divided into eight chapters:

- Chapter One provides background to the Review, including Terms of Reference and timeframes, and an overview of the qualifications and experience of the Expert Panel.
- Chapter Two provides an overview of environmental factors of salience to the Review.
- Chapter Three outlines core principles that the Panel has identified to underpin the Review.
- Chapter Four provides an overview of the issues in respect of prescription medicines.
- Chapter Five provides an overview of the issues in respect of generic medicines and biosimilars.
- Chapter Six provides an overview of the issues in respect of over-the-counter medicines.
- Chapter Seven provides an overview of the issues in respect of medical devices.
- Chapter Eight provides an overview of high level issues in respect of the advertising framework for therapeutic goods.

An additional chapter providing an overview of the issues in respect of complementary medicines will be released at a later date.

Chapters four through seven have been designed as standalone chapters. As a result the same issues and options appear in multiple chapters, resulting in duplication for those who choose to read the document in its entirety.

Have your say

The Panel is seeking feedback from stakeholders to inform its thinking. Written submissions are invited on the questions for consideration raised in this discussion paper plus any other relevant
feedback. Stakeholders are also welcome to bring other issues that fall within the Review’s Terms of Reference to the Panel’s attention.

All submissions received by the due date will be analysed and considered by the Panel in formulating its recommendations to government. The Panel has no capacity to respond to individual submissions, but may seek further information or clarification of issues as necessary.

It is the intention of the Panel to publish submissions that it receives on the Review’s webpage (follow the link at www.health.gov.au ). Please complete the Review of Medicines and Medical Devices Submission Cover Sheet (Review Cover Sheet) indicating your permission (or otherwise) for this to occur. The Review Cover Sheet is at Appendix 1 or may be downloaded from the Review’s webpage.

**Lodging your submission**

Completed submissions, in Word 2010 format and PDF format, accompanied by a Review Cover Sheet, can be lodged via email to medicines.review@health.gov.au

or posted to:

Review of Medicines and Medical Devices Regulation Secretariat  
Department of Health  
MDP 67  
GPO Box 9848  
CANBERRA ACT 2601

Submissions are due by COB **5 January 2015**.

Submissions received after this date may not be considered by the Panel.

Please email the Review Secretariat should you have any questions on the process: medicines.review@health.gov.au.
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# ACRONYMS

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<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
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<td>ACMS</td>
<td>Advisory Committee on Medicines Scheduling</td>
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<td>AIMD</td>
<td>Active Implantable Medical Device</td>
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<td>ANZTPA</td>
<td>Australia New Zealand Therapeutic Products Agency</td>
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<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
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<td>ASMI</td>
<td>Australian Self Medication Industry</td>
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<td>CA</td>
<td>Conformity Assessment</td>
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<td>CDPP</td>
<td>Commonwealth Director of Public Prosecutions</td>
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<td>CHF</td>
<td>Consumers Health Forum of Australia</td>
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<td>CMA</td>
<td>Complementary Medicines Australia</td>
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<td>CMI</td>
<td>Consumer Medicines Information</td>
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<td>CRP</td>
<td>Complaints Resolution Panel</td>
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<td>CTD</td>
<td>Common Technical Document</td>
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<tr>
<td>EAP</td>
<td>Expedited Access Pre-market Assessment (US)</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration (US)</td>
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<td>GHTF</td>
<td>Global Harmonisation Task Force</td>
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<td>GMDN</td>
<td>Global Medical Device Nomenclature</td>
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<td>GMiA</td>
<td>Generic Medicines Industry Association</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</td>
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<tr>
<td>ICMRA</td>
<td>International Coalition of Medicines Regulatory Authorities</td>
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<tr>
<td>IMDRF</td>
<td>International Medical Device Regulators Forum</td>
</tr>
<tr>
<td>IVD</td>
<td><em>In vitro</em> diagnostic</td>
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</tbody>
</table>
MA   Medicines Australia
MHRA  Medicines and Healthcare Products Regulatory Agency (UK)
MTAA  Medical Technology Association of Australia
NATA  National Association of Testing Authorities
NCCTG National Coordinating Committee on Therapeutic Goods
NCEs  New Chemical Entities
OECD  Organisation for Economic Cooperation and Development
OTC   Over-the-counter Medicines
PAGB  Proprietary Association of Great Britain
PBAC  Pharmaceutical Benefits Advisory Committee
PI    Product Information
PIC/S  Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
PIP   Poly Implant Prostheses
QMS   Quality Management System
RCPA  Royal College of Pathologists of Australasia
SUSMP Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard)
TGA   Therapeutic Goods Administration
TGAC  Therapeutic Goods Advertising Code
TGACC Therapeutic Goods Advertising Code Council
CHAPTER ONE: BACKGROUND TO THE REVIEW

On 24 October 2014 the Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash announced the establishment of an expert panel to undertake an independent Review of Medicines and Medical Devices Regulation (the Review). The Review will examine the Therapeutic Goods Administration’s regulatory framework and processes in respect of prescription, over-the-counter, and complementary medicines and medical devices with a view to identifying:

- Areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and

- Opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

Review Terms of Reference

The Panel has been asked to undertake the Review in accordance with the following Terms of Reference.

Background

1. Australia has, by a number of different measures (life expectancy, survival with cardiovascular disease, survival with a range of cancers), amongst the best health outcomes of the OECD countries.

2. The regulatory framework of the Therapeutic Goods Administration (TGA) provides an important protection to the Australian community ensuring only safe and effective medicines and medical devices are granted authority to be marketed and/or exported.

3. The TGA also performs crucial post-market roles including the regulation of advertising for therapeutic products and the monitoring of adverse events to ensure the ongoing safety of therapeutic products.

4. A safe and effective regulatory framework for medicines and medical devices should balance safety and market access priorities to the benefit of patients and industry and align with the government’s commitment to increase productivity and competitiveness.

5. It is timely to review the regulatory framework and processes under which the TGA operates, to identify opportunities to improve its operations. This will ensure the TGA is able to operate effectively and efficiently in comparison with high quality international regulators, in respect of regulatory imposts such as timeframes and costs to industry, while also maintaining appropriate public health and safety protections.

Scope of the Review

6. The Review will benchmark TGA regulatory arrangements against trusted international authorities.
7. The Review will make recommendations and related implementation information to:
   a. Ensure there is an appropriate balance between risk and benefit in the regulation of prescription, over-the-counter, complementary medicines and medical devices, as well as access for individuals to unapproved medicines and medical devices;
   b. Simplify and streamline the approval processes undertaken by TGA. This will include recommendations on:
      i. fast tracking approvals processes for medicines and medical devices;
      ii. opportunities for working together with trusted regulators in other jurisdictions, including the potential for work-sharing assessments for products marketed in multiple countries; and
      iii. exploring how risk assessments, standards and determinations of trusted regulators can be used more extensively by Australian regulators when approving the supply of medicines and medical devices.
   c. Ensure regulatory arrangements are sufficiently flexible to accommodate developments in medicines and medical devices, including exploring opportunities to streamline approvals that cross regulatory categories;
   d. Improve the processes that assist industry, researchers and consumers to navigate the regulatory system for medicines and medical devices;
   e. Support work underway on medical device reforms and clinical trial approval arrangements in Australia; and
   f. Any other matters that the review committee regards as important and relevant to the safe and efficient supply of effective medicines and medical devices to the Australian people.

8. The Review will not make recommendations in relation to:
   a. Any aspect of the Pharmaceutical Benefits Scheme;
   b. Work by the Department of Health on the reimbursement systems, including reimbursement and or subsidy of medicine and medical devices;
   c. National Health and Medical Research Council arrangements relating to research and development; or
   d. Work currently underway by the Department of Health and the Department of Industry on ethics processes for clinical trials.

9. The Review report will be provided to the Minister for Health, copied to the Prime Minister, the Assistant Minister for Health, and the Parliamentary Secretary to the Prime Minister responsible for deregulation, by 31 March 2015.

Additional requirements

In addition to the Terms of Reference the Panel has been asked to identify:

- Opportunities for reducing red tape burden in the short and long term.
Chapter One: Background to the Review

- Strategies for ensuring red tape reduction can be sustained.
- Issues threatening the achievement of reductions in regulatory burden.

Timeframe for the Review

The Panel will undertake the Review in two stages:

**Stage one** – The first stage of the Review will focus on the regulation of prescription medicines, over-the-counter medicines and medical devices. The Panel will make recommendations to government on the regulatory framework for these therapeutic goods by 31 March 2015.

**Stage two** – The second stage of the Review will focus on the regulatory framework for complementary medicines. The Panel will have a particular focus on this area of regulation during the second quarter of 2015 with a view to making recommendations to government on the regulatory framework for complementary medicines by mid-2015.

Expert Panel

**Emeritus Professor Lloyd Sansom AO (Chair)**

Professor Sansom is a distinguished educator, researcher and policy adviser. He has sat on numerous government and industry advisory groups. He played a major role in the development of Australia’s National Medicines Policy and was Chair of the Pharmaceutical Benefits Advisory Committee between 2001 and 2011.

**Mr Will Delaat AM**

Mr Delaat has over 40 years of experience in the pharmaceuticals industry in a range of roles. He was Managing Director of Merck, Sharp & Dohme (Australia/NZ) for 11 years to 2008 and the Independent Chairman of Medicines Australia until December 2011. Mr Delaat is currently on the Boards of a number of pharmaceutical companies including Pharmaxis Pty Ltd and EnGeneIC Ltd.

**Professor John Horvath AO**

Professor Horvath was the Australian Government’s Chief Medical Officer from 2003 to 2009. He continues to advise the Department of Health as principal medical consultant and is on numerous health related Boards and Committees, including the Prostheses List Advisory Committee, which he chairs.
CHAPTER TWO: ENVIRONMENTAL FACTORS OF SALIENCE TO THE REVIEW

Australian health care consumers and the broader community have an expectation that therapeutic goods available on the Australian market will be of high quality, safe to use, and efficacious. There are risks as well as benefits associated with the use of therapeutic products and information asymmetry between those who produce therapeutic goods and those who use them. That is, most health care consumers do not have the necessary knowledge to themselves assess whether a therapeutic product is of high quality and safe for them to use. As such, they rely on Government Health authorities to make this assessment on behalf of the community so that they can feel confident in their use of medicines and medical devices.

The regulation of medicines in Australia and internationally has evolved over many years. This evolution has at times been driven by tragedy, such as the discovery in 1961 of the link between use of the drug thalidomide in pregnancy and the incidence of multiple severe congenital abnormalities in babies. Prior to that time, regulation was focussed on ensuring that medicines were of good quality and that false claims about the efficacy of medications were not made. However, post thalidomide, regulation of medicines both internationally and in Australia have focussed on safety and efficacy, as well as quality. These three pillars continue to underpin Australia’s regulatory framework for medicines today and, in the Panel’s opinion, should continue to do so.

In comparison to the regulation of medicines, the regulation of medical devices internationally is relatively immature. Medical device regulation in Australia focuses on quality and safety as well as on the performance of the device as intended by the manufacturer. As the safety and efficacy of medicines and devices can only be confidently assured after the products have been used by many people in real world conditions (as opposed to clinical trial settings), post-market surveillance is critical to the regulation of all therapeutic goods. Industry, health practitioners, and consumers all have a vital role to play in such surveillance.

Australia’s National Medicines Policy (the Policy) is recognised by stakeholders, including governments, health care consumers, health practitioners, and the medicines industry, as providing an important policy framework for medicines nationally. The Policy establishes four central policy objectives, namely:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry.

While the Policy is focused on medicines, these objectives can just as easily be extrapolated to other therapeutic products, such as medical devices.

The Policy considers that the quality, safety and efficacy of medicines available in Australia should be equal to that of comparable countries and that, to this end:
• nationally standardised regulation of medicines should be managed through rational and transparent criteria and processes;
• regulation should ensure that appropriate practices are followed in the development, production, supply and disposal of medicines, and that any problems are met with a quick, effective and appropriate response;
• the level of regulation should be consistent with the potential benefits and risks for the community and based on appropriate risk-assessment processes;
• the pre-marketing assessment of medicines should aim towards both assurance of quality, safety and efficacy, and timely availability;
• there should be an effective post-market monitoring system (for example, for adverse drug reactions), to ensure ongoing assessment of safety;
• regional and international harmonisation of regulatory requirements should be pursued vigorously to reduce duplication and unnecessary restrictions and to facilitate early availability of therapeutic advances; and
• a positive and cooperative relationship should be maintained between the regulators and the medicines industry, with effective models for co-regulation being used wherever appropriate.²

The Policy also emphasises the importance of ensuring that consumers and health practitioners have timely access to accurate information and education about medicines so as to assist them to use these products judiciously and appropriately in order to maximise health outcomes while minimising risks. To the extent possible, the Policy calls on policy partners to:

Recognise the primary position of the consumer. Industry must therefore be able to communicate directly and clearly with health practitioners and provide information to potential consumers about the nature and benefits of the products. They should be able to do so by means of educational materials, Consumer Medicines Information, and responsible advertising, where to do so will enhance the health outcomes of the Australian people.³

A responsible and viable medicines industry is also seen as central to the National Medicines Policy. The Policy notes that achievement of the first three policy objectives: namely access; quality, safety and efficacy; and quality use of medicines, requires the continued existence of a responsible and viable industry in Australia. Central to this is the provision of a consistent and supportive environment for the industry and appropriate returns for the research and development, manufacture, and supply of medicines.⁴

The policy objectives and associated requirements outlined in Australia’s National Medicines Policy provide a useful reference point for the Panel in assessing the current regulatory framework for medicines and medical devices. These objectives were developed with, and continue to have the support of, key stakeholders across governments, consumers, health practitioners and industry and, as such, provide a useful touch point for the Review.

Within this context, other factors impacting the Review include: consumer advocacy; government policy settings; globalisation and innovation of the medicines and medical devices industries; and a
growing trend towards international harmonisation of regulatory practice in respect of therapeutic goods.

**Consumer advocacy**

Quality assurance of therapeutic goods is both necessary and desirable, providing an important protection for public health and safety and ensuring that health care consumers can feel confident in the products that they use. But evaluating therapeutic goods for safety, quality, and efficacy is both expensive and time consuming. Delays in the process can result in delays in access by health care consumers to therapeutic products, while the costs involved in seeking marketing approval are reflected in the eventual price of the product to the community.  

Across the globe, regulators of therapeutic products are facing increasing consumer demand for early access to novel therapies. In Australia, such advocacy often focusses on subsidised access through the Pharmaceutical Benefits Scheme, however the timeframes for Therapeutic Goods Administration (TGA) approval of such therapies and the lack of an expedited route of approval for medicines and medical devices that are: used to treat serious or life threatening conditions; represent a major advancement in treatment; or are used to treat conditions where there is significant unmet clinical need, have also been a subject of concern. Within this context, the capacity of the regulatory system to appropriately balance the benefits to consumers of having early access to promising new treatments with the risks of accessing therapies, the safety and efficacy of which are still being established, is becoming increasingly important.

**Government policy settings**

The Review is part of the Australian Government’s efforts to boost productivity and competitiveness and to reduce unnecessary or ineffective regulation.  
The Australian Government has committed to reducing regulatory burden for businesses, community groups and individuals. The Government’s deregulation agenda was set out in its election policy Boosting Productivity and Reducing Regulation. The policy:

> ...acknowledges that some degree of regulation is a desirable and essential element of efficient markets, productive industries and harmonious communities [but notes that]... excessive and unnecessary regulation reduces productivity and investment, stifles job creation, creates uncertainty and saps confidence...Achieving a reduction in regulation across the economy represents an enormous opportunity to increase Australia’s productivity and competitiveness.

The Government has set a target to reduce regulatory burden by $1 billion per annum and has put in place structures and incentives to assist with the achievement of this target.  
The regulation of therapeutic goods in Australia is fundamental to the provision of a safe and cost effective health system. But there are opportunities to revise regulatory requirements and processes so as to reduce regulatory burden on businesses while achieving the desired intent of ensuring that therapeutic products on the Australian market are safe, high quality and clinically effective. Reducing
unnecessary time delays and costs to industry also benefits health care consumers through earlier, cost effective, access to novel medicines and medical devices.

Consistent with the Terms of Reference for the Review, the Panel will be examining opportunities to remove or streamline regulatory requirements that are unnecessary, duplicative, ineffective or inefficient, without undermining the safety or quality of therapeutic goods available in Australia.

The competitiveness agenda

On 14 October 2014 the Australian Government released its *Industry Innovation and Competitiveness Agenda – An action plan for a stronger Australia*. This agenda is closely aligned with the deregulation agenda, with one of the key ambitions under the Plan being to create a lower cost, business friendly environment by: reducing the burden of regulation; reducing the burden of taxation; and improving access to international markets and opening up the economy to greater domestic and international competition. Under this initiative the Government has adopted the principle that:

> ...if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is good reason to do so.

The policy requires all Commonwealth Government regulatory and risk assessment processes to be reviewed against this principle.

There has already been significant harmonisation of regulatory standards between therapeutic goods regulators internationally, with the adoption of common data dossiers etc. However, the Review will examine how international risk assessments might be better utilised within the Australian system and whether there is ‘good reason’ to impose additional requirements in assessing medicines and medical devices for the Australian market.

As part of its Innovation and Competitiveness Agenda the Government also announced that:

- It would enable Australian manufacturers of medical devices to register routine medical devices using conformity assessment certification from European notified bodies; and
- Establish Industry Growth Centres, one of which will focus on the medical technologies and pharmaceutical sectors.

The Government’s deregulation and competitiveness agendas are consistent with the objective of the *National Medicines Policy* to support a responsible and viable medicines industry in Australia by ensuring that industry and health policies work together to provide a consistent and supportive environment for the medicine and medical device sectors. Such policies, implemented within an overarching framework of protecting public health and safety, assist industry but also have flow on impacts in terms of timely and cost effective access to safe and efficacious therapeutic products by the Australian community.
Chapter 2: Environmental Factors of Salience to the Review

The global medicines and medical devices industry

The medicines and medical devices industries represent major global markets. According to Medicines Australia, the global medicines market was valued at $942 billion in 2011 and is growing steadily.¹⁰ Globally the medical technology market was valued at $US325 billion in 2011, with a compound annual growth rate of 7 per cent since 2005.¹¹

The vast majority of medical devices and medicines, excluding over-the-counter and complementary medicines, on the Australian market are global products. Manufacturing and distribution supply chains are complex, multi-faceted and globally integrated. The ability of a regulator to assure the safety, quality and efficacy of a product in Australia requires knowledge of, and confidence in, these supply chains. Given this complexity, international regulatory collaboration is an important feature of an effective and responsive regulatory system.

The Australian medicines and medical devices industry

In 2012-13 the Australian medicines industry had a turnover of more than $23 billion¹² and in 2010-11 Australian medicines manufacturing contributed an estimated $9.7 billion to the economy.¹³ The Australian medical technology industry had a turnover of approximately $10 billion in 2012, imported goods to the value of $4.4 billion, and exported goods worth $1.9 billion.¹⁴ Taken together, medical technology (devices and diagnostics) and pharmaceuticals is Australia’s largest elaborately transformed manufacturing export sector.¹⁵

Australian medicines industry

The Australian medicines industry is a major high tech industry. It employs an estimated 41,000¹⁶ people, around 13,000 of which are in the pharmaceutical manufacturing sector, and is one of Australia’s biggest employers of science graduates.¹⁷ The Australian industry spends around $1 billion per annum on Research and Development.¹⁸

A December 2008 report by the Pharmaceuticals Industry Strategy Group notes that revenue pressures and consolidation in the multinational corporations sector are:

...fundamentally redefining the industry business model from one hitherto based on vertical integration, to one based increasingly on virtual integration, characterised by partnering at multiple points within the development chain with service providers, research based biotechnology companies, universities and medical research institutes....¹⁹

The authors of that report considered Australia well placed to exploit this trend given, for example, its successful biotechnology industry and the quality of its scientific and medical research base and infrastructure. But they asserted that there is a role for government in ensuring that ‘the regulatory environment appropriately supports high quality [research and development] and does not unduly obstruct clinical trial activity.’²⁰

Australian biotechnology industry

According to the Strategic Review of Health and Medical Research report (the McKeon Review), the biotechnology industry in Australia now includes over 1000 companies, and has grown at 17 per cent
Biomedical companies comprise the majority of biotech companies listed on the Australian Securities Exchange. According to the 2013 Scientific American Worldview Scorecard, which assesses countries against a number of measures considered to support the development of domestic biotechnology industries, Australia ranks seventh overall, of 54 countries, with Singapore the only country in the Asia-Pacific region ranking above Australia. As other countries develop their expertise and investment in the biotechnology sector there is a risk, however, that Australia’s global competitiveness may decline. As with the pharmaceutical industry, appropriate and responsive regulatory frameworks will be important in ensuring that Australia retains its standing as a leading location for biotechnology companies in the Asia-Pacific region.

**Australian medical technology industry**

The terms medical technology industry and medical device industry are both used widely. According to the Medical Technology Association of Australia, there are over 500 medical technology companies in Australia with products included on the Australian Register of Therapeutic Goods.

The industry employs over 19,000 people, with a large number of these employed in the manufacturing sector (estimated at 12,545 in 2009-10). In 2011-12 the investment in research and development by Australian medical and surgical equipment manufacturers was $237 million, an increase of approximately 9 per cent compared to the previous year. The number of Australian medical technology patent grants has grown steadily since 2011, reflecting industry innovation. In order to respond to innovation, regulators must keep abreast of scientific developments and be responsive to changing expectations from communities, health care providers, and industry about the timeliness of access to these new technologies.

**International cooperation and harmonisation**

International regulatory collaboration has made significant strides over recent years and both industry and governments recognise the proven benefit and success of enablers such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme.

The International Coalition of Medicines Regulatory Authorities (ICMRA) is a global mechanism for governance and collective strategic planning, direction, and evaluation at the Heads of Regulatory Agency level. It was established in December 2013 to facilitate international leveraging and resource savings, reduce time to market for industry by building confidence between regulators and their assessments, and by building deeper collaboration among regulators (e.g. information exchange, mutual reliance and sharing of resources). ICMRA aims to integrate, manage and leverage these initiatives and enablers more strategically and efficiently; and identify and implement opportunities for work-sharing and mutual reliance, and sharing of knowledge and best practices. This means

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1The measures are: protection of intellectual property; intensity of effort to drive innovation in biotechnology; enterprise support; education/workforce; foundations, including business expenditure on R&D; and policy and stability, including regulatory quality.
Chapter 2: Environmental Factors of Salience to the Review

regulators will have the option of placing greater reliance on data/reports from other regulators who have achieved a recognised capacity/competence. ICMRA will also drive greater convergence of national regulatory systems throughout the full life-cycle of medicinal products.

3 Ibid. p. 4.
4 Ibid.
5 Ibid, p. 6.
9 Ibid. p. ix.
11 Medical Technology Association of Australia (2013), Medical Technology: Key facts and figures 2013, p. 4.
20 Ibid. p. xix.
24 Ibid. p. 19.
26 Ibid. p. 27.
CHAPTER THREE: PRINCIPLES UNDERPINNING THE REVIEW

The Panel has identified a number of core principles which we believe should underpin the Review and provide a lens through which issues and options can be viewed.

**Principle 1**

The role of regulation is to manage risk in order to protect public health and safety.

**Principle 2**

The level of regulation should be commensurate with the risk posed by the regulated products.

**Principle 3**

A risk-benefits approach to the regulation of therapeutic goods is appropriate.

**Principle 4**

The regulation of therapeutic goods should take a whole of lifecycle approach. As a result, the regulatory system must:

- Have capacity to source and analyse data as it becomes available.
- Recognise and respond in a timely way to changes in the risk profile of products across their lifecycle.
- Provide for whole of life solutions, from product development to withdrawal/disinvestment.
- Be transparent and understood by all stakeholders, including manufacturers and sponsors of therapeutic goods, health professionals, and consumers.

**Principle 5**

The ultimate responsibility for medicines and medical devices regulation should remain with the Commonwealth.

- Australia should maintain its capacity to undertake assessments of medicines and medical devices for safety, quality, and efficacy.
- The role of the regulator undertaking this assessment should be considered in light of approaches taken internationally.

**Question for consideration:**

Are there any additional principles that should be considered?
CHAPTER FOUR: REGULATION OF PRESCRIPTION MEDICINES

All prescription medicines (referred to subsequently in this chapter as medicines) in Australia are subject to regulation, the purpose of which is to protect public health and safety. A large part of this regulation is under the *Therapeutic Goods Act 1989* (the Act), which outlines the basic characteristics, such as safety, quality, efficacy or performance that therapeutic goods, including medicines, must demonstrate before they can be lawfully imported, manufactured, supplied or exported in Australia. The Act also creates various penalties that can be imposed by the Therapeutic Goods Administration (TGA) or the courts for any breaches of these regulatory requirements.

The Australian scheme is administered by the TGA, which was established in 1989 as a division of the Department of Health. In respect of medicines, the TGA:

- conducts a pre-market assessment, prior to the medicine being entered onto the Australian Register of Therapeutic Goods (ARTG);
- undertakes post-market monitoring and enforcement of standards (once the product is on the ARTG);
- licenses Australian manufacturers; and
- verifies overseas manufacturers’ compliance with the same standards as their Australian counterparts.

Once a medicine is approved and entered onto the ARTG, the TGA continues to monitor the product in the market through therapeutic product vigilance. This may include information collection, monitoring, evaluation, and risk management. The extent of post-market monitoring required depends on what is already known about the particular medicine at the time of the TGA’s assessment.

While Australia’s regulation of medicines is highly regarded internationally and is generally viewed as effective, there are always opportunities for improvement. A range of previous reviews, inquiries and/or stakeholder consultations have examined aspects of the regulation of medicines in Australia and identified a number of issues or concerns. These issues can generally be grouped into five themes:

1. There is duplication of regulatory processes, which creates an unnecessary additional burden on industry.
2. The regulatory framework lacks the necessary flexibility required to facilitate early access to innovative products.
3. Some regulatory requirements are not considered to be commensurate with the risk posed by the regulated products.
4. The regulatory framework is overly complex and poorly understood by many of those who have to interact with it.
5. Some TGA processes are considered to be overly burdensome and out of step with technology.
An overview of the issues raised in respect of each of these areas of concern is provided below. The issues, concerns, and possible options for the future outlined in each section do not necessarily represent the views of the Panel. Rather they have been drawn from previous reports, from a summary of stakeholder views and options for change provided to the Panel by the TGA, and from a review of stakeholder submissions to a range of fora, including the Australian Government National Commission of Audit and consultations on Regulatory Impact Statements conducted by the TGA from time to time. They are documented here in order to promote discussion and to assist the Panel to form a view about whether there is a shared understanding amongst stakeholders of the issues and of options for the future.

**Theme 1: Duplication of regulatory processes**

The key area of duplication identified by stakeholders is assessment by the TGA of products that have already been assessed and approved by a trusted overseas regulator.

For medicines to be supplied and marketed in Australia they must be included on the ARTG. In respect of medicines containing new active substances, known as new chemical entities (NCEs), the TGA conducts a detailed evaluation of the product for safety, quality and efficacy, in order to determine if, on balance, the benefits of taking the medication outweigh the risks. The TGA undertakes this detailed evaluation irrespective of whether the new medicine has already been assessed by a trusted overseas regulator, such as the European Medicines Agency (EMA) or the United States Food and Drug Administration (FDA).

The duplication of effort between Australian and international regulators involved in market authorisation for these new medicines has been identified as an issue in previous reviews and is also of concern to the Australian Government. Advocates for greater use of overseas assessment reports point to the fact that very few drugs that are approved by one major regulator are subsequently rejected by another. As such, they view the TGA assessment as unnecessary and note that it creates a barrier to timely access by consumers to novel new therapies that have been approved overseas. In addition, a full TGA assessment is seen as imposing an unnecessary regulatory and cost burden on industry, as it necessitates the sponsor of the medicine submitting a comprehensive data dossier and addressing any queries from the TGA, thus duplicating their effort in getting the product approved in other key markets.

As outlined in the *Industry Innovation and Competitiveness Agenda, An action plan for a stronger Australia*, the Australian Government has adopted the principle that:

> ...if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so. All Commonwealth Government regulatory standards and risk assessment processes will be reviewed against this principle.¹

In the context of medicines, this principle means that where a medicine has been approved under a trusted overseas risk assessment, the TGA should not impose any additional requirements, unless there is good reason to do so. This raises a number of issues for consideration:

1. How might a ‘trusted overseas regulator’ be defined?
2. Is there good reason why Australia should ‘impose additional requirements’ in respect of the approval of medicines?

3. What does approval of a ‘product’ mean in the context of medicines? Does the product have to be identical in all regards or can there be variations that do not necessitate a full or partial re-assessment? How should this be determined?

**Issue 1 – How might a trusted overseas regulator be defined?**

Most countries assess medicines for safety and efficacy prior to approving them for market, but the nature and extent of the assessment that is undertaken can vary markedly. If Australia were to register medicines based on an assessment by an overseas regulator, how is the Australian public to be reassured that this assessment will have been conducted with the same skill, depth of knowledge, and rigour as currently occurs in Australia? One option may be to develop a set of transparent criteria against which overseas regulators would be assessed in order to designate them as ‘trusted’.

**Questions for consideration:**

What options are available for determining ‘trusted overseas regulators’?

If a criteria based approach were to be adopted, what criteria should apply in determining whether or not an overseas regulator is trusted?

If Australia was to identify trusted overseas regulators whose assessment decisions it would accept, there may be occasions where one trusted regulator approves a medicine for certain indications while another trusted regulator rejects the medicine for the same indications. While this situation is only likely to occur infrequently, it is inevitable that it will happen from time to time. Such situations may cause consternation among consumers and health professionals if Australia was to always err on the side of the approving authority. One option to manage such situations would be for the TGA to undertake an appropriate assessment of its own in such situations, where the medicine is not yet included on the ARTG. Such an assessment could look at the evidence that contributed to the disparate decision by the two authorities. If the medicine has already been included on the ARTG, rejection of the medicine for the same indications by a trusted overseas regulator could trigger a review by the TGA whereby it examines the reasons for the rejection and their implications for the continued inclusion of the medicine on the ARTG.

**Questions for consideration:**

If the TGA receives an application for registration of an NCE in Australia and the NCE has been approved by one trusted overseas regulator but rejected by another, should the submission be assessed by the TGA? If not, why not?

What other options would ensure that the health and safety of Australian consumers is protected?

If a trusted overseas regulator rejects an application for marketing of a medicine for the same indications for which that medicine has been registered in Australia, should this spark a review by the TGA?
Issue 2 – Is there good reason for Australia to impose additional requirements?

The Common Technical Document (CTD) is a set of specifications for a dossier for the registration of medicines which is utilised by many regulators internationally. The CTD was developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and adopted by the TGA in 2004. The CTD is a harmonised format for applications for registration of NCEs, however, actual content requirements may still differ between countries that have adopted the CTD.

The CTD is divided into five modules. Module 1 includes administrative information and prescribing information specific to the country in which the application is being lodged. Modules 3-5 address quality, safety (non-clinical study reports), and efficacy (clinical study reports) respectively, while Module 2 provides a summary of Modules 3-5. As such, all things being equal (for example, same indications, same dose, same route of administration, same site of manufacture), if an application for registration of an NCE has been assessed and approved by a trusted overseas regulator, that regulator would have assessed, for the proposed indications, the quality, safety and efficacy data provided by the sponsor. It could be argued that, unless there are aspects of quality, safety and efficacy that need to be considered in the Australian context, or that new data has become available that may impact the assessment of the product’s safety, quality or efficacy, further assessment by the TGA represents unnecessary duplication which acts as a barrier to timely access by consumers to safe and efficacious new medicines.

Questions for consideration:

Should the TGA approve the registration of a medicine on the ARTG on the basis that it has been approved for the same indications by a trusted overseas regulator? If not, why not?

What value do you believe an assessment by the TGA adds in cases where such an assessment has already been undertaken by a trusted overseas regulator?

Are there aspects of safety, quality or efficacy that need to be considered in the Australian context? If so, what aspects?

Would consideration of these aspects necessitate a full assessment of the entire application by the TGA? If so, why?

Module 1 of the CTD is unique to the country to which the application for registration is being made. Under Module 1, sponsors are required to provide a range of information including:

- Administrative information, for example contact details of the applicant and information about product patents;
- Product Information, for example information and/or mock ups of package inserts, Consumer Medicines Information, and proposed Australian labelling;
- Information relating to the Good Manufacturing Practice (GMP) status of the manufacturer(s) of the medicine;
- Information about applications for registration internationally; and
- Documentation relating to the pharmacovigilance activities for the new medicine.
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While some of the information provided by sponsors as part of Module 1 is purely factual information that does not need to be assessed, other aspects of the information, such as the details of proposed packaging and labelling or consumer medicines information, would need to be assessed to ensure that it complies with Australian requirements. This would be the case unless Australia was prepared to accept such materials in whatever form they are required by the trusted overseas regulator, an approach which would make it more difficult for consumers and health professionals to access important information to facilitate safer use, as there would be no standard format across all products.

Questions for consideration:

Should sponsors of medicines that have been approved by a trusted overseas regulator have to submit an Australian specific Module 1 of the CTD to the TGA for assessment? If not, why not?

What do you see as the risks and benefits of not requiring sponsors to submit an Australian specific Module 1?

The rationale for accepting assessments of trusted overseas regulators is two-fold. Firstly, it reduces the regulatory burden on sponsors, who would no longer have to prepare a complete CTD for Australia. Rather, if an Australian specific Module 1 is necessary, they could submit this, along with a copy of Modules 2-5 of the CTD submitted to the international regulator, a copy of the regulator’s assessment report and a copy of the certificate of registration. Secondly, it should provide consumers with more timely access to new medicines. If sponsors were to delay applying for registration in Australia until the outcomes of their international applications were known, however, this may potentially result in delayed access by Australian consumers to novel therapies.

That is, the median approval time\(^1\) for new medicines in Australia was 350 days in 2013, compared to 478 days in Europe; 342 days in Japan and 304 days in the United States of America. As such, where applications are made simultaneously to a number of regulators, including the TGA, reliance on the outcomes of an international evaluation may actually delay the registration of a medicine on the ARTG. Similarly, if a sponsor awaits the outcome of an international application before applying to Australia, this could result in significant delays, especially if additional assessment was required by the TGA due to changes that may impact safety, quality or efficacy.

In addition, timely access by Australian consumers to new medicines is generally dependent on timely decisions about both product registration and subsidy. The TGA and the Pharmaceutical Benefits Advisory Committee (PBAC) currently have parallel processes, whereby a submission to the PBAC may be lodged at any time from the date of lodgement of a TGA registration dossier. Any delay by sponsors in lodging a dossier with the TGA would, therefore, have potential flow on effects to subsidy decisions.

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\(^1\) Total calendar days, including both days the application is with the regulator and days that the application is with the commercial sponsor in order to respond to questions from the regulator.
Questions for consideration:

What would be the likely quantum of savings to industry per application, if Australia was to accept assessments of trusted overseas regulators, with or without a requirement to submit an Australian specific Module 1 of the CTD to the TGA for assessment?

Would such an approach:

- Result in delayed access to new medicines by the Australian public? If not, why not? If yes, are there strategies that could be put in place to prevent this from occurring?
- Undermine TGA-PBAC parallel processing mechanisms? If so, how might this be managed?

Issue 3 – What is meant by product approval?

It is not unusual for the sponsor of a medicine to adapt their application for approval of a new clinical entity to the specific market. For example: the sponsor may apply for approval for the medicine to be used for different indications in different countries, taking into account usual clinical practice (which may vary between countries), or there may be changes between countries to other aspects of the product, such as product components and composition; manufacturing sites and process, or containers and closures. Given this, it is likely that an application to Australia to market an NCE will differ in some ways to that approved overseas. Should this negate the principle that where a product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements?

It would undermine the intent of the principle if any change to a medicine or its indications for use in Australia vis a vis that approved by a trusted overseas regulator, resulted in a full assessment of the product by the TGA. Such an approach would also create an incentive for sponsors to keep their application identical rather than adapt it appropriately to the Australian context, which may create perverse outcomes.

Accepting an approval by a trusted overseas regulator irrespective of any change to the medicine or its indications would create risk for Australian consumers, however, as some changes could have a potential impact on safety, quality and efficacy. For example, if the Australian application was for a different indication than that approved overseas, an assessment of the medicine’s toxicity and clinical efficacy in the patient cohort would be required. Similarly, if the manufacturing process was different, it would be appropriate for the Australian regulator to assess the appropriateness of the proposed approach and associated testing procedures.

A risk based approach that is consistent with the underlying principle might be to adopt a policy whereby any change to any aspect of the NCE (as assessed and approved by the trusted overseas regulator) that has the potential to impact safety, quality or efficacy would necessitate further review by the TGA. This review could be limited to those aspects of the application where a change has occurred rather than requiring the TGA to duplicate the assessment of the complete data dossier. This would facilitate a more timely assessment while maintaining safety and quality protections.
Questions for consideration:

Should a change to a medicine that has been approved by a trusted overseas regulator necessitate a further assessment by the TGA in circumstances where that change may impact safety, quality or efficacy? If not, why not?
If yes, should the assessment by the TGA be limited only to those aspects of the application that are impacted by the change?

The introduction of accelerated approval processes internationally also raises issues to be considered by Australia in terms of acceptance of marketing approvals by trusted overseas regulators. Such processes, including adaptive licensing, may see medicines provisionally or conditionally approved based on more limited clinical data than is traditionally required. In these instances the international regulator may impose conditions on the sponsor, such as limiting the use of the drug to defined patient populations and/or requiring further clinical data to be obtained and provided to the regulator so that the risk-benefit balance of the drug can be reassessed (with the potential for the drug to be withdrawn if safety or efficacy concerns emerge).

Questions for consideration:

If Australia was to accept approvals of medicines by trusted overseas regulators, should this include conditional/provisional approvals? If not, why not?
If yes, should the marketing conditions/provisions imposed by the trusted overseas regulator also apply in Australia? If not, why not?
Should there be capacity for Australia to impose its own conditions, either in addition to, or in place of, those imposed by the trusted overseas regulator and if so, why?

Theme 2: Lack of flexibility required to facilitate early access to innovative products

Concerns have been raised by industry, consumers and health professionals that the regulatory framework for medicines is too rigid and cannot accommodate accelerated approval of promising new medicines.

Across the globe, regulators of therapeutic products are facing increasing consumer demand for early access to novel therapies. In response, a number of countries have implemented accelerated approval processes and there are calls for Australia to also have a mechanism for accelerated approval in certain circumstances. For example, in evidence to the House of Representatives Standing Committee on Health, a representative from Merck Sharp and Dohme called for the introduction of expedited registration for life saving medicines. In some markets, efforts have been made to address this demand through mechanisms such as formalised accelerated approval in the United States (US) and conditional marketing authorisation (provisional approval) schemes in the European Union (EU), respectively.
The FDA has implemented four accelerated approval schemes:

1. **FDA Fast Track** to facilitate development, and expedite review, of medicines to treat serious conditions and fill an unmet medical need. Under the fast track scheme the FDA provides:
   - More frequent meetings with the sponsor to discuss the medicine’s development plan and ensure collection of appropriate data needed to support marketing approval.
   - More frequent written correspondence from the FDA to the sponsor about such things as the design of the proposed clinical trials and use of biomarkers.
   - Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.
   - Rolling review, which allows the sponsor to submit portions of a marketing application before submitting the complete application.

2. **FDA Breakthrough** therapy program for medicines for serious or life threatening conditions where preliminary clinical evidence demonstrates the medicine may have substantial improvement on at least one clinically significant endpoint over available therapy. Medicines being considered under the breakthrough program are eligible for:
   - All Fast Track designation features.
   - Intensive FDA guidance on an efficient medicine development program, beginning as early as Phase 1.
   - Organisational commitment involving senior FDA managers.
   - Rolling review and priority review.

3. **FDA Accelerated Approval** Program to allow for earlier approval of medicines that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint. Companies are still required to conduct Phase 4 clinical trials to confirm the anticipated clinical benefit and the medicine can be withdrawn from market if clinical benefit is not demonstrated.

4. **FDA Priority Review**, which directs overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Priority review shortens the review goal date to six months.

The FDA makes the decision whether to accept applications for these four schemes or alternatively to refer the sponsor back to the standard approval process. The fees payable by the sponsor for fast track approvals reflect the additional FDA effort involved in the schemes. The approval rate is about 50 per cent. While the regulatory consideration phase is accelerated under the four schemes, the main reported advantage to industry is assistance with design and facilitation of clinical trials. These schemes usually, but not always, require the full Phase 3 trials to be completed.

In contrast, the EMA is conducting a pilot project on adaptive licencing, which it defines as:

> ...a prospectively planned, adaptive approach to bringing drugs to market. Starting from an authorised indication (most likely a ‘niche’ indication) for a given drug, through iterative
phases of evidence gathering and progressive licensing adaptations concerning both the authorised indication and the potential further therapeutic uses of the drug concerned [adaptive licencing] seeks to maximize the positive impact of new drugs on public health by balancing timely access for patients with the need to provide adequate evolving information on benefits and harms.  

Adaptive licencing utilises different evidentiary requirements (e.g. provisional approval based on the results of Phase 2 rather than full Phase 3 trials). This approach recognises the need for ongoing reassessment of the risk-benefit balance throughout the life-cycle of the medicine as experience is obtained with a patient population. It is anticipated that commercial use of the medicine after provisional approval would commence in a small group of patients with a narrowly-defined indication and potentially be expanded as clinical experience with the medicine grows.

Some patient groups, as well as industry, are advocating for Australia to formally consider ‘rapid approval’ approaches, at least for innovative therapies where there are not currently adequate treatment options. The demand is greatest in oncology but is also present for some other diseases. Such demands need to be balanced against the willingness of patients, health care practitioners, and governments to accept inherent uncertainties about the benefits and risks of products that are an inevitable accompaniment to expedited access.

Factors which have impinged internationally in jurisdictions that have implemented priority or provisional access schemes include: prescriber and patient acceptance (including whether labelling advises that medicines have only been provisionally approved); what mechanisms exist for discontinuing market authorisation if the medicine is subsequently shown to be of limited efficacy; and treatment of provisionally approved medicines by reimbursement authorities.

Given the risks inherent in accelerated approval programs, it is essential that such programs appropriately balance the potential benefits to patients of early access to promising new therapies against the potential serious adverse consequences to which patients may be exposed. This balance is impacted by the patient cohort to whom the medicine is targeted and raises the issue of what criteria should apply to accelerated approval programs. That is, the risks vs benefits of providing accelerated approval for a promising new therapy for patients with advanced pancreatic cancer is very different than the risk vs benefits of providing accelerated approval of a promising new therapy to treat a chronic condition for which therapies are already available. As such, should accelerated approval processes only be available in limited circumstances, such as for NCEs for the treatment of life threatening illnesses?

Questions for consideration:

Should Australia introduce an accelerated approval program(s)? What are the potential risks and benefits of such programs and how might the risks be managed and the benefits maximised?

If Australia were to introduce an accelerated approval program:

- Should there be a single pathway (as per the EU model) or multiple pathways (as per the US approach) to apply?
- What eligibility criteria should apply to the pathway(s)? That is, under what circumstances
Questions for consideration:

could a sponsor apply for accelerated approval of an NCE?

If medicines were to be provisionally approved, based on more limited clinical data than is traditionally required for a full approval:

• What additional requirements, if any, might be appropriate to alert prescribers and/or consumers to the provisional approval and its implications?

• What requirements would need to be in place to manage withdrawal of the medicine from the Australian market if safety or efficacy concerns emerged?

Theme 3: Regulatory requirements are not commensurate with risk

In respect of medicines, stakeholders have identified a number of areas where they believe Australian regulatory requirements are excessive and out of step with requirements internationally. These relate to:

1. The requirement to get TGA approval of most variations to a registered medicine.

2. Approval processes for minor variations to a medicine for the purpose of export.

3. Access by patients with non-life threatening conditions to unapproved medicines under the Special Access Scheme.

4. Inadequate emphasis on post-market surveillance and supportive data collection and analysis.

Issue 1 – Approval of variations

The standard conditions of registration that apply to all prescription medicines require the sponsor to notify the TGA of changes or variations in respect of any information concerning the medicine, and provides that, where necessary, the changes or variation shall not be implemented until approved by the TGA delegate. This means that once a medicine is entered on the ARTG the information cannot be changed without approval. There are some minor exceptions, such as changes to the local handling agent of the active pharmaceutical agent and excipient; or to the supplier or manufacturer of non-sterile containers or container components, but the vast majority of changes relating to a registered medicine must be both notified to, and approved by, the TGA.

The Therapeutic Goods Act 1989 provides for sponsors to request:

• updates to an ARTG entry that is incomplete or incorrect;

• safety-related variations to an ARTG entry and consequential changes to the Product Information, such as removing an indication or adding a warning or precaution; and

• other variations to an ARTG entry that do not have the effect of creating a separate and distinct good, provided that the change does not reduce the quality, safety or efficacy of the medicine.

If the variation creates a separate and distinct good, sponsors must apply to the TGA for approval of a new registered medicine. Variations that would create a separate and distinct good include new
strengths, new dosage forms, different directions for use, formulation changes, changes in trade name, and extensions of indication.

The timeframes for approval of variations by the TGA differ depending on the nature of the variation requested. Major variations which require evaluation of a full dataset, or any combination of quality, nonclinical, clinical and bioequivalence data, have a statutory timeframe of between 175 and 255 working days. Variations that only require evaluation of quality-related data (Category 3 applications) and lower risk variations for which the sponsor can provide an assessment of their own data for the TGA to verify (known as self-assessable requests), have a statutory timeframe of 45 working days. Requests to correct an incorrect or incomplete ARTG entry or to make safety-related variations to the ARTG entry have no statutory timeframes.

These requirements are considered highly risk-averse by many in the industry and do not align with regulatory approaches taken by other trusted regulators internationally. For example, from October 2010 the EU implemented a simpler and more flexible legal framework for variations to marketing approvals aimed at reducing burden on industry and further harmonising requirements across the EU while maintaining public protections.\(^4\)

Under these reforms, the EU classified variations into a number of categories, based on the level of risk they posed to public health and their impact on the quality, safety and efficacy of the medicinal product concerned. These categories include:

- **Minor variations Type IA**, covering variations such as:
  - A change to the name and/or address of the marketing authorisation holder;
  - A change in the name of the active substance;
  - A change in the name and/or address of a manufacturer of the finished product;
  - A change to pack size of the finished product that is already within the currently approved range;
  - Minor changes to an approved test procedure.

As long as predefined conditions are met, such changes are subject to a ‘do and tell’ procedure, whereby the sponsor may implement the changes and notify the EMA. In most instances the notification must be within 12 months but a subset of Type IA variations (referred to as Type IA IM), which require continuous supervision, must be notified to the EMA immediately after implementation.

- **Minor variations Type IB**; are defined as a minor variation that is neither a Type IA variation nor a Type II variation nor an Extension. Examples include: minor changes to an approved test procedure for a biological excipient; change in pack size of a finished product that is outside the currently approved range; and addition of new tests and limits applied during the manufacture of the product.

Type IB variations must be notified to the EMA by the sponsor prior to implementation, but do not require a formal approval. Upon acknowledgement of receipt of a valid notification, the sponsor must wait a period of 30 days to ensure that the notification is deemed acceptable before implementing the change (‘Tell, Wait and Do’ procedure).\(^5\)
Similarly, the FDA allows a range of ‘minor changes’ to be included in a sponsor’s annual report rather than be approved prior to implementation. FDA Guidance lists examples of variations that they consider to have a minimal potential to have an adverse effect on product quality in areas such as product components and composition; manufacturing sites, process, batch size, and equipment; containers and closures; and labelling. The United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) has also done significant work on variations that only need to be notified rather than approved. There are, therefore, opportunities to learn from international experience in this sphere.

Questions for consideration:

Should Australia adopt a risk-based regime for variations, which allows notifications and/or annual reporting for changes that are at low risk of impacting the quality, safety or efficacy of the product? If not, why not?

If yes, what might such a regime look like? How might notification/reporting procedures be designed so as to minimise burden on sponsors?

Issue 2 – Approval processes for minor variations to a medicine for the purpose of export

For many countries importing medicines from Australia, it is generally considered desirable or mandatory for the medicine to be approved for use and on the market in Australia. Therefore, it is not uncommon for Australian exporters to seek approval for domestic supply before exporting the medicine to another country. In such instances the sponsor may wish to make minor modifications to the domestically approved medicine (e.g. to colouring or flavouring) in order to enhance its acceptance in a particular export market.

As outlined above, however, TGA approval is required for most changes to a medicine that has been entered on the ARTG. Currently, these minor modifications almost invariably lead to the medicine being considered a different product under the Act and therefore the original approval is no longer valid for the export variant. As such, the sponsor must prepare an application for listing of the varied product on the ARTG as an export-only medicine which, when combined with the subsequent assessment of the application by the TGA, can take several months, thereby delaying access to the export market.

If Australia’s approach to the notification and/or approval of variations is to be revised, consideration might be given to how to streamline the process for minor variations to export medicines, without compromising health and safety. This would allow Australian exporters more timely access to export opportunities.

Question for consideration:

How might the process for minor variations for export-only medicines be streamlined so as to facilitate more timely access to export opportunities without compromising health and safety?
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**Issue 3 – Access by patients to unapproved medicines under the Special Access Scheme**

Patients with illnesses that cannot be successfully treated with medicines and medical devices approved in Australia currently have access to unapproved therapeutic goods under a variety of schemes administered by the TGA. The Special Access Scheme allows individual patients to access unapproved therapeutic goods under a range of circumstances. Under the Scheme, patients are classified as either Category A or Category B.

Category A patients are defined as ‘persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment’. A medical practitioner who believes that his or her patient falls into Category A can import/supply an unapproved therapeutic good without approval from the TGA. To do so they must complete a ‘Category A Form Special Access Scheme’ and send it to the product sponsor. This form gives the sponsor legal authority to provide the medicine in question. A copy of the form is to be provided to the TGA within four weeks. This approach would appear to provide timely access to unregistered medicines for Category A patients without imposing an unreasonable administrative burden on medical practitioners.

Question for consideration:

**Is the Special Access Scheme efficient and effective for Category A patients? Are there issues or concerns with the way in which the Scheme currently runs?**

For patients with non-life threatening conditions, who fall into Category B, access to unapproved goods requires TGA approval. Application can be made by phone (where there is an urgent medical need), facsimile or in writing to a TGA medical officer who has delegation under the Act to make a decision regarding the request. In assessing the application, the TGA medical officer considers evidence in respect of the safety and efficacy of the product, the seriousness of the patient’s condition and the qualifications of the requesting medical practitioner. As a general rule, the less serious the clinical need, the higher the degree of evidence needed to support the use of the product. Decisions are generally made within five days.

An application to use an unregistered medicine in Category B patients is required regardless of the level of risk. For example, even if the medicine requested has been approved by a trusted overseas regulator for the indication for which it will be used, an application must be lodged by the medical practitioner and assessed by the TGA delegate. A more risk-based approach could be considered, which focuses scrutiny only on: medicines with high risks of adverse events; medicines proposed for use in novel clinical situations; or those that have not been approved by trusted overseas regulators. In 2013 the TGA received almost 22,000 applications for approval to use an unregistered medicine in a Category B patient. Given these numbers, the implementation of a more risk-based approach to the current approvals process has the potential to improve timeliness and reduce administrative burden for a significant number of patients and their doctors.

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ii A limited number of delegates have also been appointed in some hospitals in respect of a small number of drugs. Applications can be made in writing to these delegates.
Questions for consideration:

Should the Special Access Scheme be revised to narrow the range of circumstances in which TGA approval is required for use of an unregistered medicine in a Category B patient?

- If yes, what criteria might be applied to determine when an approval is required?
- If no, why not? What do you perceive as the risks of such an approach?

**Issue 4 – Inadequate emphasis on post-market surveillance**

The lifecycle of a medicine has traditionally been divided by regulators into two stages: pre-market and post-market. During the pre-market stage, access to the medicine is generally limited to patients who are allocated to the treatment arm of a clinical trial. Once the medicine is registered this changes abruptly, as access is expanded ‘from a relatively small number of highly selected trial subjects to millions of real-world patients who might not fit treatment eligibility requirements as specified on the label.’

This poses challenges for regulators charged with protecting public health and safety.

Clinical trials are used to assess the safety and efficacy of a medicine and to collect data to support an application for marketing approval. Clinical trials provide information about many of the possible adverse effects of a medicine, but they do not detect all possible adverse effects because they generally do not:

- continue for long enough to detect adverse events that may develop over a long period of time;
- include enough patients to detect adverse events that occur only rarely; and
- include all of the different types of people who might eventually use the medicine and who might be more susceptible to some adverse events, such as older people, children, pregnant women, or people with comorbidities.

As such, it is important for effective post-market surveillance to occur in order to identify possible issues with safety or efficacy that may emerge when the medicine is used in a real world setting. This becomes even more important in the face of trends towards early licencing schemes, such as adaptive licensing. Such schemes are being developed by regulators internationally as a means of responding to calls from physicians and consumers for more timely access to novel new therapies. Adaptive licencing seeks to manage a medicine across its lifecycle, including ‘conditional’ approval of promising new therapies, which may ‘involve a trade-off between earlier access for some patients vs an increased level of acceptable uncertainty about benefits and risks, although the degree of uncertainty is expected to diminish with additional evidence generation.’

The TGA currently undertakes post-market monitoring of medicines through: adverse events reporting; monitoring of sponsor’s risk management plans; and environmental scanning, including reviewing the medical literature, reviewing regulatory news, and seeking confidential advice from other regulators. But there have been calls from some stakeholders for the TGA to enhance its post-market surveillance activities, including exploration of issues such as mandated (and remunerated) reporting of adverse events and the adoption of an early post-marketing system to
alert practitioners and consumers to medicines that are only newly registered on the Australian market.

For example, the Review to improve the transparency of the Therapeutic Goods Administration, noted calls by the TGA’s Advisory Committee on the Safety of Medicines to introduce a scheme similar to the UK’s black triangle (▼) alert system, which was designed to alert consumers and health practitioners to the level of risk in the early post-market period. This scheme had been in place for some years in the UK and was considered to have played a useful role in identifying problems in the products that had not emerged in pre-market trials.\(^{11}\)

Stakeholders have also pointed to the potential for interrogation and analysis of large scale, diverse, population data sets, such as the Pharmaceutical Benefits Scheme and Medical Benefits Schedule datasets (and potentially, personally controlled electronic health records), to significantly enhance Australia’s pharmacovigilance capacity. This follows similar calls in the US, where reports by the General Accounting Office and the Institute of Medicine have recommended that the FDA obtain large-scale datasets for post-marketing studies in order to enhance its medication safety activities.\(^{12}\)

Questions for consideration:

Does Australia’s post-market surveillance of medicines need to be enhanced? If so, how might this occur? What would be the features of an effective post-market surveillance system?

If not, why not? Why do you consider the current system effective?

Theme 4: Complex regulatory framework

The Strategic Review of Health and Medical Research\(^{13}\) (the McKeon Review) found that while Australian researchers are making significant discoveries, Australia is slow to translate research into practice and/or to successfully commercialise its discoveries. As a result, benefits to patients (through quicker access to more effective treatments); benefits to governments (through enhanced cost effectiveness and health system performance); and economic growth (from the availability of new medical devices and pharmaceuticals developed or produced in Australia) may not be fully realised.

While there are many factors that impact the translation of research into practice, difficulties experienced by product developers/sponsors in understanding and complying with requirements for pre-market approval, including data requirements, have been identified as problematic. This is particularly the case for small to medium sized enterprises, who struggle to navigate the regulatory system without guidance and/or advice. While there is written guidance available through the TGA website, the correct piece of information can be difficult to find, guidance documents are often voluminous and difficult to navigate, and information may be spread over multiple documents, making it difficult for sponsors to reassure themselves that they are across all requirements. As a result, there have been calls for the TGA to take a more active role in providing regulatory advice and in working with sponsors to assist them to navigate the pre-market approval system.
Questions for consideration:

Is there a role for the TGA in providing a regulatory advice service to product developers/sponsors? If yes, what should the nature and scope of this advice service be? How could risks of regulatory capture be avoided? If not, why not?

Is current guidance material easy to locate, navigate and understand? If not, what are the main issues and concerns? How might this material be improved?

Is the TGA website easy to navigate? If not, how might it be improved?

Theme 5: Overly burdensome processes

Stakeholders have identified a number of TGA systems and processes that they consider to be unnecessarily burdensome. These relate to:

1. Multiple systems and manual processes.
2. Registration of additional indications.

Issue 1 – Multiple systems and manual processes

The TGA currently uses a range of systems in the regulation of medicines and medical devices and still relies on the submission of a significant amount of paper documentation for key processes. Manual transactions place an additional impost on sponsors and health practitioners compared to electronic transactions and also impacts timeliness. Manual processes may also reduce transparency. For example, electronic processes would allow those submitting information to know instantly if it has been received, and could be configured to allow sponsors or health practitioners to track the status of their application through the system.

There is significant scope for TGA processes to be digitised to achieve efficiencies through reduced document preparation, printing, engagement, and through improved application wait times. On-line access to visible milestones and expected completion dates would improve an applicant’s understanding of when approval is likely to be granted, and in turn, assist with forward planning for getting their product to market.

The TGA has advised that it is working towards implementing a single, online portal through which it can transact with industry and medical professionals, which will include use of pre-populated ‘smartforms’ and applicant access to milestone dates and expected completion dates for their applications.

Question for consideration:

What TGA processes do you consider most burdensome and why? How might these be improved?

Issue 2 – Registration of additional indications

In order to extend the registered indications for a medicine to other indications, including paediatric use, the sponsor must submit a full standard application to the TGA. The statutory evaluation time
period available for the TGA to evaluate the application is 255 working days and the fee payable by
the sponsor is $131,600. This cost and time impost acts as a disincentive to sponsors to register the
additional indications, even where clinical practice has demonstrated the benefits of the medicine in
these indications. Registering additional indications for a medicine, especially for use in paediatric
populations, ensures that information about the use of the drug in those circumstances is available
to all health professionals and consumers.

Questions for consideration:

Do current regulatory requirements, costs, and timeframes act as a disincentive to the
registration of additional indications for medicines?

If yes, how might the regulatory framework or processes be changed to reduce the disincentives
and/or provide incentives for the registration of additional indications, especially in paediatric
populations?

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CHAPTER FIVE: REGULATION OF GENERIC MEDICINES AND BIOSIMILARS

Generic Medicines

Similar to the regulation of new prescription medicines, generic medicines are subject to regulation by the Therapeutic Goods Administration (TGA) to protect public health and safety. A generic medicine is a product that:

- has the same quantitative composition of therapeutically active substances as an originator product;
- is bioequivalent to an originator product, or considered to be therapeutically equivalent in the case of topical products; and
- has the same safety and efficacy properties as an originator product.\(^1\)

In the absence of a licensing agreement, generic medicines can only be marketed by a new sponsor once any relevant patent over the originator medicine has expired.\(^2\) Unlike new prescription medicines (new chemical entities), which undergo a full review by the TGA of a clinical dossier that demonstrates the safety, quality and efficacy of the medicine, new generic medicines are assessed for quality\(^3\) and for bioequivalence to the original reference product.

The use of generic medicines has grown rapidly in recent years, and is expected to continue growing as governments around the world adopt strategies to promote use of generics as a means of managing health care costs.\(^3\) The generic medicines sector has been estimated to account for 35 per cent of the Australian pharmaceutical market by volume and 10 per cent by value\(^4\) and industry stakeholders have identified a number of ways in which the sector could expand through streamlining and simplifying the regulatory system.

Biosimilars

A similar biological medicinal product or biosimilar is a version of an already registered biological medicine that has demonstrable similarity in physiochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies.\(^5\) Unlike generic medicines which have the same active ingredient as the reference product, biosimilars are complex microheterogeneous mixtures of isoforms of the desired substance, meaning that evaluation of biosimilars cannot occur in the same way as evaluation of generic medicines.\(^6\) Instead, comprehensive comparability studies are required to generate evidence substantiating the similar nature in terms of quality, safety and efficacy of the biosimilar to the reference product.\(^7\)

As a result, biosimilars are more costly to develop than generic drugs, as they require significant investment in comprehensive studies to produce sufficient data to demonstrate comparability.\(^8\) The

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\(^1\) This comprises assessing the quality of the manufacturing process and the quality of the ingredients of the final product.
The market for biosimilars is at a relatively early stage of development,\textsuperscript{ii} with the United States (US) only introducing a separate registration pathway for biosimilars in 2010.\textsuperscript{9} Industry stakeholders argue that the growth of biosimilars presents an opportunity to reduce costs and promote access to additional treatments.\textsuperscript{10}

**Overview of the key issues**

Previous inquiries, reviews, and/or stakeholder consultations have identified a number of issues or concerns relating to the regulation of generic medicines. These fall into three main themes:

1. There is duplication of regulatory processes, which creates an unnecessary additional burden on industry.
2. Some regulatory requirements are not considered to be commensurate with the risk posed by the regulated products.
3. Some TGA processes are considered to be overly burdensome and out of step with technology.

An overview of the issues specific to generic medicines raised in each of these areas is provided below. With respect to biosimilars, the key issue raised relates to the duplication of regulatory processes.

The issues and views included in this chapter do not necessarily represent the views of the Panel. Rather they have been drawn from previous reports, summaries of stakeholder views provided by the TGA to the Panel, and from a review of stakeholder submissions to various reviews and inquiries. As a number of the concerns raised with respect to generic medicines are similar to those in respect of prescription medicines, this chapter duplicates some of the discussion in Chapter Four.

**Theme 1: Duplication of regulatory processes**

The key issue that has been identified by industry is the duplication of regulatory processes that occurs when the TGA reviews a product already assessed and approved by a trusted overseas regulator. Prior to registration of generic medicines on the Australian Register of Therapeutic Goods (ARTG), the TGA conducts an evaluation of the bioequivalence of the generic to the originator product, as well as reviewing information concerning the quality of the medicine.\textsuperscript{11} This assessment is undertaken regardless of whether the generic medicine has been approved as bioequivalent by a trusted overseas regulator such as the Food and Drug Administration (FDA) or the European Medicines Agency (EMA) and is considered by some to be unnecessary duplication.

In relation to biosimilars, Australia has adopted a number of the EMA's guidelines for assessment of biosimilars, as well as an International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guideline on the assessment of comparability.\textsuperscript{12} As such, TGA review of a comparability assessment that has already been reviewed by a trusted overseas regulator may be viewed by some as unnecessary duplication.

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\textsuperscript{ii} The European Medicines Agency was the first regulatory body to publish guidance on biosimilars in 2005.
Duplication of effort and processes between Australian and international regulators is an issue of concern for both industry and the Australian Government. In the case of generic medicines, duplication of effort through TGA assessment has been viewed as unnecessary, particularly given that most applications for registration of new generic medicines do not involve TGA review of new safety or efficacy data.

The Australian Government has adopted the principle that:

...if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so.\(^\text{13}\)

This principle means that where a generic medicine or biosimilar has been approved under a trusted international risk assessment, the TGA should not impose any additional requirements, unless there is good reason to do so. This raises a number of issues for consideration:

1. How might a ‘trusted overseas regulator’ be defined?
2. What does approval of a ‘product’ mean in the context of generic medicines and biosimilars?
3. Is there good reason why Australia should ‘impose additional requirements’ in respect of the approval of generic medicines and/or biosimilars?

**Issue 1 – How might a ‘trusted overseas regulator’ be defined?**

Most countries assess generic medicines for bioequivalence to the reference product prior to approving them for market, but the nature and extent of the assessment that is undertaken can vary. In the case of biosimilars, regulatory processes are still developing and assessments regarding the comparability of biosimilars to the original reference biological medicine may vary between regulators.

If Australia was to register generic and biosimilar medicines based on an assessment by an overseas regulator, how is the Australian public to be reassured that this assessment will have been conducted with the same skill, depth of knowledge, and rigour as currently occurs in Australia? One option may be to develop a set of transparent criteria against which overseas regulators would be assessed in order to designate them as ‘trusted’.

**Questions for consideration:**

- What options are available for determining ‘trusted overseas regulators’?
- If a criteria based approach were to be adopted, what criteria should apply in determining whether or not an overseas regulator is trusted?

If Australia was to identify trusted overseas regulators whose assessment decisions it would accept, there may be occasions where one trusted regulator approves a generic medicine as bioequivalent to a reference product, while another does not. Similarly, it is possible that assessments regarding the comparability of biosimilars to the original reference product could vary between various regulators. For example, although the EMA guidelines on biosimilars have a number of similarities...
with FDA guidance, the EMA and FDA have different definitions of a biological medicine\textsuperscript{iii} which may lead to variances in assessment due to the different regulatory requirements applicable\textsuperscript{.14}

In respect of a generic medicine, if this situation was to occur and the reference products in both jurisdictions were demonstrated to be identical or interchangeable, it may cause consternation among consumers and health professionals if Australia was to always err on the side of the approving authority. One option to manage such situations would be for the TGA to undertake an appropriate assessment of its own in such situations, where the medicine is not yet included on the ARTG. If the medicine has already been included on the ARTG, rejection of the generic medicine as bioequivalent by a trusted overseas regulator could trigger a review by the TGA whereby it examines the reasons for the rejection and their implications for the continued inclusion of the medicine on the ARTG.

Questions for consideration:

If the TGA receives an application for registration of a generic medicine or biosimilar in Australia which has been approved by one trusted overseas regulator but rejected by another, should the submission be appropriately assessed by the TGA? If not, why not?

What other options would ensure that the health and safety of Australian consumers is protected?

\textbf{Issue 2 – What does approval of a ‘product’ mean?}

In the context of generic medicines, the ‘product’ is a generic version of a previously approved originator medicine which is identical in dosage and indication. As such, considerations about whether a difference in an overseas and Australian product (e.g. in indication or dosage) could affect safety, efficacy or performance would not normally apply to generic medicines.\textsuperscript{iv}

For biosimilars, the ‘product’ is a biological medicine that, based on comprehensive comparability studies, has been determined to be similar in nature to the original reference product. A particular issue arises where the original reference product has more than one indication, as it would generally be necessary to demonstrate similarity separately for each of the claimed indications,\textsuperscript{15} unless it is possible to extrapolate therapeutic similarity shown in one indication to other indications.\textsuperscript{v} As there may be good reason for sponsors of biosimilars to apply for different indications in different markets, an issue could arise whereby the application for registration of a biosimilar would differ in indication from an application overseas.

\textsuperscript{iii} For example, in the United States for largely historical reasons low molecular weight heparins are classified as generic drugs whereas in the EU they are classified as biosimilars.

\textsuperscript{iv} The consideration may apply where the generic medicine sponsor applied for additional indications and provided additional supporting safety and efficacy data, at which point it would be assessed as an application for an additional indication.

\textsuperscript{v} Appropriate scientific justification would be required, for example clinical experience, available literature data and whether or not the same mechanisms of action or the same receptors are involved in all indications.
Similar to the approach suggested for approval of new chemical entities (NCEs), an option consistent with the underlying principle might be to adopt a policy whereby any change to any aspect of the biosimilar (as assessed and approved as comparable by the trusted overseas regulator) that has the potential to impact the comparability of the biosimilar in terms of safety, quality or efficacy would necessitate further review by the TGA. This review could be limited to those aspects of the application where a change has occurred rather than requiring the TGA to duplicate the comparability assessment for the indication already approved overseas. This would facilitate a more timely assessment while maintaining safety and quality protections.

**Questions for consideration:**

Should a change to a biosimilar that has been approved by a trusted overseas regulator necessitate a further assessment by the TGA in circumstances where that change may impact the comparability of the biosimilar? If not, why not?

If yes, should the assessment by the TGA be limited only to those aspects of the application that are impacted by the change?

**Issue 3 – Is there good reason for Australia to impose additional requirements?**

**Generic Medicines**

The TGA reviews applications to register an NCE (an originator medicine), which are approved after reviewing a full dossier of chemical, biological, pharmaceutical, pharmacological-toxicological and clinical data. For generic medicines that have the same dosage regimen and indication as an originator medicine that is on the ARTG, no further safety or efficacy data needs to be submitted. Instead, the sponsor may rely on safety and efficacy data previously submitted in relation to the originator medicine (or reference product). However, submission of bioequivalence data is required.

The sponsor of a generic medicine must generally demonstrate that the generic product is bioequivalent to the reference product currently on the market in Australia. The sponsor can only submit studies showing bioequivalence to an overseas reference product in certain circumstances. That is, a sponsor may only use such studies where the reference product is:

- A conventional, immediate-release, oral dosage form (tablet, capsule or suspension) or an enteric-coated tablet or capsule formulation that releases the medicine promptly once the enteric coating has dissolved;
- Registered in, and obtained from, a country with a regulatory system comparable to Australia;
- Marketed in the country of origin by the same innovator company/corporate entity that currently markets the same medicine in the same dosage form and strength in Australia;

vi If a data protection period under Section 25A of the *Therapeutic Goods Act 1989* (Cth) is applicable, a sponsor of a generic medicine cannot rely on safety or efficacy data submitted by another sponsor in relation to the originator product.
• Marketed in the country of origin through a licensing arrangement with the innovator company or corporate entity that currently markets the medicine in Australia.\(^{17}\)

Additionally, the sponsor must establish that the overseas reference product is identical to the Australian reference product, either by providing:

• a declaration from the innovator company that the overseas and Australian reference products are identical in all respects including formulation and method of manufacture; or

• evidence to justify that the overseas and Australian reference products are identical.\(^{18}\)

The evidence required to justify that the overseas and Australian reference products are identical includes copies of the product label and product information for both products, comparative dissolution profiles of the overseas and Australian reference product, and evidence that the overseas product contains the same nominal quantity of the drug substance as the reference product marketed in Australia, amongst other requirements.\(^{19}\) Unless the sponsor of the generic medicine can demonstrate that the overseas reference product is identical to or interchangeable with the Australian reference product and meets the conditions specified above, the Sponsor must conduct studies showing the bioequivalence of the generic medicine to the Australian reference product.

It is important to show bioequivalence to an Australian reference product as the generic product will be used interchangeably with the Australian originator product by Australian consumers. As such, patients and their health practitioners need to be confident that the generic medicine will behave in the same way as the originator medicine otherwise patients may experience adverse consequences. The need to establish bioequivalence with an Australia reference product does, however, raise issues in respect of the acceptance of assessments of generic medicines by trusted overseas regulators.

That is, the overseas regulator will have assessed the generic medicine against the originator product available in that market, which may or may not be identical to, or interchangeable with, the relevant originator product that is available on the Australian market. In such circumstances, the TGA would need to assure itself that the overseas reference product and the Australian reference product were either identical or interchangeable. Failure to do so would potentially place the health and safety of Australian health care consumers who switch to the generic product at risk.

One option to address this issue may be for the TGA to accept an assessment of bioequivalence of a generic medicine undertaken by a trusted overseas regulator on the condition that the sponsor of the generic medicine submits evidence to demonstrate that the originator product on the overseas market is identical to, or interchangeable with, the originator product that is available on the Australian market.
Questions for consideration:

Should the TGA approve the registration of a generic medicine on the ARTG on the basis that:

- a trusted overseas regulator has assessed it as being bioequivalent to a reference product available in the overseas market; and
- the sponsor provides evidence that the overseas reference product and the Australian reference product are identical or interchangeable? If not, why not?

What value do you believe an assessment of bioequivalence by the TGA would add in such circumstances?

Alternatively, if the application to register the generic medicine was lodged simultaneously to both the TGA and a trusted overseas regulator, an option could be to engage in work-sharing arrangements between the regulators, as has been trialled between the TGA and Health Canada and between medicines regulators in the EU, Australia, Chinese Taipei and Switzerland.  

Questions for consideration:

Could work sharing initiatives between regulators improve timeframes for approval of generic medicines? If so, how?

In what ways could TGA processes for assessment of generic medicines be better harmonised with international practice?

Biosimilars

The sponsor of a biosimilar must generally demonstrate that the biosimilar is comparable to the reference product registered in Australia. Additionally, the reference product must be a biological medicine registered by means of a full data submission which has been marketed for a suitable duration and have a volume of marketed use so that there is likely to be a substantial body of acceptable data regarding safety and efficacy. Reference products manufactured overseas may be used provided that the product is registered in Australia and a bridging comparability study between the Australian-sourced product and all batches of the reference product is provided. The bridging comparability study may be abbreviated if evidence is provided that the product marketed in Australia is sourced from the same manufacturing facility as that used for the reference product.

It is particularly important to demonstrate comparability with an Australian reference product, due to the fact that biosimilars are not generic versions of the reference product and full bioequivalence generally cannot be demonstrated though comparability studies. As a result, substitution of a biological medicine for a biosimilar can only be authorised by the prescriber (i.e. the clinician) and is not permitted at the pharmacy level. Therefore, clinicians need to have confidence that the biosimilar is comparable to the Australian reference product in order to make effective prescribing decisions. This does, however, raise issues with respect to acceptance of assessments of comparability by trusted overseas regulators based on an overseas reference product.

One option to address this issue may be for the TGA to accept an assessment of comparability by a trusted overseas regulator on the condition that the sponsor of the biosimilar submits evidence to
demonstrate that the originator product on the overseas market is identical to the originator product that is available on the Australian market, in the form of bridging comparability studies between the Australian product and all batches of the overseas reference product.

Questions for consideration:

Should the TGA approve the registration of a biosimilar on the ARTG on the basis that:

- a trusted overseas regulator has assessed it as being biosimilar to a reference product available in the overseas market; and
- the sponsor provides evidence that the overseas reference product and the Australian reference product are identical? If not, why not?

What value do you believe an assessment of biosimilarity by the TGA would add in such circumstances?

Theme 2: Regulatory requirements are not commensurate with risk

In respect of generic medicines, stakeholders have identified two areas where they believe Australian regulatory requirements are excessive and out of step with requirements internationally. These relate to:

1. The requirement to get TGA approval of most variations to a registered generic medicine.
2. Approval processes for minor variations to a generic medicine for the purpose of export.

Issue 1 – Approval of Variations

The standard conditions of registration that apply to all prescription medicines, including generic medicines, require the sponsor to notify the TGA of changes or variations in respect of any information concerning the medicine, and provides that, where necessary, the changes or variation shall not be implemented until approved by the TGA delegate. This means that once a medicine is entered on the ARTG the information cannot be changed without approval. There are some minor exceptions, such as changes to the local handling agent of the active pharmaceutical agent and excipient; or to the supplier or manufacturer of non-sterile containers or container components, but the vast majority of changes relating to a registered medicine must be both notified to, and approved by, the TGA.

The Therapeutic Goods Act 1989 (the Act) provides for sponsors to request:

- updates to an ARTG entry that is incomplete or incorrect;
- safety-related variations to an ARTG entry and consequential changes to the Product Information (PI), such as removing an indication or adding a warning or precaution; and
- other variations to an ARTG entry that do not have the effect of creating a separate and distinct good, provided that the change does not reduce the quality, safety or efficacy of the medicine.

If the variation creates a separate and distinct good, sponsors must apply to the TGA for approval of a new registered medicine. Variations that would create a separate and distinct good include new
strengths, new dosage forms, different directions for use, formulation changes, changes in trade name, and extensions of indication.

The timeframes for approval of variations by the TGA differ depending on the nature of the variation requested. Major variations which require evaluation of a full dataset, or any combination of quality, nonclinical, clinical and bioequivalence data, have a statutory timeframe of between 175 and 255 working days. Variations that only require evaluation of quality-related data (Category 3 applications) and lower risk variations for which the sponsor can provide an assessment of their own data for the TGA to verify (known as self-assessable requests), have a statutory timeframe of 45 working days. Requests to correct an incorrect or incomplete ARTG entry or to make safety-related variations to the ARTG entry have no statutory timeframes.

These requirements are considered highly risk-averse by many in the industry and do not align with regulatory approaches taken by other trusted regulators internationally. For example, from October 2010 the European Union (EU) implemented a simpler and more flexible legal framework for variations to marketing approvals aimed at reducing burden on industry and further harmonising requirements across the EU while maintaining public protections.

Under these reforms, the EU classified variations into a number of categories, based on the level of risk they posed to public health and their impact on the quality, safety and efficacy of the medicinal product concerned. These categories include:

- **Minor variations Type IA**, covering variations such as:
  - A change to the name and/or address of the marketing authorisation holder;
  - A change in the name of the active substance;
  - A change in the name and/or address of a manufacturer of the finished product;
  - A change to pack size of the finished product that is already within the currently approved range;
  - Minor changes to an approved test procedure.

  As long as predefined conditions are met, such changes are subject to a ‘do and tell’ procedure, whereby the sponsor may implement the changes and notify the EMA. In most instances the notification must be within 12 months but a subset of Type IA variations (referred to as Type IA IM), which require continuous supervision, must be notified to the EMA immediately after implementation.

- **Minor variations Type IB**; are defined as a minor variation that is neither a Type IA variation nor a Type II variation nor an Extension. Examples include: minor changes to an approved test procedure for a biological excipient; change in pack size of a finished product that is outside the currently approved range; and addition of new tests and limits applied during the manufacture of the product.

  Type IB variations must be notified to the EMA by the sponsor prior to implementation, but do not require a formal approval. Upon acknowledgement of receipt of a valid notification, the
A sponsor must wait a period of 30 days to ensure that the notification is deemed acceptable before implementing the change (‘Tell, Wait and Do’ procedure).25

Similarly, the FDA allows a range of ‘minor changes’ to be included in a sponsor’s annual report rather than be approved prior to implementation. FDA Guidance26 lists examples of variations that they consider to have a minimal potential to have an adverse effect on product quality in areas such as product components and composition; manufacturing sites, process, batch size, and equipment; containers and closures; and labelling. The UK MHRA has also done significant work on variations that only need to be notified rather than approved. There are, therefore, opportunities to learn from international experience in this sphere.

Questions for consideration:

Should Australia adopt a risk-based regime for variations, which allows notifications and/or annual reporting for changes that are at low risk of impacting the quality, safety or efficacy of the product? If not, why not?

If yes, what might such a regime look like? How might notification/reporting procedures be designed so as to minimise burden on sponsors?

**Issue 2 – Approval processes for minor variations to a medicine for the purpose of export**

For many countries importing generic medicines from Australia, it is generally considered desirable or mandatory for the medicine to be approved for use and on the market in Australia. Therefore, it is not uncommon for Australian exporters to seek approval for domestic supply before exporting the medicine to another country. In such instances the sponsor may wish to make minor modifications to the domestically approved generic medicine (e.g. to colouring or flavouring) in order to enhance its acceptance in a particular export market.

As outlined above, however, TGA approval is required for most changes to a medicine that has been entered on the ARTG. Currently, these minor modifications almost invariably lead to the medicine being considered a different product under the Act and therefore the original approval is no longer valid for the export variant. As such, the sponsor must prepare an application for listing of the varied product on the ARTG as an export-only medicine which, when combined with the subsequent assessment of the application by the TGA, can take several months, thereby delaying access to the export market.

If Australia’s approach to the notification and/or approval of variations is to be revised, consideration might be given to how to streamline the process for minor variations to export medicines, without compromising health and safety. This would allow Australian exporters more timely access to export opportunities.

Question for consideration:

How might the process for minor variations for export-only medicines be streamlined so as to facilitate more timely access to export opportunities without compromising health and safety?
Theme 3: Overly burdensome processes

Stakeholders have identified that some TGA processes are overly burdensome and could be improved in line with technological developments. Specifically, stakeholders have identified that:

1. The timeframe for registration of generic medicines is not significantly less than that for NCEs.
2. The processes involved in updating Product Information in line with updates to the reference product is overly burdensome.
3. The process for approving additional trade names for generic medicines is inefficient.

Issue 1 – Timeframes for registration of generic medicines

Generic medicines undergo the same application workflow process as NCEs, with the only difference being that it is not mandatory for applications for registration of generic medicines to be referred to the Advisory Committee on Prescription Medicines. The legislative timeframe for the assessment of a generic medicine application is 255 working days. The exception is for Category 2 applications which include completed evaluation reports from two other specified jurisdictions (which are rare), where the legislated timeframe is 175 working days. Should the TGA need to seek further information from the applicant, the clock is stopped.

Stakeholders in the generic medicines industry view these timeframes as highly inefficient, and point to the fact that approval times for generic medicine applications are only marginally faster than the approval times for NCEs, despite the fact that the TGA generally does not review safety and efficacy data for generic medicine applications. This is borne out by data for the first quarter of 2014 provided to the Panel by the TGA. As outlined in Figure 1, this data indicates that there is little difference in the average and median number of days taken to approve a generic medicine compared to NCEs.

Figure 1: Average and Median Approval Times (in working days)

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Average</th>
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<tr>
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<tr>
<td>Major Variations</td>
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</tr>
<tr>
<td>New Generics</td>
<td>193</td>
<td>202</td>
</tr>
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</table>

The current timeframes for evaluation of generic medicines are designed to allow the TGA to request further information from sponsors at several points in the registration process. It has been argued that this slows the assessment process down for all sponsors, including those who submit complete applications.
A number of options have been identified by stakeholders to improve approval times for generic medicines. These include:

- Streamlining TGA processes, and providing enhanced guidance to sponsors, such as check lists, to assist them to meet TGA requirements.
- The introduction of an abbreviated time period in the pre-submission planning phase for generic medicines that do not require submission of Module 2 data.

**Questions for consideration:**

Do you consider the timeframes for assessing applications for registration of new generic medicines to be unreasonable?

How do they compare with timeframes achieved by overseas regulators such as the FDA and the EMA?

What do you think are the main factors impacting TGA timeframes for assessment of generic medicines and how might these factors be addressed?

The Generic Medicines Industry Association (GMiA) has also previously requested the creation of separate pathways for registration of generic medicines and NCEs. This approach has been in practice in the US since 1984, with generic medicines going through an Abbreviated New Drug Application pathway rather than the New Drug Application required for NCEs. It is, however, unclear the extent to which this process has resulted in faster approval times in the US, with the TGA citing advice from the Office of Strategic Programs, Centre for Drug Evaluation and Research in the FDA that mean and median approval times for new generic medicines in Australia are currently half the time or less than those achieved in the US.

**Questions for consideration:**

Would the creation of a separate registration pathway for generic medicines achieve more timely approvals and more appropriately align regulatory processes with risk? If not, why not?

If yes, what would the generic approvals pathway look like? How would it differ from the process for NCEs?

**Issue 2 – Process for making general updates to Product Information**

Currently, adding an indication to an already approved generic medicine to reflect an indication added to the originator product is treated as a new generic medicine and requires a standard application to be lodged. Stakeholders have argued that this is costly and inefficient, as it involves a statutory evaluation period of up to 255 working days and a fee of $131,600.

Given that the TGA would have undertaken an assessment at the time that the indication was added for the originator product and that, therefore, the assessment of the generic product application should only need to focus on the PI and Consumer Medicines Information (CMI), it has been argued that it should be possible for updates of this nature to occur in a more timely and cost efficient manner. One option that has been proposed is that PI updates that are in line with the originator
product and do not require further clinical, non-clinical, or bio-equivalence data should be treated as variations rather than new generic medicines, allowing for a reduced statutory evaluation period.

Questions for consideration:

Should an update to the indications for a generic medicine which is in line with the originator medicine, be treated as a variation, rather than as creating a separate and distinct good?

What are the risks and benefits of this approach?

Issue 3 – Process for approval of additional trade names

Sponsors of generic medicines must apply to the TGA to register a new trade name on the ARTG in order to allow legal supply of the product in Australia, as an additional trade name creates a new product for supply under Section 16 of the Act. Such applications currently have a statutory application period of 255 working days. The TGA undertakes an evaluation of the proposed trade name from a quality use of medicines perspective, to ensure that it cannot be confused with another medicine and therefore contribute to medication errors that pose a risk to public health and safety. Concerns have been raised about the timeframe for evaluating applications for additional trade names, which has been described as a major barrier to transparency and predictability of the current regulatory framework in Australia.

Questions for consideration:

Do you believe that the process for applying for an additional trade name is burdensome? If yes, how do you propose it could be modified?

What do you think would be a reasonable statutory assessment timeframe for consideration of an application for an additional trade name?

6 Ibid.


17 Ibid. pp.11-12.

18 Ibid. p. 12.

19 Ibid. p. 13.


22 Ibid.


CHAPTER SIX: REGULATION OF OVER-THE-COUNTER MEDICINES

Over-the-counter (OTC) medicines are lower risk products than prescription medicines and are comprised of ingredients that have a long history of safe use. Generally, OTC medicines are suitable for self-treatment of minor ailments and symptoms. OTC medicines are subject to either registration or listing on the Australian Register of Therapeutic Goods (ARTG) depending on their level of risk. The Pharmaceuticals Industry Strategy Report in 2008 noted that increasing health care costs were driving an increased focus by governments around the world on involving individuals in health care, particularly through encouraging the use of OTC medicines.\(^1\)

Whether a medicine is classified as prescription or OTC is determined by the scheduling of substances on the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), known as the Poisons Standard. Scheduling decisions are given effect in state and territory drug and poisons legislation, with national uniformity in scheduling promoted through the Scheduling Policy Framework.

The Scheduling Policy Framework

The Scheduling Policy Framework was developed by the now defunct National Coordinating Committee on Therapeutic Goods (NCCTG), and is a national system for regulating access to all poisons, including medicines for human use, veterinary, agricultural, domestic and industrial chemicals where there may be risk to human health and public safety.\(^2\) Under the Scheduling Policy Framework, substances are classified according to the level of regulatory control required to protect public health and safety. As such, scheduling controls how medicines and poisons are made available to the public by appropriately classifying the active ingredient (substance) contained within the medicine or poison.\(^1\) Under the Therapeutic Goods Act 1989 (the Act), a person may apply to amend the Poisons Standard through addition of a new substance or rescheduling of an existing substance.\(^3\)

Medical substances intended for human therapeutic use may be classified as Schedule 8 (controlled drugs), Schedule 4 (prescription medicines), Schedule 3 (pharmacist only) and Schedule 2 (pharmacy only) or may be unscheduled. Medicines containing substances on Schedules 4 and above may only be sold with a prescription, whereas medicines on Schedules 3 and 2 may be sold in pharmacies. In some states, Schedule 2 medicines may also be sold by licenced medicine sellers. Unscheduled medicines may be sold generally, for example, through supermarkets.

Prior to 2010, scheduling decisions were made by the National Drugs and Poisons Committee, with the NCCTG providing policy advice on amending the Poisons Standard to decision-makers. However, since 1 July 2010 scheduling decisions have been made by the Secretary of the Department of Health (in practice a delegate), who may be advised by either the Advisory Committee on Medicines Scheduling (ACMS) or the Advisory Committee on Chemicals Scheduling, as applicable. When making a scheduling decision, the delegate is obliged under the Act to take into consideration:

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\(^1\) Generally, combination products are scheduled in line with the substance that is scheduled more restrictively, however there are instances where a combination has been scheduled more restrictively than either of its components (e.g. the combination of ibuprofen and paracetamol).
• the risks and benefits of the use of a substance;
• the purposes for which a substance is to be used and the extent of use of a substance;
• the toxicity of a substance;
• the dosage, formulation, labelling, packaging and presentation of a substance;
• the potential for abuse of a substance; and
• any other matters the delegate considers necessary to protect public health.\(^4\)

Additionally, the delegate is obliged to take into account any recommendations from the ACMS and to comply with any guidelines of the NCCTG. This includes the 2010 Scheduling Policy Framework and associated ‘scheduling factors’, which were developed by the NCCTG.\(^5\)

**Scheduling Factors**

When making scheduling decisions, the delegate (and the relevant advisory committee) considers a number of ‘scheduling factors’ to determine the appropriate classification for a substance,\(^6\) as outlined in Figure 1. Scheduling decisions for medicines are made according to a ‘cascading principle’ with the substance first assessed using the factors for Schedule 8 (highest risk) then, if they are not applicable, the substance is assessed against Schedule 4 factors, and if these are not applicable, against Schedule 3 factors and so on and so forth.

The scheduling classification system and associated factors ‘underpins the need for particular health care professionals to be involved in the supply of certain medicinal substances in order to promote safe and quality use.’\(^7\)
### Schedule 8 (Controlled Drugs)
- The substance is included in Schedule I or II of the *United Nations Single Convention on Narcotic Drugs 1961* or in Schedule II or III of the *United Nations Convention on Psychotropic Substances 1971*.
- The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.
- The substance has an established therapeutic value but by reason of its novelty or properties carries a substantially increased risk of producing dependency, misuse, abuse or illicit use.

### Schedule 4 (prescription medicines)
- The ailments or symptoms that the substance is used for require medical/dental intervention.
- The use of the substance requires adjunctive therapy or evaluation.
- The use of the substance at established therapeutic dosage levels may produce dependency but has a moderate propensity for misuse, abuse or illicit use.
- The seriousness, severity and frequency of adverse events are such that monitoring or intervention by a medical/dental practitioner is required to minimise the risk of use.
- The margin of safety between the therapeutic and toxic dose of the substance is such that it requires medical or dental intervention to minimise the risk of using the substance.
- The seriousness or severity and frequency of the interactions of the substance (medicine-medicine, medicine-food, medicine-disease) are such that monitoring or intervention is required by a medical or dental practitioner.
- The use of the substance has contributed to, or is likely to contribute to, communal harm (e.g. the development of resistant strains of microorganisms).
- The experience of the use of the substance under normal clinical conditions is limited.

### Schedule 3 (pharmacist only)
- The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.
- The use of the medicine at established therapeutic dosages is not expected to produce dependency. Where there is a risk of misuse, abuse or illicit use identified, the risk can be minimised through monitoring by the pharmacist.
- The risk profile of the medicine is well defined and the risk factors for adverse effects and interactions are well known, identifiable and manageable by a pharmacist.
- The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.

### Schedule 2 (pharmacy medicine)
- The quality use of the medicine can be achieved by labelling, packaging, and/or provision or other information; however access to advice from a pharmacist is available to maximise the safe use of the medicine.
- The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.
- The use of the medicine at established therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used.
- The risk profile of the medicine is well defined and the risk factors can be identified and managed by a consumer through appropriate packaging and labelling and consultation with a medical practitioner if required.
- The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.
Overview of key issues

A range of previous reviews, inquiries and/or stakeholder consultations have examined aspects of the regulation of medicines in Australia and identified a number of issues or concerns. Those relevant to OTC medicines can generally be grouped into the following themes:

1. Some regulatory requirements are not considered to be commensurate with the risk posed by the regulated products.
2. Some Therapeutic Goods Administration (TGA) processes are considered to be overly burdensome and out of step with technology.
3. The regulatory framework is overly complex and poorly understood by many of those who have to interact with it.

An overview of the issues specific to OTC medicines is provided below in respect of each of these areas of concern. The issues, concerns and possible options to address them do not necessarily represent the views of the Panel. Rather, they have been drawn from previous reports, from a summary of stakeholder views and options for change provided to the Panel by the TGA, and from a review of stakeholder submissions to relevant reviews and inquiries. These issues are outlined in this chapter to help identify areas for discussion and assist the Panel in determining whether there is consensus on the key issues and options for reform.

Theme 1: Regulatory requirements are not commensurate with risk

Stakeholders have identified a number of aspects of the regulation of OTC medicines where they believe Australian requirements are not commensurate with risk. These relate to:

1. Australia’s current scheduling framework.
2. Advertising of pharmacist-only medicines.
3. Regulation of some lower risk OTC products.
4. Approval of variations, including minor variations to a medicine for the purposes of export.

Issue 1 – Scheduling Framework

In submissions to previous reviews and inquiries, some stakeholders have stated that Australia has begun to lag behind comparable international jurisdictions in the range of medicines available for self-medication. These stakeholders cite a number of studies, including those by Gauld et.al., which indicate that whilst Australia appeared to be further advanced in down-scheduling medicines than either the United Kingdom (UK) or New Zealand in the early 2000s more recently Australia has fallen behind both countries in conducting first in the world switches of substances from prescription to non-prescription. The Australian Self Medication Industry (ASMI) asserts that the current process is risk-averse compared to the UK and New Zealand and this fact, coupled with the cost and complexity involved, has deterred many sponsors from applying to reschedule substances. In contrast, input from the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia to the 2013 Review of Arrangements for Scheduling Substances under Part 6-3 of the Therapeutic Goods
Chapter 6: Regulation of Over-the-counter Medicines

Act 1989 (the 2013 Review of Scheduling) asserts that scheduling decisions have become less risk averse in recent times. Nevertheless, some stakeholders have questioned whether the current scheduling system appropriately classifies substances according to risk. In particular concerns have been expressed that the current scheduling factors place undue emphasis on consideration of risk without enough focus on the potential benefits of rescheduling in terms of improved clinical outcomes, access to effective medicines, and increased consumer involvement in health care. The transparency of the scheduling system has also been drawn into question. Industry stakeholders have observed that there does not appear to be a consistent or transparent methodology for considering the risks and benefits of the use of a substance and that, in the view of sponsors/applicants, risks that occur rarely or outside of the proposed use of the OTC medicine can be given ‘disproportionate’ emphasis. Moreover, stakeholders argue that statements of reasons for scheduling decisions provided by the delegate do not provide enough detail regarding what issues have been considered and how the Scheduling Policy Framework was applied. An option suggested by industry to improve the scheduling system is the introduction of a more formal methodology for assessing the risks and benefits of scheduling decisions. Relevantly, the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) in its most recent guidelines on reclassification of medicines suggested that sponsors of medicines could utilise a value-tree risk-benefit framework to identify key risks and benefits prior to commencing an application for reclassification. Industry stakeholders have argued that adoption of such methods could assist both sponsors and the decision-maker, and enable discussion on how to minimise risk and determine the appropriate level of access. Other benefits identified by industry include the possibility of non-industry stakeholders applying for rescheduling, and enabling objective examination of proposals that are not limited to ‘acute, self-limiting ailments but that may encompass maintenance therapy of certain chronic medical conditions’. The Review Panel notes that the 2013 Review of Scheduling found that there ‘is a need for greater clarity, transparency and guidance about the process to amend the Poisons Standard’ and recommended, among other things, that consideration be given to ‘the utility of a more structured approach or framework for risk benefit assessment (such as that which is currently available for medicines in the UK and under consideration in other countries). The Panel is not aware of any response by the Government to the 2013 Review of Scheduling.

Questions for Consideration:

Do Australian decisions regarding the scheduling and/or rescheduling of medicines appropriately balance risk and benefit? If not, why not?

Are the current scheduling classifications and factors suitable for appropriately assessing substances based on risk? If not, in what way could they be improved?

What would be the advantages/disadvantages of adopting a formal methodology for assessment of risks and benefits to inform scheduling decisions? What might such a methodology look like?

How could the transparency of the scheduling process be improved?
Issue 2 – Direct-to-consumer advertising of Schedule 3 Medicines

Australia’s regulatory scheme for restricting the supply of ‘poisons’ to the general public involves assessing the safety of these substances and including them, if required, in an appropriate schedule to the current Poisons Standard. ‘Pharmacist Only’ medicines contain substances that are included in Schedule 3 to the current Poisons Standard on the basis that:

- the safe use of the substance requires professional advice; and
- the substance should nevertheless be available to the public from a pharmacist without a prescription.

It is an offence under Section 42DL(1)(f) of the Act to advertise substances listed in Schedules 3 and 4 of the Poisons Standard. However, there is an exception for those Schedule 3 substances listed in Appendix H to the current Poisons Standard. Currently, a prospective advertiser may apply to the Secretary of the Department of Health for an amendment of Appendix H to include a Schedule 3 substance, allowing that substance to be advertised to the general public. Industry stakeholders note, however, that the arrangements for Appendix H decisions have not been updated for 14 years and that with the disbandment of the NCCTG there is no clear forum to conduct a review of, or to revise, the Guidelines for brand advertising of substances included in Schedule 3 of the Standard for Uniform Scheduling of Drugs and Poisons (the Schedule 3 Advertising guidelines).

Furthermore, only ten ingredients are currently included in Appendix H, which industry stakeholders argue is due to the resource costs involved with satisfying evidentiary requirements. That is, under the 2000 Schedule 3 Advertising guidelines, the delegate considers a range of issues when determining an application for inclusion in Appendix H, including:

- The potential public health benefit, for example more appropriate use of scarce health resources or a better informed community
- The likelihood of advertising of the substance leading to inappropriate patterns of medication use.
- Whether the application may result in the advertising of goods for an indication other than those included in the Australian Register of Therapeutic Goods.
- The desire of consumers to manage their own medication and the level of patient education necessary to ensure correct use.

Whilst there is no specific evidentiary standard specified in the guidelines, addressing these and other matters outlined in the guidelines would necessitate sponsors providing a range of quantitative and qualitative data, which may be both costly and time consuming to collect and/or develop.

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See also Chapter 8, Framework for Advertising Therapeutic Goods.

Where it is not possible to present data to quantify the extent of any claim of public benefit, qualitative data may be acceptable.
Restrictions on the advertising of Schedule 3 medications in Australia are generally considered to be out of step with international practice and recent media reports, along with submissions to the TGA, have called for advertising of Schedule 3 medicines to be brought in line with jurisdictions such as the UK, Canada, New Zealand and the United States.\(^{21}\) In this situation unless it can be demonstrated that direct-to-consumer advertising of a particular Schedule 3 medicine is not in the public interest, advertising of Schedule 3 medicines to consumers would no longer be prohibited. Advocates argue that allowing advertising direct-to-consumer for Schedule 3 medicines could increase the level of information available to assist consumers in making informed decisions when choosing Schedule 3 medicines. These recent submissions and media statements have, however, failed to articulate the view of opponents to advertising of Schedule 3 medicines.

**Questions for consideration:**

1. What are the risks and benefits of allowing direct-to-consumer advertising of Schedule 3 Medicines?
2. How might any risks be managed?

**Issue 3 – Regulation of low-risk therapeutic goods**

Products are regulated by the TGA if they fall within the definition of ‘therapeutic goods’ which includes products that are ‘represented’ for therapeutic use.\(^{22}\) Industry stakeholders have identified that the threshold at which some products are classified as therapeutic goods is too low, and that certain low-risk products should be subject to less stringent regulatory requirements or exclusion from regulation as therapeutic goods entirely. Generally, these products are unscheduled medicines that are ‘listed’ on the ARTG and have been assessed by the TGA for safety and quality but not efficacy.\(^{iv}\) In the context of OTC medicines, examples of the products suggested for exclusion include medicated soaps, desensitising toothpastes and gels, and personal care products such as anti-nappy rash treatments.

In particular, industry stakeholders view the uniquely Australian approach of regulating sunscreens as medicines as unnecessary and overly burdensome given their risk profile.\(^{23}\) Industry has called for a lighter touch regulation of sunscreens and, amongst other proposals, has suggested regulating all secondary sunscreens\(^{v}\) as cosmetics under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth). Additionally, industry stakeholders have raised issues regarding Good Manufacturing Practice (GMP) clearance processes for overseas manufacturers of sunscreens. As sunscreens are regulated as cosmetics in most overseas jurisdictions, stakeholders assert that they do not go through routine audits by overseas regulatory authorities, meaning that the TGA must conduct a mandatory audit of the manufacturing facility overseas. Industry stakeholders argue that this imposes an unnecessary cost unique to overseas manufacturers of sunscreens seeking access to the Australian market.\(^{24}\)

\(^{iv}\) Whilst the TGA does not individually assess listed medicines for efficacy, Sponsors are required to hold evidence to substantiate their product’s claims: *Therapeutic Goods Act 1989* (Cth), Section 26A(2).

\(^{v}\) Secondary sunscreens are products that have a primary function other than sun protection whilst providing some protection of the skin from UV radiation, such as moisturising products with sun protection properties.
Possible advantages of excluding low risk products from regulation would be reduced regulatory burden on industry, particularly through removal of GMP requirements, and the freeing up of resources for the TGA to re-direct to higher-risk products. There may also be flow on effects to consumers through lower prices for such products. Additionally, removing the requirement to be listed on the ARTG and regulating certain products as consumer goods may provide greater clarity to consumers regarding the fact that the TGA has not directly assessed the efficacy of these products. One option to identify goods for exclusion from regulation could be to maintain therapeutic goods regulation for products with higher level indications (e.g. treatment of a condition or a disease) or products that are comprised of higher risk ingredients and exclude those that have a lower risk profile.

Questions for consideration:

Is the threshold at which some products are classified as medicines too low? If so, what criteria could be used to determine which types of products were more suited to regulation as consumer goods?

What are the advantages and disadvantages of excluding some low risk products from the Therapeutic Goods Act 1989?

Issue 4 – Variations to registered OTC medicines

The standard conditions of registration that apply to all registered OTC medicines require the sponsor to notify the TGA of changes or variations in respect of any information concerning the medicine, and provides that, where necessary, the changes or variation shall not be implemented until approved by the TGA delegate. This means that once a medicine is entered on the ARTG the information cannot be changed without approval. There are some minor exceptions, such as changes to the local handling agent of the active pharmaceutical agent and excipient, or to the supplier or manufacturer of non-sterile containers or container components, but the vast majority of changes relating to a registered medicine must be both notified to, and approved by, the TGA.

The Therapeutic Goods Act 1989 provides for sponsors to request:

- updates to an ARTG entry that is incomplete or incorrect;
- safety-related variations to an ARTG entry and consequential changes to the Product Information, such as removing an indication or adding a warning or precaution; and
- other variations to an ARTG entry that do not have the effect of creating a separate and distinct good, provided that the change does not reduce the quality, safety or efficacy of the medicine.

If the variation creates a separate and distinct good, sponsors must apply to the TGA for approval of a new registered medicine. Variations that would create a separate and distinct good include new strengths, new dosage forms, different directions for use, formulation changes, changes in trade name, and extensions of indication.

The timeframes for approval of variations by the TGA differ depending on the nature of the variation requested. Major variations which require evaluation of a full dataset, or any combination of quality, nonclinical, clinical, and bioequivalence data, have a statutory timeframe of between 175 and
255 working days. Variations that only require evaluation of quality-related data (Category 3 applications) and lower risk variations for which the sponsor can provide an assessment of their own data for the TGA to verify (known as self-assessable requests), have a statutory timeframe of 45 working days. Requests to correct an incorrect or incomplete ARTG entry or to make safety-related variations to the ARTG entry have no statutory timeframes.

These requirements are considered highly risk-averse by many in the industry and do not align with regulatory approaches taken by other trusted regulators internationally. For example, from October 2010 the European Union (EU) implemented a simpler and more flexible online system for variations to marketing approvals aimed at reducing burden on the industry and further harmonising requirements across the EU while maintaining public protections.25

Under these reforms, the EU classified variations into a number of categories, based on the level of risk they posed to public health and their impact on the quality, safety and efficacy of the medicinal product concerned. These categories include:

- **Minor variations Type IA**, covering variations such as:
  - A change to the name and/or address of the marketing authorisation holder;
  - A change in the name of the active substance;
  - A change in the name and/or address of a manufacturer of the finished product;
  - A change to pack size of the finished product that is already within the currently approved range;
  - Minor changes to an approved test procedure.

  As long as predefined conditions are met, such changes are subject to a ‘do and tell’ procedure, whereby the sponsor may implement the changes and notify the European Medicines Agency (EMA) through a simple online process. In most instances the notification must be within 12 months but a subset of Type IA variations (referred to as Type IA IM), which require continuous supervision, must be notified to the EMA immediately after implementation.

- **Minor variations Type IB**; are defined as a minor variation that is neither a Type IA variation nor a Type II variation nor an Extension. Examples include: minor changes to an approved test procedure for a biological excipient; change in pack size of a finished product that is outside the currently approved range; and addition of new tests and limits applied during the manufacture of the product.

  Type IB variations must be notified to the EMA by the sponsor prior to implementation, but do not require a formal approval. Upon acknowledgement of receipt of a valid notification, the sponsor must wait a period of 30 days to ensure that the notification is deemed acceptable before implementing the change (‘Tell, Wait and Do’ procedure).26

Similarly, the US Food and Drug Administration (FDA) allow a range of ‘minor changes’ to be included in a sponsor’s annual report rather than be approved prior to implementation. FDA Guidance27 lists examples of variations that they consider to have a minimal potential to have an adverse effect on product quality in areas such as product components and composition;
manufacturing sites, process, batch size, and equipment; containers and closures; and labelling. The UK MHRA has also done significant work on variations that only need to be notified rather than approved. There are, therefore, opportunities to learn from international experience in this sphere.

Questions for consideration:

Should Australia adopt a risk-based regime for variations, which allows notifications and/or annual reporting for changes that are at low risk of impacting the quality, safety or efficacy of the product? If not, why not?

If yes, what might such a regime look like? How might notification/reporting procedures and mechanisms be designed so as to minimise burden on sponsors?

Additionally, stakeholders have raised issues regarding the approval process for minor variations to a medicine for the purpose of export. For many countries importing medicines from Australia, it is generally considered desirable or mandatory for the medicine to be approved for use and on the market in Australia. Therefore, it is not uncommon for Australian exporters to seek approval for domestic supply before exporting the medicine to another country. In such instances the sponsor may wish to make minor modifications to the domestically approved medicine (e.g. to colouring or flavouring) in order to enhance its acceptance in a particular export market.

As outlined above, however, TGA approval is required for most changes to a medicine that has been entered on the ARTG. Currently, these minor modifications almost invariably lead to the medicine being considered a different product under the Act and therefore the original approval is no longer valid for the export variant. As such, the sponsor must prepare an application for listing of the varied product on the ARTG as an export-only medicine which, when combined with the subsequent assessment of the application by the TGA, can take several months, thereby delaying access to the export market.

If Australia’s approach to the notification and/or approval of variations is to be revised, consideration might be given to how to streamline the process for minor variations to export medicines, without compromising health and safety. This would allow Australian exporters more timely access to export opportunities.

Question for consideration:

How might the process for minor variations for export-only medicines be streamlined so as to facilitate more timely access to export opportunities without compromising health and safety?

Theme 2: Overly burdensome processes

With respect to OTC medicines, stakeholders have identified TGA processes to be overly burdensome in relation to the approval of additional trade names. Sponsors must make application to the TGA to register a new trade name on the ARTG in order to allow legal supply of the product in Australia, as an additional trade name creates a new product for supply under Section 16 of the Therapeutic Goods Act 1989. Such applications currently have a statutory evaluation time period of 255 working days. The TGA undertakes an evaluation of the proposed trade name from a quality use
of medicines perspective, to ensure that it cannot be confused with another medicine and therefore contribute to medication errors that pose a risk to public health and safety. Concerns have been raised about the timeframe for evaluating applications for additional trade names, which has been described as a major barrier to transparency and predictability of the current regulatory framework in Australia.

Questions for consideration:
Do you believe that the process for applying for an additional trade name is burdensome? If yes, how do you propose it could be modified?
What do you think would be a reasonable statutory assessment timeframe for consideration of an application for an additional trade name?

Theme 3: Complex Regulatory Framework

Many stakeholders have commented on the difficulties that they have experienced in navigating the regulatory framework for OTC medicines, including the lack of transparency in respect of decision making and processes, for example, scheduling. In particular, industry stakeholders have raised concern about the complexity of the process for applying to reschedule substances and the poor integration of this process with other TGA processes. They argue that this complexity is a reason why down-scheduling of substances to OTC may have fallen behind comparable international regulators. Two scenarios have been identified in particular:

1. New product applications which require a related scheduling decision (e.g. for new OTC medicines or rescheduling for different dosage forms or strengths).
2. Applications to reschedule existing substances which then require evaluation of new labelling warning statements on an existing product by the TGA.  

**Issue 1 – New product applications which require a related scheduling decision**

Scheduling decisions relate to the active substance in a product, rather than to a particular branded product. As such, if a sponsor wants to register a medicine on the ARTG that includes an active substance which is currently Schedule 4 or above, but market the medicine OTC, the sponsor must both apply for registration of the product and for rescheduling of the substance. In such circumstances, however, the TGA is not permitted to accept the application to register the new OTC medicine until the re-scheduling process has been completed. This may result in significant time delays in getting the product to market.

**Issue 2 – Applications to reschedule substances which require evaluation of new product labels**

Where an application is submitted to reschedule a substance from prescription to OTC, this will require evaluation of new product labels. Product labels are particularly important for OTC medicines in terms of promoting quality use. In respect of Schedule 4 medicines and above, such labels are primarily a means of correctly identifying the medicine, as instructions for use are provided by a medical practitioner. But in the case of OTC medicines the product label should give consumers the information necessary to make an informed choice about the appropriateness of the
medicine and to understand how to use the medicine safely and effectively.\textsuperscript{30} Review of such labels by the TGA is therefore an important step in ensuring public safety.

Industry stakeholders have expressed concern that the down-scheduling process must be completed before the TGA will evaluate a new labelling warning statement for the product previously registered on the ARTG as a prescription medicine, resulting in delays. In addition, the advice of the Advisory Committee on Non-Prescription Medicines is required before finalising decisions on labelling, resulting in further delays.\textsuperscript{31} An option identified to address both scenarios is provision for parallel processing of applications. That is, the TGA could:

\begin{itemize}
  \item accept and process the application for registration of a new OTC and an application to reschedule the active substance in parallel; and
  \item consider rescheduling applications and labelling alterations in parallel.
\end{itemize}

One disadvantage of parallel processing identified by the TGA in response to the 2013 Scheduling Review was the potential loss of sponsor fees paid to process registration applications if the scheduling decision does not support the application.\textsuperscript{32} This could be mitigated if the sponsor was willing to assume the risk of lost sponsor fees in order to reduce the time to market.\textsuperscript{33} A further potential disadvantage of this option is that it may reduce the time available to pharmacies to implement changes to scheduling, particularly as one scheduling decision on a particular substance can impact multiple products across a number of different brands.\textsuperscript{34}

### Questions for consideration:

Are scheduling and registration processes poorly aligned? If so, what approach could be adopted to achieve better harmonisation?

Would efficiency be improved and complexity reduced by introducing parallel processing of:

\begin{itemize}
  \item scheduling and registration applications?; and
  \item rescheduling applications and related labelling alterations?
\end{itemize}

What are the advantages/disadvantages of such an approach?

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\textsuperscript{3} \textit{Therapeutic Goods Act 1989} (Cth), Section 52EAA.

\textsuperscript{4} Ibid, Section 52E.

\textsuperscript{5} Ibid, Section 52E(2).


\textsuperscript{7} Ibid, p. 15.

Chapter 6: Regulation of Over-the-counter Medicines


13 Ibid.


22 Therapeutic Goods Act 1989 (Cth), Section 3.


33 Ibid.
34 Ibid.
CHAPTER SEVEN: REGULATION OF MEDICAL DEVICES

A medical device is defined as any instrument, apparatus, appliance, or accessory to a medical device, intended to be used for human beings, for:

- the diagnosis, prevention, monitoring, treatment, alleviation of disease;
- replacement or modification of anatomy; and
- control of contraception;

that does not do so by pharmacologic, immunological or metabolic means.

All medical devices in Australia are subject to regulation, the purpose of which is to protect public health and safety. The regulatory framework for medical devices is set out in numerous documents including the:

- Therapeutic Goods Act 1989 (the Act) (in particular, Chapter 4).
- Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations).
- Therapeutic Goods Orders.
- Excluded Goods Orders.
- Medical Device Standards Orders (MDSOs).
- Conformity Assessment Standards Orders (CASOs).

The Regulations outline the basic characteristics, such as safety, quality, efficacy and performance that medical devices must demonstrate before they can be lawfully imported, manufactured, supplied or exported. It should be noted that ‘efficacy’ in the context of medical devices refers to ‘the performance of the device as the manufacturer intended.’ The Act also creates various penalties that can be imposed by the Therapeutic Goods Administration (TGA) or the courts for any breaches of these regulatory requirements.

The Australian scheme is administered by the TGA, which was established in 1989 as a division of the Department of Health. In respect of medical devices, the TGA:

- Verifies overseas manufacturers’ compliance with the same standards as their Australian counterparts.
- Assesses compliance of Australian manufacturers with Good Manufacturing Practice (GMP) requirements.
- Office of Devices Authorisation is responsible for pre-market regulation of medical devices, and it conducts a pre-market assessment, prior to the medical device being entered onto the Australian Register of Therapeutic Goods (ARTG).
- Office of Product Review is responsible for post-market regulation (of all therapeutic goods) and undertakes post-market monitoring and enforcement of standards.
Comparing the regulatory framework for medical devices to the medicines regulatory framework is not straightforward. There are many idiosyncrasies of the medical devices framework that are directly related to the broad variety, intended use, method of delivering a therapeutic benefit, and risk profile of these therapeutic products. Additionally, the classification system of medical devices and the processes to demonstrate performance and safety according to risk profiles are not comparable across international regulatory frameworks. Whilst there is considerable international effort to harmonise the international medical device regulatory frameworks, the frameworks are still relatively immature in comparison to the global medicines regulatory landscape.

How does the Australian medical devices framework work?

The Australian medical devices regulatory framework is based on the principles of conformity assessment developed by the Global Harmonisation Task Force (GHTF). The GHTF was created in 1992 with the aim of harmonising medical devices regulation. Its founding members included Australia, the European Union (EU), the United States (US), Canada and Japan, each with very different regulatory frameworks. Australia adopted the GHTF model, which is based on the European regulatory system, in 2002 with a view to providing more opportunities in the global market for Australian manufacturers. As a result, the Australian and European systems of device regulation are closely aligned, though not identical. Aspects of the GHTF model have also been adopted by other jurisdictions, but the extent to which this has occurred varies. The GHTF was replaced by the International Medical Device Regulators Forum (IMDRF) in 2011, and harmonisation efforts are continuing.

Medical devices include a wide range of products, from lower risk devices such as bandages and tongue depressors to higher risk products such as catheters, breast implants, artificial hips, heart valves and pacemakers. Medical equipment, such as dialysis machines, incubators, MRI scanners and X-ray machines, also fall within the definition of a device.

To supply a medical device in Australia, the legislation requires that it is included on the ARTG. The ARTG provides a record of devices that can be supplied in Australia and a record of all the sponsors who are legally responsible for the medical devices on the market. Therefore an application to supply a device that is identical to an ARTG listed device is required, even if it is by the same manufacturer.

While the way in which medical devices are assessed by the TGA (and the information required to be provided by the device sponsor) differs from requirements in respect of medicines, both are underpinned by a risk based approach. That is, there is a correlation between the TGA regulatory activity and the risk posed by the medical device and its use, because it would be inefficient to regulate a tongue depressor with the same rigour as a pacemaker.

The higher the potential risks of a medical device, the greater the pre-market scrutiny. Low risk devices (such as elastic bandages) rely on the applicant’s certification of compliance with regulatory requirements (in a similar way to listed medicines), whereas higher risk devices (such as pacemakers) involve a direct evaluation of the available evidence assembled to support the quality
safety and performance of the device. This evaluation, which is known as Conformity Assessment (CA) may be undertaken by the TGA or by an EU Notified Body, depending on the classification of the product and, until recently, whether or not it is manufactured in Australia.¹

The manufacturer of the device is responsible for determining the risk classification of a device using a set of classification rules that are influenced by the:

- intended use of the device (external versus internal application, measuring versus sterile collection);
- length of time of use of the device;
- likelihood of harm from use of the device; and
- inherent risks associated with the device composition, (i.e. a biological or additional medicine delivery function).⁵

The classification levels are:⁶

<table>
<thead>
<tr>
<th>Classification</th>
<th>Level of risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (non-measuring / non sterile)</td>
<td>low</td>
</tr>
<tr>
<td>Class I—supplied sterile</td>
<td>low–medium</td>
</tr>
<tr>
<td>Class I—incorporating a measuring function</td>
<td></td>
</tr>
<tr>
<td>Class IIa</td>
<td></td>
</tr>
<tr>
<td>Class IIb</td>
<td>medium–high</td>
</tr>
<tr>
<td>Class III including Active implantable medical devices (AIMD)</td>
<td>high risk</td>
</tr>
</tbody>
</table>

Note: In vitro diagnostic medical devices (IVDs) are regulated as a subset of medical devices, and separately categorised in Classes 1 to 4,⁷ with similar risk levels to medical devices, and based on the same GHTF recommendations.⁸

**Conformity Assessment**

Conformity Assessment refers to a systematic examination of evidence generated by a device manufacturer, and procedures undertaken by that device manufacture, in order to determine that a medical device is safe and performs as intended and therefore conforms to the Essential Principles. The Essential Principles are set out in the Section 41C of the Act, and must be complied with before a device can be imported, supplied or exported. There are six general Essential Principles and a further nine Essential Principles about design and construction that may apply to medical devices on a case

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¹ On 14 October 2014, as part of its Industry Innovation and Competitiveness Agenda, the Government announced that it will enable Australian medical device manufacturers to use European conformity assessments in applications for ARTG inclusion, except for all Class III and some defined high risk devices.
by case basis. As noted above, the risk classification of a medical device determines the conformity assessment procedures a manufacturer can choose to ensure that a device is adequately assessed. The documentary evidence that is necessary to demonstrate compliance with the Essential Principles is used to substantiate a conformity assessment.

**Application for inclusion of a device on the ARTG**

Following conformity assessment, an application is made to the TGA to include the medical device on the ARTG. Depending on the device class, inclusion on the ARTG may occur with no further assessment by the TGA or, for higher risk devices, the device may be subject to an application audit by the TGA. That is, the legislation requires that the TGA conduct an evaluation of the conformity assessment documentation that demonstrates compliance with the Essential Principles for:

- Australian manufacturers. (Note, this will shortly change. On 14 October 2014, as part of its Industry Innovation and Competitiveness Agenda, the Government announced that it will enable Australian medical device manufacturers to use European conformity assessments in applications for ARTG inclusion, except for all Class III and some defined high risk devices).

- Specific high-risk devices, including devices that contain:
  - materials of animal, microbial or recombinant origin;
  - derivatives of human blood or plasma; and/or
  - a medicine.

Other medical devices that must undergo a mandatory application audit prior to being included in the ARTG include:

- a medical device (other than a condom) that is indicated to be a barrier for contraception or for prevention of the transmission of disease in the course of penile penetration during sexual intercourse;

- a medical device that is an implantable contraceptive device;

- a medical device that is an implantable breast prosthesis containing material of fluid consistency (other than water only or a saline solution only);

- a medical device that is specifically intended by the manufacturer to be used for disinfecting another medical device;

- an Active Implantable Medical Device (AIMD);

- a medical device that is a prosthetic heart valve;

- a medical device that is an implantable intra ocular lens;

- a medical device that is an intraocular visco-elastic fluid; and

- a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement.

When a device is included on the Register, it is assigned a unique device number.
Chapter 7: Regulation of Medical Devices

In summary, the pathway to preparing a submission to register a medical device in Australia consists of the following steps:

1. The manufacturer determines the classification of the medical device.
2. The manufacturer establishes that the medical device complies with the Essential Principles.
3. The manufacturer determines the appropriate Conformity Assessment process and obtains certification.
4. The manufacturer prepares an Australian Declaration of Conformity.
5. The sponsor (who may also be the manufacturer) applies for inclusion on the ARTG.

Fees and timeframes

The TGA charges fees for most aspects of device regulation, including an application fee for inclusion of the device on the ARTG (with the exception of Class 1 non-sterile, non-measuring devices, where inclusion is automatic and no fee is payable). Timeframes for various aspects of device regulation vary, depending on the device. TGA conformity assessments have a statutory timeframe of 255 working days. The timeframe for inclusion on the ARTG of a low to medium risk medical device that is accompanied by a valid conformity assessment certificate can vary from 3 to 8 weeks.\(^9\) The Regulations do not specify timeframes for inclusion of higher level devices on the ARTG, but guidance\(^10\) documents produced by the TGA indicate that processing times for such devices may vary depending on the number of applications on hand in the TGA, risk classification of the device, and whether an application audit is required. The Regulations specify that an applicant has 20 working days to provide additional documentation if requested by the TGA to inform an application audit.

There are provisions to allow fee reductions for low value, low volume products, or reductions in audit and assessment fees, but there is no provision in the therapeutic goods legislation to allow a reduction in ARTG application fees.\(^11\)

The European and US Approach

The EU device regulation system shares a similar classification system with Australia, but devices are not directly subject to any pre-market authorisation by a regulatory authority. They are, however, subject to a conformity assessment which, for medium and high risk devices, involves a commercial independent third party, known as ‘notified body’. There are around 80 notified bodies across Europe, which are designated and monitored by member states and act under control of national authorities.

Manufacturers are free to choose any notified body that has been designated to carry out the conformity assessment procedure in question according to the applicable EU directive. Once certified by any of these bodies, devices bear a CE Mark which enables the product to be freely traded across EU markets. However, individual jurisdictions may require local registration of the device, and may impose requirements regarding the language in which device information is provided.
The Food and Drug Administration (FDA) is responsible for regulation of medical devices in the US. Manufacturers and distributors of medical devices intended for sale in the US are required to register annually with the FDA. The US classification system for devices is different than that used by Australia and Europe. The FDA classifies devices based on risk and level of regulatory control, and there is a greater level of pre-market approval scrutiny for novel or higher risk devices than for devices that are substantially equivalent to an already approved medical device or lower risk devices.

There are two ways of obtaining pre-market clearance/approval. For medical devices that can demonstrate they have substantial equivalence to medical devices that are already approved, the 510(k) pathway enables faster approval and market access. Following assessment, the FDA system allows listing of some devices by a pre-market notification, however if a pre-market review is required, there are 12 third party organisations accredited to undertake a 510(k) primary review, and they may charge a fee. On receipt of the review recommendations, the FDA will issue a final determination within 30 days, without additional charge.

Higher risk devices and those that do not have a substantially equivalent predicate that would enable market access through the 510(k) process undergo Premarket Approval (PMA), which is a process of scientific and regulatory review to evaluate the safety and effectiveness of the device. The process involves the compulsory submission of clinical data to support claims made for the device. In contrast, clinical data is only referred to in about 15 per cent of 510(k) device reviews. Fees are applicable, although there are provisions for reductions or waivers for small businesses and devices to be used in clinical studies in order to collect safety and effectiveness data to support a future PMA or Premarket Notification 510(k) submission to the FDA. The FDA also charges annual registration fees.

The FDA regulations also cover the specific requirements for manufacturing quality systems, labelling, and adverse events reporting.

**Regulation of Devices in Australia - Identified Issues**

Nationally, there have been a range of previous reviews, inquiries and/or stakeholder consultations that have examined aspects of the regulation of medical devices in Australia. Through these processes, a number of issues and concerns have been identified.

These issues can generally be grouped into the following themes:

1. There is duplication of regulatory processes, which creates an unnecessary additional burden on industry.
2. The regulatory framework lacks the necessary flexibility required to facilitate early access to innovative products.
3. Some regulatory requirements are not considered to be commensurate with the risk posed by the regulated products.
4. Some TGA processes are considered to be overly burdensome and out of step with technology.
5. The regulatory framework is overly complex and poorly understood by many of those who have to interact with it.

An overview of the issues raised in respect of each of these areas of concern is provided below. The issues, concerns, and possible options for the future outlined in each section do not necessarily represent the views of the Panel. Rather they have been drawn from previous reports, from a summary of stakeholder views and options for change provided to the Panel by the TGA, and from a review of stakeholder submissions to a range of fora, including the Australian Government National Commission of Audit and consultations on Regulatory Impact Statements conducted by the TGA from time to time. They are documented here in order to promote discussion and to assist the Panel to form a view about whether there is a shared understanding amongst stakeholders of the issues and of options for the future.

**Theme 1: Duplication of regulatory processes**

The key area of duplication identified by stakeholders is the requirement for pre-market assessment by the TGA of some medical devices that have already been conformity assessed and approved by a trusted overseas regulator. This has been identified as an issue in previous reviews and is also of concern to the Australian Government.

As outlined in the *Industry Innovation and Competitiveness Agenda, An action plan for a stronger Australia*, the Australian Government has adopted the principle that:

> …if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so. All Commonwealth Government regulatory standards and risk assessment processes will be reviewed against this principle.\(^{13}\)

In the context of devices, this principle means that where a medical device has been approved through a trusted international risk assessment, the TGA should not impose any additional requirements, unless there is good reason to do so.

This raises a number of issues for consideration:

1. How might a ‘trusted overseas regulator’ be defined?
2. Is there good reason why Australia should ‘impose additional requirements’ in respect of the approval of medical devices?
3. What does approval of a ‘product’ mean in the context of medical devices? Does the device have to be identical in all regards or can there be variations that do not necessitate a full or partial re-assessment? How should this be determined?

**Issue 1 – How might a trusted overseas regulator be defined?**

Australia has to some extent already identified ‘trusted overseas regulators’ for the purpose of many medical devices – namely EU notified bodies. As outlined previously, the TGA accepts conformity assessment certificates provided by a EU notified body without further assessment for many products – generally lower to medium risk. For higher risk products the TGA does mandatory
application audits, during which it reviews relevant documentation, including in some instances the clinical evaluation report from the notified body that undertook the conformity assessment.

In recent years, the European system has been shown to have systemic weaknesses,14 which has led to concerns about the quality of conformity assessment undertaken by some EU notified bodies. This resulted in the TGA auditing all applications for inclusion of medical devices in the ARTG that use supporting evidence from eight EU notified bodies of concern.15 Concerns about the competency of some EU notified bodies has highlighted the fact that the Australian Government does not have any legislative basis to influence the accreditation/approval of EU notified bodies and therefore to ensure that their assessment procedures are robust enough to satisfy Australian regulatory requirements.

The European Commission is reviewing its regulatory framework for devices and this is expected to include implementing stronger supervision of the independent notified bodies.16 Nevertheless, the question remains as to whether Australia should have mechanisms in place which allows it to undertake its own assessment of the competency of EU notified bodies, thus assuring the Australian public that EU assessments accepted by Australia are conducted with the necessary skill and rigour. This would also potentially reduce duplication, in that, if the TGA had confidence in the notified bodies, it would not need to undertake application audits at the same frequency.

Alternatively, given the concerns with the EU system, should Australia look to recognise other international regulators as ‘trusted’ for the purpose of device approvals? For example, the FDA would be a logical alternative given its reputation as a competent regulator and the size of the US device market. As noted above, however, the US classification system for devices and the process by which devices are assessed differ from the models adopted by the EU and Australia and may raise issues in terms of automatic acceptance of device approvals.

A comparison of the FDA and EU approval processes by the Boston Consulting Group in 2012 looked at device registration data from 2000 to 2011 and found that:

- the same devices had been approved and made available to patients in Europe three or more years before they were approved in the US; and
- devices approved by the Premarket Approval (PMA) process in the US had been available in Europe for an average of 43 months before being made available in the US.17

In addition, a recent examination of the US’ regulatory system for devices found issues with the process to list medical devices based on an equivalent approved (predicate) device (i.e., the 510k process), including a lack of scientific data to support the claim of substantial equivalence, particularly clinical data.18

The recent criticisms of EU and US device regulation highlight that, unlike the regulatory framework for medicines, which is relatively mature and stable, the regulation of medical devices is still evolving. The nature and extent of assessment undertaken can vary markedly between countries. This raises the question of whether Australia should develop a set of transparent criteria against which overseas device regulators would be assessed in order to designate them as ‘trusted’. As the international regulatory frameworks are not static, any criteria that are developed would need to be
able to accommodate the dynamic regulatory conditions and would need to consider how to manage conflicting decisions by different trusted regulators, should this occur.

Questions for consideration:

Should the TGA undertake its own assessment of the competency of EU notified bodies? If yes, how might this occur? If not, why not?

Alternatively, given the concerns with the EU system, should Australia look to recognise other international regulators as ‘trusted’ for the purpose of device approvals?

If yes, what criteria should apply in determining whether or not an overseas regulator is trusted?

Should any criteria take into account different device classifications? For example, a regulator could be designated trusted for some classes of devices but not others.

Issue 2 – Is there a good reason for Australia to impose additional requirements?

As noted previously, the TGA accepts conformity assessments from EU notified bodies but imposes additional requirements in respect of some (generally higher risk) devices. Following concerns about some EU notified bodies the TGA now also imposes additional requirements in respect of devices that were conformity assessed by specified EU notified bodies.

Notwithstanding any concerns about EU notified bodies, in theory if a device sponsor obtains a conformity assessment certificate for a medical device from a EU notified body and then subsequently applies to include on the ARTG the identical device for the same purpose, it can be interpreted that the manufacturer:

- has already established that the device meets the Essential Principles, and
- has attained a Conformity Assessment that substantiates the device meets the appropriate manufacturing, performance and safety regulations.\(^{ii}\)

Given this, is there a rationale for the TGA to impose additional requirements? The primary rationale is the immaturity of device regulation internationally and the need to build confidence in the assessment of devices by conformity assessment bodies. This is particularly important in relation to higher risk devices, including implantable devices, where the consequences to patients should the device fail may be significant. This was demonstrated most recently with the failure of PIP breast implants and the metal on metal hip replacements.

In addition to concerns raised in the British Medical Journal about some EU notified bodies,\(^{19}\) post-market assessments by the TGA and FDA have also identified deficiencies in notified body performance, such as inadequate Quality Management System (QMS) inspections that resulted in medical device faults. In May 2012 the FDA issued a report\(^{20}\) that argued (in very strong terms) that

\(^{ii}\) In respect of other overseas regulators that might be deemed ‘trusted’, it is less clear how their assessment processes relate to the Essential Principles. This would need to be considered in the development of any criteria/assessment process for recognising ‘trusted’ regulators.
the EU’s regulatory system fails to ensure safety of high-risk medical devices it approves. The report cited 12 examples of high-risk devices approved in the EU and then later deemed ineffective or dangerous. The FDA report contends that EU regulators require less clinical evidence of device safety than the US premarket approval and premarket notification schemes, and that EU medical device approval requirements focus too heavily on technical performance rather than safety.

It could, therefore, be argued that, in order to protect health and safety and to provide reassurance to Australian consumers, additional assessment of higher risk devices is warranted until such time as the Australian regulator is completely confident in overseas conformity assessments.

**Questions for consideration:**

Should the TGA approve the inclusion of a medical device on the ARTG on the basis that it has been approved for the same purpose by a ‘trusted’ overseas regulator?

- If yes:
  - should this occur regardless of the class of the device?
  - How could concerns about the quality of some overseas conformity assessments be managed?

- If not, why not? What value do you believe an assessment by the TGA adds?

Are there aspects of safety, quality or efficacy that need to be considered in the Australian context? If so, what aspects?

Another instance in which Australia imposes additional requirements on device sponsors is where there are differences in the classification of a device between Australia and the EU, in which case the conformity assessment procedure requirements may be different in Australia. On these occasions the manufacturer may be required to obtain additional conformity assessment evidence. Where the manufacturer is not able to obtain the appropriate additional conformity assessment evidence from their EU notified body, they may need to obtain a TGA Conformity Assessment Certificate.

Additionally, under the current regulatory framework, depending on the risk profile of the medical device there are some Australian specific requirements for labelling, advertising, and post market monitoring. These additional requirements would appear to be unavoidable unless Australia was prepared to adopt the EU classification system in its entirety and not impose Australian specific requirements with respect to labelling etc.
Questions for consideration:

Where there are differences in device classification between Australia and the EU, should sponsors be required to meet additional conformity assessment requirements? If not, why not?

Should Australia adopt the EU classification system? If not, why not? What are the strengths of the Australian device classification system that cannot be found in the EU system?

Should Australia maintain Australian specific requirements with respect to labelling and post market monitoring? If not, why not? If yes, what value do these requirements add?

Issue 3 – What is meant by product approval?

Product approval for medical devices in Australia is currently a two stage process. Firstly, obtaining conformity assessment (from either an EU notified body or the TGA); and secondly, approval to include the product on the ARTG. In applying for inclusion of a device on the ARTG, the device sponsor provides a conformity assessment certificate obtained by the device manufacturer for that specific device (with the exception of some Class 1 devices which are self-assessed). As such, there is no question that the device being marketed in Australia is the same in all respects to the device that was conformity assessed in Europe.

This may not be the case, however, if Australia was to recognise other device regulators as ‘trusted’ regulators. That is, in the absence of a conformity assessment linked to the specific device manufacturer, there would not necessarily be a clear link between the manufacturer and device approved by the ‘trusted’ regulator and the device submitted for inclusion on the ARTG. For example, a device that is approved by the FDA for the US market might be manufactured in the US, but the same device for the Australian market might be manufactured in the Asia Pacific region. As such, it may be necessary to establish that the device and associated manufacturer and manufacturing site and methods are the same. If they are not, it may be necessary for the TGA to undertake some additional assessment where any differences have the potential to impact the quality, safety or performance of the device.

Questions for consideration:

Should a difference in a medical device that has been approved by a trusted overseas regulator necessitate a further assessment by the TGA in circumstances where that difference may impact safety, quality or performance? If not, why not?

If yes, should the assessment by the TGA be limited only to those aspects of the application that are impacted by the difference?

Would this approach apply to all classes of medical devices?

The introduction of accelerated approval processes for devices by international regulators also raises issues to be considered by Australia in terms of acceptance of device approvals by trusted overseas regulators. For example, the FDA has released guidelines proposing a new expedited access premarket approval process for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions.\(^1\) Such
programs may see medical devices provisionally or conditionally approved based on more limited clinical data than is traditionally required. In these instances the international regulator may impose conditions on the sponsor, such as requiring greater post market surveillance.

Questions for consideration:

If Australia was to accept approvals of medical devices by trusted overseas regulators, should this include conditional/provisional approvals? If not, why not?
Would this approach apply to all classes of medical devices?
If yes, should the marketing conditions/provisions imposed by the trusted overseas regulator also apply in Australia? If not, why not?
Should there be capacity for Australia to impose its own conditions, either in addition to, or in place of, those imposed by the trusted overseas regulator and if so, why?

Theme 2: Lack of flexibility

Two issues have been identified in respect of the flexibility of the regulatory framework for devices in Australia:

1. No provision for accelerated access in certain circumstances; and
2. Ability of the framework to accommodate technological advancements in medical devices.

Issue 1 – Accelerated access

Concerns have been raised by consumers, industry and health professionals that the regulatory framework for medical devices is too rigid and cannot accommodate accelerated approval of promising new medical devices. The Medical Technology Association of Australia (MTAA) has proposed the introduction of a provisional or conditional registration for a limited time (e.g. two years) to enable a company to utilise a high risk device to generate additional clinical data prior to full registration. The proposal is that this would be available in circumstances where the medical device is used in the prevention or treatment of life-threatening conditions and where the device is likely to provide clinically significant therapeutic benefits to patients over existing treatments. As noted previously, accelerated device approval processes in similar circumstances are being considered by regulators internationally, including the FDA.

The US Expedited Access PMA (EAP) has been designed to facilitate more timely access by patients to promising medical devices by expediting their development, assessment and review, while providing reasonable assurance of safety and effectiveness. The pathway is available in circumstances where the medical device addresses unmet medical needs for life threatening or irreversibly debilitating diseases or conditions. The program provides for:

- earlier and more interactive engagement between the FDA and the device sponsor during the device’s development, assessment and review;
- use of intermediate and surrogate endpoints;
• less manufacturing information to be provided in a sponsor’s PMA application (where appropriate); and
• the FDA to, at its discretion, forgo inspections of certain manufacturing sites until after the product is approved.\(^\text{23}\)

The FDA has indicated that it intends to impose post-market requirements on devices expedited under the EAP, including conditional approval on the basis of ‘continuing evaluation and periodic reporting on the safety, effectiveness and reliability of these devices for their intended use...’ \(^\text{24}\)

The call for access to accelerated approval schemes for medical devices must be balanced against the willingness of patients, health care practitioners, and governments to accept inherent uncertainties about the benefits and risks of products that are an inevitable accompaniment to expedited access. Factors which would need to be considered include: clinician and patient acceptance and how to ensure that both clinicians and patients are aware that a device has only been provisionally approved; what mechanisms exist for discontinuing market authorisation if the device becomes the subject of safety concerns or is shown to be of limited efficacy; and treatment of provisionally approved devices by reimbursement authorities.

Questions for consideration:

Should Australia introduce an accelerated approval program(s) for higher risk medical devices? If yes:
• What eligibility criteria should apply to the accelerated approval pathway? That is, under what circumstances could a sponsor apply for accelerated approval of a device?
• What are the potential risks and benefits of such programs and how might the risks be managed and the benefits maximised?

If higher risk medical devices were to be provisionally approved, based on more limited clinical data than is traditionally required for a full approval:
• What additional requirements, if any, might be appropriate to alert clinicians and/or consumers to the provisional approval and its implications?
• What requirements would need to be in place to manage withdrawal of the device from the Australian market if safety or efficacy concerns emerged?
• What additional post-market surveillance would need to be in place for medical devices that were provisionally approved?

Issue 2 – Ability to accommodate technological developments

Medical devices are becoming increasingly sophisticated. Use of converging technologies is more common, as is the inclusion of interactive software. This has implications for the risk profile (and therefore classification and assessment) of devices. The regulatory framework and classification system for medical devices needs to be flexible enough to accommodate these rapid technological advancements so as to ensure timely access to these devices on the Australian market. Similarly,
post market surveillance needs to be designed to allow both internal and external risks to be identified, monitored and responded to in a timely manner.

**Question for consideration:**

Is the current regulatory framework and classification system flexible enough to accommodate new and emerging medical device technologies? If not, why not? How could it be improved?

**Theme 3: Regulatory requirements are not commensurate with risk**

Stakeholders have identified a number of areas where they believe Australian regulatory requirements are not commensurate with risk. These relate to:

1. The balance between managing risk and minimising unnecessary regulatory burden.
2. Approval of variations to devices.
3. Inadequate emphasis on post market surveillance and supportive data collection and analysis.
5. Regulation of *in vitro* diagnostic medical devices (IVDs).

**Issue 1 – The balance between risk management and regulatory burden**

As noted previously, the regulation of medical devices internationally is still relatively immature and the diversity of products represent a wide range of risk profiles, from very low to very high. There are, therefore, competing views about whether the regulation of medical devices in Australia achieves the right balance between managing risk and minimising regulatory burden. For example, some stakeholders argue for more rigorous assessment of clinical evidence prior to inclusion of higher risk devices on the ARTG, while others recommend no additional TGA assessment of devices that have undergone a EU conformity assessment, regardless of risk level.

At the lower risk end, some have questioned what purpose is served by including on the ARTG medical devices that undergo no independent assessment. The risk profile of these products may be more closely aligned to that of general consumer goods than a therapeutic device and it might be argued that their regulation as therapeutic products creates unnecessary burden on industry but does little to manage risk. In addition, inclusion of such goods on the ARTG may provide false assurance to consumers and health professionals by giving the impression that the goods have undergone an independent assessment of their safety, quality, and performance, when in fact that may not be the case.
Questions for consideration:

Does the current regulatory framework for medical devices in Australia provide an appropriate balance between managing risk and minimising unnecessary regulatory burden? If not, why not? Please provide examples.

Should low risk medical devices that are not subject to an independent conformity assessment be included on the ARTG?

- If not, why not? Are there any risks involved in not including such products on the ARTG?
- If yes, why? What are the benefits of these products being included on the ARTG?

Issue 2 – Variations to Medical Devices

Many modifications to medical devices are made as a result of continuous development following real world use. Variations must be either notified to, or approved by, the TGA, and some stakeholders have questioned whether the regulatory scrutiny of some medical device variations is commensurate with the risk they pose.

Where a variation to a medical device relates to the information contained on the ARTG entry, the variation must be submitted to the TGA irrespective of the class of the device. However, changes in relation to a device included on the ARTG that do not change the classification or the intended purpose of the device are not required to be submitted to the TGA. For example, a change to labelling or instructions for use would not need to be submitted to the TGA, but a change in the name or address of the manufacturer would need to be submitted.

Where the variation is to the device itself, the TGA requires information to be submitted to ensure that the risk-benefit profile of the device has not changed and does not require consequential changes to the ARTG inclusion. In instances where the TGA has actually issued the conformity assessment certificate, any change to either the: details on the certificate; device; or quality management system, must be advised to the TGA. The TGA then assesses the changes to ensure that the risk-benefit profile of the devices supported by the certification remains acceptable.

According to the MTAA:

> These submissions for assessment of changes can take over 18 months to review. During this time, the overseas manufacturer, which has had the change assessed and approved by FDA (notification) and the EU Notified body (one month), may have to stock pile the superceded version of the device for supply in Australia until TGA has completed its review. Due to the unpredictability of TGA review time frames the stored products may expire resulting in users having to switch to using a different device, which poses usage risks, until the TGA review process is complete.25

As intimated by MTAA, a number of overseas regulators manage variations to medical devices on a risk basis, including through notification, annual reporting of changes (FDA), or variation assessment mechanisms (EU notified bodies). Timeframes for these processes are considered to be significantly shorter than those of the TGA.
Questions for consideration:

Should Australia adopt a risk-based regime for variations, which allows notifications and/or annual reporting for changes to medical devices that are at low risk of impacting the quality, safety, or performance of the device?

If yes, what might such a regime look like? How might notification/reporting procedures be designed so as to minimise burden on sponsors?

If not, why not?

Issue 3 – Post-market surveillance and supportive data collection and analysis

The lifecycle of a medical device has traditionally been divided by regulators into two stages; pre-market and post-market. During the pre-market stage, the conformity assessment requirements for clinical evidence and product performance are not equal across all device classes. Low risk medical devices undergo little or no independent clinical and performance assessment and the emphasis is on post-market surveillance. Higher risk medical devices are required to provide more data to support a conformity assessment, but the evidence standards for medical devices are less rigorous than for medicines. As such, post market surveillance of medical devices is critical to ensuring public health and safety.

Post market surveillance becomes even more important in the context of accelerated approval or provisional licensing schemes under which medical devices may be provisionally approved based on a different standard of clinical evidence, such as intermediate and surrogate end points. The benefit is earlier access to promising new devices for some patients, which is weighed against the increase in the level of uncertainty about benefits and risks known at that time. Such programs will require a higher degree of post market surveillance, including ongoing data collection and analysis to ensure that risks are minimised and benefits realised.

Post-market monitoring of medical devices by the TGA may include checking evidence of conformity; conducting periodic inspections of manufacturers’ QMS and technical documentation; and imposing specific reporting requirements for manufacturers and sponsors. It is a condition of inclusion on the ARTG that the sponsor reports to the TGA on adverse incidents, overseas regulatory actions and the results of investigations undertaken by the manufacturer. Manufacturers also have obligations in respect of their particular device which will vary depending on the applicable CA procedure. For example, the manufacturer is required to have, as part of its QMS, a procedure for gathering information on the performance and safety of the device in the post-market phase and to ensure any information gathered continues to demonstrate compliance of the device with the Essential Principles throughout the product’s life.
Chapter 7: Regulation of Medical Devices

Questions for consideration:

Does Australian have the balance right between pre-market and post-market regulation of medical devices?

If not, why not? How could it be improved?

What are the features of an effective post-market surveillance system?

Issue 4 – Access to unapproved medical devices

Patients with conditions that cannot be successfully managed or treated with medical devices included on the ARTG currently have access to unapproved therapeutic goods under a variety of schemes administered by the TGA. These programs provide access in certain circumstances to: medical devices for patients that initially had access through a clinical trial; medical devices that may have been withdrawn from the Australian market for commercial reasons; or medical devices available overseas but not marketed in Australia.

The Special Access Scheme allows individual patients to access unapproved therapeutic goods under a range of circumstances. Under the Scheme, patients are classified as either Category A or Category B. Category A patients are defined as ‘persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.’ A medical practitioner who believes that his or her patient falls into Category A can import/supply an unapproved therapeutic good without approval from the TGA. To do so they must complete a ‘Category A Form Special Access Scheme’ and send it to the product sponsor. This form gives the sponsor legal authority to provide the device in question. A copy of the form is to be provided to the TGA within four weeks. This approach would appear to provide timely access to unregistered devices for Category A patients without imposing an unreasonable administrative burden on medical practitioners.

Questions for consideration:

Is the Special Access Scheme efficient and effective for Category A patients?

Are there issues or concerns with the way in which the Scheme currently runs?

For patients with non-life threatening conditions, who fall into Category B, access to unapproved goods requires TGA approval. Application can be made by phone (where there is an urgent medical need), facsimile or in writing to a TGA medical officer who has delegation under the Act to make a decision regarding the request. In assessing the application, the TGA medical officer considers evidence in respect of the safety and efficacy of the product, the seriousness of the patient’s condition and the qualifications of the requesting medical practitioner. As a general rule, the less serious the clinical need, the higher the degree of evidence needed to support the use of the product. Decisions are generally made within five days.

An application to use an unregistered device in Category B patients is required regardless of the level of risk. For example, even if the device requested has been approved by a trusted overseas regulator
for the purpose for which it will be used, an application must be lodged by the medical practitioner and assessed by the TGA delegate.

Similarly, under the ‘Authorised Prescriber’ scheme, a medical practitioner may be granted authority to become an authorised prescriber of a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of recipients) with a particular medical condition. An application is required for all medical device classes, regardless of the level of risk.

A more risk-based approach could be considered, which focuses scrutiny only on: devices with high risks of adverse events; devices proposed for use in novel clinical situations; or those that have not been approved by trusted overseas regulators.

In 2009–10 the TGA approved 5,341 registrations of medical devices and approved 2,991 Special Access Scheme medical devices.

Questions for consideration:

Should the Special Access Category B and the Authorised Prescriber schemes be revised to narrow the range of circumstances in which TGA approval is required for use of an unregistered medical device?

- If yes, what criteria might be applied to determine when an approval is required?
- If no, why not? What do you perceive as the risks of such an approach?

Issue 5 – Regulation of IVDs

Prior to the implementation of the IVD framework in 2010, the TGA did not regulate most IVDs (except for some home-use tests and HIV and HCV testing kits). For laboratories that used in-house IVDs (not intended for commercial supply), the quality of the testing equipment was assured through the accreditation of the laboratory by the National Association of Testing Authorities (NATA), while the ability of the pathologist to interpret test results was ensured through accreditation by the Royal College of Pathologists of Australasia (RCPA).

Under the new regulatory framework, IVDs are considered a subset of medical devices, and they are classified based on the risk posed to the health of the public or an individual, and the risks associated with an incorrect result arising from the use of the IVD. They include pregnancy self-tests, glucose monitors, and tissue tests for transplantation. The level of conformity assessment required is dependent on the class of the IVD, and whether it is used ‘in-house’ or commercially supplied.

For Class 1 to 3 in-house IVDs, NATA and RCPA accreditation demonstrates compliance with the National Pathology Accreditation Advisory Council standard for in-house IVDs, which evidences conformity with relevant IVD essential principles. These IVDs are notified to the TGA, whereas Class 4 in-house IVDs must obtain TGA conformity assessment and apply for inclusion on the ARTG. If the laboratory is part of an organisation with NATA corporate accreditation, it may distribute the Class 1 to 3 in-house tests within its network under the same approval. However, if the laboratory
supplies the IVDs outside of their network, they are considered a commercial IVD manufacturer, and must comply with the IVD medical device conformity assessment and ARTG inclusion processes.

The IVD framework commenced in July 2010 with a four year transition period, (which was recently extended until up to 30 June 2017, depending on the IVD). At the time the framework was implemented there were concerns raised that it may lead to adverse outcomes in clinical diagnosis and management because:

*manufacturers of IVDs will conform to existing regulatory standards ahead of clinical best practice standards, and... future improvements to clinical best practice standards may not be translated into clinical practice because the regulatory burden may act as an impediment to manufacturers to undertake any future improvements in existing IVDs.*

More recently IVD Australia has raised concerns about the length of time being taken by the TGA to assess applications for conformity assessment, noting that there are no statutory timeframes for assessment of IVDs under the regulations introduced in 2010.

**Questions for consideration:**

Has the regulatory framework for IVD’s resulted in a reduced emphasis on clinical best practice? If so, how. Please provide examples.

Should there be statutory timeframes for assessment of applications for inclusion of an IVD on the ARTG?

**Theme 4: Overly burdensome processes**

Stakeholders have identified a number of TGA systems and processes that they consider to be unnecessarily burdensome. These relate to:

1. Multiple systems and manual processes.
2. Process for inclusion of devices on the ARTG.
3. Instructions for medical devices.
4. Registration of additional intended purposes for a device.

**Issue 1 – Multiple systems and manual processes**

The TGA currently uses a range of systems in the regulation of medical devices and medicines and still relies on the submission of a significant amount of paper documentation for key processes. Manual transactions place an additional impost on sponsors and health practitioners compared to electronic transactions and also impacts timeliness. Manual processes may also reduce transparency. For example, electronic processes would allow those submitting information to know instantly if it has been received, and could be configured to allow sponsors or health practitioners to track the status of their application through the system.

There is significant scope for TGA processes to be digitised to achieve efficiencies through reduced document preparation, printing, engagement, and through improved application wait times. On-line
access to visible milestones and expected completion dates would improve an applicant’s understanding of when approval is likely to be granted, and in turn, assist with forward planning for getting their product to market.

The TGA has advised that it is working towards implementing a single, online portal through which it can transact with industry and medical professionals, which will include use of pre-populated ‘smartforms’ and applicant access to milestone and expected completion dates for their applications.

**Question for consideration:**

What TGA processes do you consider most burdensome and why? How might these be improved?

**Issue 2 – Process for inclusion of medical devices on the ARTG**

Concerns have been raised about the process for including a device system or ‘family’ on the ARTG. Some medical devices have a range of component parts which cannot work without the other parts of the system. For example a hip replacement device may include an acetabular cup and liner and a femoral head and femoral step. Such a device may be assessed by an EU notified body as a system of devices. However, according to the MTAA, because of the mandatory use by the TGA of Global Medical Device Nomenclature (GMDN) codes used to describe a ‘kind’ of device, a device system must be included in the ARTG by its component parts. This means that the sponsor of a device system may have to submit multiple applications and sets of technical documentation to the TGA in order to include the system on the ARTG.

There are provisions under the *Therapeutic Goods Act 1989* for inclusion of medical device systems on the ARTG as a single medical device. But this requires that the goods are supplied to the user as a system, and this is impractical for many devices. That is, in the case of the hip implant, if a patient already had an implant and only one component (for example the femoral head) failed, the sponsor would not be able to provide a replacement head unless that component was individually registered on the ARTG. The TGA argues that it is also important for high risk devices to have unique product identifiers for post market surveillance purposes.

**Questions for consideration:**

How might the processes required to include a device family on the ARTG be streamlined without undermining public health and safety?

Are there other concerns with the inclusion of devices on the ARTG? How might these be addressed?

**Issue 3 – Instructions for medical devices**

The *Therapeutic Goods (Medical Devices) Regulations 2002* establish that the product information and instructions for use of a medical device must meet the Essential Principles. The principles relating to design and construction specify that the instructions for use must be on the device itself, on the packaging for the device, or on a leaflet or document supplied with the device. There are
exceptions for Class I devices that can be used safely for their intended purpose without instructions. For many medical devices this is not possible, impractical, or out of step with technology.

For some medical devices it is more effective to provide electronic instructions for use, such as the use of a CD, DVD, USB or embedded software. Under the Regulations, these alternatives can only be used if the manufacturer can justify that the provision of information on the device itself is impracticable. This stringent requirement imposes a regulatory burden on the device manufacturer and sponsor. Greater flexibility in permissible formats for instructions of use would be consistent with emerging electronic technologies and the emerging global trend of allowing electronic instructions for use of medical devices.

**Question for consideration:**

Should the TGA allow a broader range of permissible formats for instructions for the use of medical devices? If not, why not?

**Issue 4 – Registration of additional intended purposes for a device**

The classification of a medical device is linked to its intended purpose, including where it will be used in the body. Changing its intended purpose (or adding an additional intended purpose) will give rise to the creation of a distinct and separate medical device. As such, to include a device on the ARTG for a new intended purpose, the manufacturer must undertake another conformity assessment and Declaration of Conformity process and the sponsor must apply for inclusion of the device in the ARTG for that intended purpose.

The cost and time impost associated with another full ‘registration’ process may act as a disincentive to sponsors registering the device for additional intended purposes. This in turn has implications for the capture and sharing of data and experience between health professionals and manufacturers and vice versa.

Failure to register the medical device for additional intended purposes does not preclude health professionals from using the medical device in different ways, similar to the ‘off-label’ usage of medicines. Whereas data is available for the off-label use of medicines that indicates the practice is common, the differing degrees of post-market monitoring across class categories for devices, and the wide range of end users poses challenges to obtaining similar data for devices.

Off-label usage brings with it a number of clinical, safety and ethical issues, but registration of additional intended purposes or indications for a device ensures that information about the use of the medical device in those circumstances is available to all health professionals and consumers.
Questions for consideration:

Do current regulatory requirements, costs, and timeframes act as a disincentive to the registration of additional intended purposes for medical devices?
If yes, how might the regulatory framework or processes be changed to reduce the disincentives and/or provide incentives for the registration of additional intended purposes?

Theme 5: Complex regulatory framework

Stakeholder concerns about the complexity and transparency of the medical devices regulatory framework relate to:

2. Transparency of regulatory decisions.
3. Interaction with other regulatory frameworks.

Issue 1 – Categorisation of medical devices

Stakeholders have identified difficulties experienced by medical device manufacturers and sponsors in understanding and complying with requirements for pre-market approval, including data requirements. This is particularly the case for small to medium sized enterprises, who struggle to navigate the regulatory system without guidance and/or advice.

A manufacturer or sponsor wishing to include a medical device on the ARTG must determine what category a device falls into and then demonstrate compliance with: relevant standards for the device, manufacturing standards, and conformity with legislative requirements.

As the range and diversity of goods defined as medical devices is vast, the rules for categorising devices according to risk are extremely complex, with many caveats to try and deal with every device permutation. In addition, the classification rules are applied separately to each medical device that is used in a combination and some elements of the device, such as software, may be classed as an accessory and therefore classified separately to the device itself, adding to the complexity.

The interplay between the various factors that need to be taken into account in classifying a device can make assessment of the correct class of medical device very difficult. It is possible to classify some medical devices into more than one category, with the manufacturer and sponsor faced with different next steps and pre and post market obligations for each choice.

As the level of scrutiny that a medical device is subjected to is determined by the categorisation of the device, failure by manufacturers to correctly categorise their device could result in some higher risk devices being supplied on the Australian market without being adequately assessed. Alternatively, where a manufacturer over-categorises their device, it may result in unnecessary cost and delay in getting the device to market.
While the TGA has produced a number of guidance documents on the regulatory framework and process for medical devices iii there does not appear to be a single, definitive source of information to guide manufacturers and sponsors through the process. Nor does there appear to be a decision tool that would assist manufacturers to correctly classify their device by, for example, walking them through a series of ‘if this, then that’ questions.

**Questions for consideration:**

- Is the classification system for medical devices too complex? If yes, how might it be simplified without impacting public health and safety?
- Do manufacturers require assistance, such as online decision tools, to assist them to correctly classify medical devices? If not, why not?
- If yes, what sorts of assistance would be most effective?
- Is the pre-market assessment of medical devices considered overly complex in other ways? If yes, in what way? What are the major pressure points and how might these be addressed?

Concerns about the complexity of the regulation of medical devices has resulted in some calls for the TGA to take a more active role in providing regulatory advice and in working with sponsors to assist them to navigate the pre-market approval system, similar to the early engagement approach adopted by European and US regulators. This would be particularly helpful for small to medium sized enterprises that do not have access to regulatory advice in house.

**Questions for consideration:**

- Is there a role for the TGA in providing a regulatory advice service to product developers/manufacturers/sponsors? If not, why not?
- If yes, what should the nature and scope of this advice service be? How could risks of regulatory capture be avoided?
- Is current guidance material easy to locate, navigate and understand?
- If not, what are the main issues and concerns? How might this material be improved?
- Is the TGA website easy to navigate? If not, how might it be improved?

**Issue 2 – Transparency of regulatory decisions**

Stakeholders have expressed concern that the complexity of the regulatory system makes it difficult to anticipate the outcome of a medical device application, which affects business decisions and forward planning. They argue that the level of transparency could be improved by publishing specific information about regulatory decisions, similar to the Australian Public Assessment Reports for

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prescription medicines (AusPARs) that summarise the evaluation process that led the TGA to make a decision to approve or not approve a medicine for use in Australia. This would assist industry, but may also assist consumers and health practitioners, who would have access to information to inform decision making about a product’s suitability. Publishing other regulatory decisions related to the outcomes of reviews and post-market audits would also increase the transparency of post-market activities.

Publishing detailed information from applications or other documentation, including clinical evaluations used to support the assessment of higher risk medical devices, may be of concern to industry where they include commercial or other sensitive data.

Questions for consideration:

Should information about regulatory decisions in respect of medical devices be publicly available? For example, an evaluation report or other relevant information.

- If not, why not? What do you see as the risks?
- If yes, how would this benefit consumers, clinicians and industry? How could any risks be managed?

Should other regulatory findings relating to medical devices be made public, for example, reports on audits or post-market reviews?

- If not, why not? What do you see as the risks?
- If yes, how would this benefit consumers, clinicians and industry? How could any risks be managed?

Could the regulation of medical devices be made more transparent in other ways? If so how, and what would be the risks and benefits of the proposed approach?

Issue 3 – Interaction with other regulatory frameworks

The emergence of hybrid technologies and co-dependent technologies, by virtue of their composition and mode of operation, can mean that a device is subject to multiple regulatory frameworks. For example, a device that includes a genetically modified organism may be subject to regulation by both the TGA and the Gene Technology Regulator, each of whom will have their own requirements, processes and timeframes. Similarly, a medical device that includes a medication will be subject to regulation as both a device and a medicine.

Question for consideration:

Is the system overly complex for manufacturers/sponsors of devices using hybrid/convergent/co-dependent technologies? If yes, how could the process be streamlined without undermining public health and safety?
Chapter 7: Regulation of Medical Devices

Issue 4 – Consumer understanding of medical devices regulation

The regulatory framework for medical devices may not be as transparent to health professionals and consumers as the framework for medicines in terms of which products are independently assessed and the role of the TGA in undertaking assessments. That is, the AUST R and AUST L labelling of medicines gives an indication to consumers and health professionals about the level of scrutiny to which a medicine has been subjected prior to approval, but there is no similar labelling requirement for medical devices. In addition, as consumers are not the target audience for TGA information and resources, there is a lack of consumer understanding about the role of the TGA in approving or rejecting products for sale and use.33

Questions for consideration:

Is the regulation of medical devices transparent enough in terms of informing health professionals and consumers about the level of scrutiny that a device has undergone? If not, how could it be improved?

Should there be a system for medical devices similar to the AUST R and AUST L system for medicines? If not, why not?

5. Ibid., pp. 74-104.
6. Ibid., p. 74.
8. Ibid.
10. Ibid.


19 Cohen D., op.cit.


31 IVD Australia, Submission to the Consultation Paper: ‘Description of a possible joint regulatory scheme for therapeutic products under Australian and New Zealand Therapeutic Products Agency (ANZTPA)’ February 2013, p. 6.


CHAPTER EIGHT: FRAMEWORK FOR ADVERTISING THERAPEUTIC GOODS

Many industries, including the pharmaceutical industry, have codes of conduct to cover the advertising of their products, in addition to the requirements of the Australian Consumer Law. However, the advertising of certain categories of medicines is unique in Australia in that pre-approval from the Government is required before advertising most over-the-counter (OTC) and complementary medicines to consumers.

The requirement for Government involvement in pre-approval of advertising is out of step with industry self-regulatory approaches in most other areas of the economy and is increasingly dated, as it does not cover advertisements in ‘new media’ such as those broadcast on Pay TV or published on the Internet. This creates inconsistency in the regulation of these products, as an advertisement for the same product may or may not need to be approved, depending on where it is published or broadcast. Such an approach is also inconsistent with a risk based regulatory framework for therapeutic goods, whereby regulatory restrictions on advertising should align with potential harm associated with the product being advertised, rather than the medium in which the advertisement occurs. Similarly, the framework does not provide for pre-approval of advertising of medical devices to the general public, irrespective of the risk classification of the device.

Advertising or promotion of therapeutic products is generally directed at two sectors – health professionals and the general public, but the regulation of such advertisements differs between the two target groups. This chapter provides a brief overview of the self-regulatory schemes that apply to the promotion of therapeutic goods to health professionals, but focusses primarily on advertisements to consumers, which are subject to co-regulation by industry and government (Therapeutic Goods Administration), and therefore falls within the terms of reference for the Review.

Advertising of therapeutic goods to health professionals

Advertising of medicines and medical devices to health professionals is permitted in Australia and is self-regulated by the medicines and devices industries. Such advertisements must also comply with the Competition and Consumer Act 2010. The requirements in relation to pre-publication approval of medicine advertisements, set out in the Therapeutic Goods Regulations 1990 (the Regulations), are not applicable for advertising to health professionals.

Current industry codes of practice governing the relationship between health care professionals and therapeutic goods companies vary in their definitions, member obligations, scope of application, enforcement, and penalties and there is a broad acceptance by industry of the need to reform the existing self-regulatory arrangements. In 2011, an industry led Working Group on Promotion of Therapeutic Products developed a high level statement of principles and recommended coverage of industry codes. A Code of Conduct Implementation Advisory Group was established to guide implementation of the Working Group’s recommendations relating to self-regulation. This Advisory Group has met on several occasions but is currently in abeyance.
Prescription medicines

Advertisements for prescription medicines must comply with requirements of:

- the *Competition and Consumer Act 2010*;
- Section 22(5) of the *Therapeutic Goods Act 1989* (the Act), which establishes an offence where therapeutic goods are advertised with indications other than for which they have been accepted in the Register; and
- any other conditions which may be assigned to the marketing approval of the product.

A condition of registration of therapeutic goods on the Australian Register of Therapeutic Goods (ARTG) is that the promotion of all prescription products, whether by a member or non-member of Medicines Australia, complies with the requirements of the Medicines Australia Code of Conduct.\(^2\)

The Medicines Australia Code of Conduct sets the standards for the ethical marketing and promotion to health professionals of prescription pharmaceutical products in Australia. Included in the Code of Conduct are standards for appropriate advertising, the behaviour of medical representatives, and relationships with health care professionals, among other things.\(^3\) The Code of Conduct complements the legislative requirements set out in the Competition and Consumer Act and the Therapeutic Goods Act. Medicines Australia also administers an audit function whereby all promotional material for a selected therapeutic area are reviewed by an independent panel (the Code of Conduct Review Panel), and any infringements are referred to the Medicines Australia Code of Conduct Committee for adjudication.

Complaints about possible breaches of the Code are considered by the Medicines Australia Code of Conduct Committee. In the case of non-members, the complaint is forwarded to the non-member with an invitation to have the complaint adjudicated by the Medicines Australia Code of Conduct Committee. If the non-member declines the invitation, Medicines Australia may forward the complaint to the Therapeutic Goods Administration (TGA) or the Australian Competition and Consumer Commission (ACCC), depending on the nature of the complaint.

Where the Committee determines that a breach of the Code of Conduct has occurred, the Committee may impose a range of sanctions, depending on the nature of the breach, including to:

- cease the activity and withdraw the materials found in breach (the minimum sanction); and/or
- issue a corrective letter or advertisement; and/or
- pay a monetary fine.

The Committee may also recommend to the Medicines Australia Board that a member be suspended or expelled.

If a company found in breach of the Code refuses to comply with a sanction, and the issues cannot be resolved, Medicines Australia will refer the matter to the TGA or the ACCC, depending on the nature of the complaint.
Chapter 8: Framework for Advertising Therapeutic Goods

The Generic Medicines Industry Association (GMiA) also has a Code of Practice for the ethical marketing of generic medicines. The Code notes that, unlike originator products, marketing of generic medicines typically seeks to change behaviour at the point of dispensing, not at the point of prescribing and, as such, tends to be directed towards pharmacists. Clause 6.92 of the GMiA Code requires members to comply with the Medicines Australia Code of Conduct to the extent it applies to promotional material of prescription medicines as a condition of registration on the ARTG.\(^4\)

The regulation of advertising of prescription medicines to health professionals in Australia is consistent with other overseas regulators. For example, in the United Kingdom (UK) advertising of prescription medicines to health care professionals is permitted.\(^5\)

**Non-prescription medicines**

Advertisements and promotions to health professionals for non-prescription medicines are also self-regulated. As with prescription medicines, advertisements of non-prescription medicines to health professionals must comply with the Competition and Consumer Act and the Therapeutic Goods Act. Complementary Medicines Australia (CMA) administers a Code of Practice that sets out principles for the marketing of complementary medicines to both consumers and health professionals. The Australian Self Medication Industry (ASMI) Code of Practice sets the ethical standards for advertising and promotion of non-prescription consumer health care products to consumers and for marketing support directed to health care professionals.

**Medical Devices**

Advertisement or promotion of medical devices to health professionals is also self-regulated. Both IVD Australia and the Medical Technology Association of Australia (MTAA) have Codes of Conduct/Practice that set out requirements for the ethical promotion of these products to health professionals. Compliance with the Codes is compulsory for member organisations. Non-member organisations are also encouraged to comply with the Codes.

**Advertising of therapeutic goods direct-to-consumers**

Advertising of prescription medicines and most Schedule 3 (pharmacist only) medicines to consumers is prohibited under Section 42DL (1)(f) of the *Therapeutic Goods Act 1989* which provides that:

\[
(1) \text{ A person must not publish or broadcast an advertisement about therapeutic goods...:}
\]

\[
(f) \text{ that contains a statement referring to goods, or substances or preparations containing goods, included in Schedule 3, 4 or 8 to the current Poisons Standard, other than a statement authorised or required by a government or government authority (including a foreign government or foreign government authority).} \quad \text{\textsuperscript{6}}
\]

Advertising of other medicines and of medical devices to consumers is permitted. In respect of medicines, however, such advertising is subject to pre-publication approval where the advertisement is destined to appear in free-to-air broadcast transmissions; mainstream print media; cinema advertising; and/or billboards/posters on public transport or in places such as shopping malls.
The effectiveness and efficiency of Australia’s regulatory framework for advertising therapeutic goods direct-to-consumers has been questioned by some stakeholders. There is considerable interest in this area, as evidenced by the large number of submissions (1100+) to a TGA consultation paper mooting changes to advertising requirements, but views varied on how best to move forward. In response to the TGA consultation, stakeholders raised a large number of issues and concerns about the operation of the current advertising framework. While this chapter touches on those issues, its main focus is on exploring a number of high level issues in respect of advertising, namely:

1. Advertising of Schedule 4 prescription medicines to consumers.
2. Advertising of Schedule 3 medicines to consumers.
3. Co-regulation and the pre-approval process.
4. Management of complaints and enforcement powers.
5. Advertising of medical devices.

**Issue 1 – Advertising of Schedule 4 prescription medicines to consumers**

Australia’s regulatory scheme for restricting the supply of ‘poisons’ to the general public involves assessing the safety of these substances and including them, if required, in an appropriate schedule to the current *Poisons Standard*. Medicines that can only be supplied on prescription are included in either Schedule 4 or Schedule 8 of the Standard. Schedule 8 medicines are controlled drugs, which have a high propensity for misuse, abuse or illicit use. Schedule 4 medicines (‘prescription medicines’) include a vast range of substances used in the treatment of conditions that require assessment and/or intervention by a medical (or dental) practitioner.

As noted above, direct-to-consumer advertising of prescription medicines is an offence under the Act. This approach is consistent with that adopted by most international regulators, with the United States (US) and New Zealand the only two countries in the developed world that allow advertising of ‘Prescription Only’ medicines direct to the consumers. The rationale for the prohibition of direct-to-consumer advertising is to protect the health and safety of consumers. Prescription only medications are generally more toxic than OTC medicines and treat more serious conditions which require the assistance of a clinician for diagnosis and treatment. However, advocates of direct-to-consumer advertising argue that it can promote greater involvement of consumers in managing their own health care; improve diagnosis and treatment; improve compliance with treatment; and enhance the patient-physician relationship. In addition, Auton argues that direct-to-consumer advertising is the wave of the future due to:

- the ageing population, which will mean that more people will develop and live with medical conditions for a long period of time; and
- the information age, which means that these ageing people will have access to information about their medical conditions via the internet.

Auton cites studies that ‘…portray a tectonic shift in the ways in which patients obtain health and medical information, with more patients looking for information online before talking with their
physicians’ and argues that these factors make direct-to-consumer advertising of prescription medicines an ‘unstoppable force.’

Those who oppose direct-to-consumer advertising query the legitimacy of claims that such advertising results in better care, consumer empowerment or shared treatment choices, and argue that there is no public health rationale for its introduction. In addition, they assert that direct-to-consumer advertising:

...does lead to more frequent medicine use and to substitution of expensive new brands for equally effective, less-costly alternatives. It has led to the use of unnecessarily harmful medicines and can expand the market for drug classes to those unlikely to benefit and encourage treatment of milder health problems for which nondrug solutions are often more appropriate....

Question for consideration:
Should Australia allow advertising of prescription medicines to the general public? If not, why not? If yes, what risks might this create and how could these be mitigated?

Issue 2 – Advertising of Schedule 3 medicines to consumers

Schedule 3 or ‘pharmacist only’ medicines include substances that are considered to be substantially safe but with the potential for harm if used inappropriately, and thus requiring pharmacist intervention to ensure the quality use of the medicine.

It is an offence under Section 42DL(1)(f) of the Act to advertise substances listed in Schedules 3 and 4 of the Poisons Standard. However, there is an exception for those Schedule 3 substances listed in Appendix H to the current Poisons Standard. Currently, a prospective advertiser may apply to the Secretary of the Department of Health for an amendment of Appendix H to include a Schedule 3 substance, allowing that substance to be advertised to the general public. Industry stakeholders note, however, that the arrangements for Appendix H decisions have not been updated for 14 years and that with the disbandment of the National Coordinating Committee on Therapeutic Goods there is no clear forum to conduct a review of, or to revise, the Guidelines for brand advertising of substances included in Schedule 3 of the Standard for Uniform Scheduling of Drugs and Poisons (the Schedule 3 Advertising guidelines).

Furthermore, only ten ingredients are currently included in Appendix H, which industry stakeholders argue is due to the resource costs involved with satisfying evidentiary requirements. That is, under the 2000 Schedule 3 Advertising guidelines, the delegate considers a range of issues when determining an application for inclusion in Appendix H, including:

- The potential public health benefit, for example more appropriate use of scarce health resources or a better informed community.

Where it is not possible to present data to quantify the extent of any claim of public benefit, qualitative data may be acceptable.
• The likelihood of advertising of the substance leading to inappropriate patterns of medication use.

• Whether the application may result in the advertising of goods for an indication other than those included in the ARTG.

• The desire of consumers to manage their own medication and the level of patient education necessary to ensure correct use.  

Whilst there is no specific evidentiary standard specified in the guidelines, addressing these and other matters outlined in the guidelines would necessitate sponsors providing a range of quantitative and qualitative data, which may be both costly and time consuming to collect and/or develop.

Restrictions on the advertising of Schedule 3 medications in Australia are generally considered to be out of step with international practice and recent media reports, along with submissions to the TGA, have called for advertising of Schedule 3 medicines to be brought in line with jurisdictions such as the UK, Canada, New Zealand and the US. In this situation unless it can be demonstrated that direct-to-consumer advertising of a particular Schedule 3 medicine is not in the public interest, advertising of Schedule 3 medicines to consumers would no longer be prohibited. Advocates argue that allowing advertising direct-to-consumer for Schedule 3 medicines could increase the level of information available to assist consumers in making informed decisions when choosing Schedule 3 medicines. These recent submissions and media statements have, however, failed to articulate the view of opponents to advertising of Schedule 3 medicines.

Questions for consideration:

What are the risks and benefits of allowing direct-to-consumer advertising of Schedule 3 medicines?

How might any risks be managed?

Issue 3 - Co-regulation and the pre-approval process

As noted above, advertising of most OTC medicines (Schedule 2 and unscheduled) and complementary medicines direct-to-consumers is allowed, but is subject to pre-publication approval if the advertisements are to appear in free-to-air broadcast transmissions; mainstream print media; cinema advertising; and billboards/posters on public transport or in places such as shopping malls. Pre-approval is not compulsory where the advertisements appear in other media, such as on the internet or pay TV, although pre-approval may still be encouraged by industry associations.

These regulatory requirements are administered via a co-regulatory scheme whereby requirements are set out in legislation, such as the Act; the Regulations; and the Therapeutic Goods Advertising Code 2007 (the Code), and the TGA has ultimate responsibility for ensuring compliance, but administration of the pre-approval requirement has been delegated to industry peak bodies, namely ASMI and CMA. Under this delegation:
ASMI is responsible for the pre-approval of all non-prescription medicines (OTC and complementary) advertising appearing in broadcast media; and for advertisements for OTC medicines appearing outdoors or in print media; and

CMA is responsible for the pre-approval of complementary medicines advertising appearing outdoors or in print media.

The compulsory requirement for advertising and marketing campaigns aimed at the general public to be pre-approved is regarded by some stakeholders as unnecessary and out of step with international practice. For example, in New Zealand and Canada pre-vetting by peak industry bodies, while strongly encouraged, is not mandated by government. Rather, industry self-regulates by making pre-vetting of advertisements a requirement of organisational membership of industry associations.

The efficacy and efficiency of Australia’s pre-publication approval process has been questioned by many stakeholders. Issues identified include:

- The efficacy of the scheme, in particular, the fact that some pre-approved advertisements are still deemed to have breached the Code (although the proportion is low); and the lack of effective enforcement powers and penalties, with many stakeholders viewing the TGA as a ‘toothless tiger.’
- The complexity of the current scheme, including the need for some advertisements to be approved by multiple bodies, depending on the product and the type of media in which the advertisement will occur; and multiple bodies dealing with complaints, leading to confusion for those who may wish to avail themselves of the complaints mechanism.
- Whether advertising requirements are commensurate with the risk posed by the regulated products. In particular, stakeholders question the pre-publication approval of advertisements for listed medicines. These have not been assessed for efficacy prior to listing on the ARTG and, as such, the application of Section 22(5) of the Act, which establishes an offence where therapeutic goods are advertised with indications other than for which they have been accepted in the ARTG, is viewed as a bit of a nonsense. It also creates a situation whereby therapeutic claims for these products may be first assessed through the advertising complaints process, but the process is not designed for such purposes. Stakeholders also question why pre-approval only applies to advertisements in some forms of media and not others.

Internationally, authorities still seek to protect consumers from false and misleading advertising of medicines, but do so with a lighter touch on industry. This is generally achieved through either:

- Self-regulatory schemes, whereby pre-vetting of advertisements direct-to-consumers is strongly encouraged but not required by government. However, the peak industry associations require it as a condition of membership; or

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These organisations vet advertisements against requirements but do not ‘approve’ the advertisement. Responsibility for ensuring compliance with the requirements remains with the sponsor/advertiser.
Through more risk based pre-vetting requirements, combined with self-regulation (as in the UK).

In Canada health product advertisements directed to consumers are self-regulated. Advertisements are reviewed and pre-cleared by independent agencies that have notified Health Canada that they have publicly attested to meeting Health Canada’s *Recommended criteria for the preclearance of advertising material of non-prescription drugs and natural health products directed to consumers*. These criteria include: written policies, procedures, and standards to ensure consistent, accurate and complete assessments of advertising materials consistent with the Canadian Food and Drugs Act and its Regulations, policies and guidelines; an objective and timely complaints mechanism; and meaningful self-regulatory sanctions that are proportional to the level and frequency of infraction. Such agencies are also required to have a process in place to refer to Health Canada complaints or issues where:

- health and safety risks are identified;
- it relates to advertising of unauthorized health products;
- it relates to cases of wilful non-compliance; or
- it relates to advertising of other health products such as prescription drugs to consumers.

Health Canada adopts a risk based approach in its compliance and enforcement activities and reserves the right to enforce the advertising provisions contained in federal legislation.

In the UK the advertising of medicines is controlled by a combination of statutory measures enforced by the Medicines and Healthcare Products Regulatory Agency (MHRA), and self-regulation through Codes of Practice for the pharmaceutical industry, administered by trade associations. The national trade association representing manufacturers of branded OTC medicines and food supplements in the UK, the Proprietary Association of Great Britain (PAGB), administers a consumer advertising *Code of Practice*. It is a condition of membership of the PAGB that all OTC medicines advertising that is aimed at consumers must be approved by PAGB prior to its release into the public domain. In addition, the MHRA pre-vets a small number of advertisements (approximately 50 per annum) largely based on the properties of the product and the compliance history of the sponsor. That is, the MHRA pre-vets advertisements in the following circumstances:

- newly licensed products subject to intensive monitoring, including all new active substances;
- reclassification of existing products (e.g. from ‘Prescription Only’ to ‘Pharmacy Only’); and
- new advertisements for products that have previously breached Regulations.

The MHRA also has a role in monitoring advertising to identify possible non-compliance with Part 14 of the *Human Medicines Regulations 2012* (which sets out requirements for medicine advertisements among other things) and in considering complaints in respect of such advertisements. It is also responsible for deciding if legal action will be taken against an advertiser. Breaches of the *Medicines Act 1968* and the *Human Medicines Regulations 2012* may invoke civil sanctions; such as a requirement to withdraw or amend an advertisement, injunctive powers to prevent issue of an advertisement or a requirement to publish a corrective statement; or criminal sanctions, such as a fine or imprisonment.
In 2013 the MHRA received 283 complaints, the vast majority of which were from industry/competitors (n=202).\textsuperscript{17} This compares to 211 complaints considered by the Australian Complaints Resolution Panel in 2012-13.\textsuperscript{18} Thus the level of complaints in Australia would appear to be higher per capita than in Great Britain, despite the compulsory pre-publication approval process.

Questions for consideration:

Should Australia continue to require compulsory pre-vetting of medicines advertised direct-to-consumers or should it move towards a self-regulatory, or combined statutory and self-regulatory, model?

If Australia was to adopt a self-regulatory model or a model which combined risk based regulation with self-regulation (such as the UK) what key elements would need to be in place to ensure that public health and safety was protected, while minimising regulatory burden?

**Issue 4 – Management of complaints and enforcement powers**

As noted above, a range of stakeholders have raised concerns that the current regulatory framework for direct-to-consumer advertising of OTC and complementary medicines lacks effective and efficient complaints management processes and sufficiently robust penalties and enforcement powers.

In respect of complaints, previous submissions to the TGA have expressed concern about the lack of clarity and transparency in respect of complaints processes and poor understanding of, and difficulty accessing, complaints mechanisms.\textsuperscript{19} The Complaints Resolution Panel, which is established under the Regulations, is responsible for considering complaints about advertisements or generic information about therapeutic goods broadcast on television, radio and the internet, exhibited in cinemas, published or inserted in newspapers or magazines or displayed outdoors. Other complaints are considered by the respective industry bodies. However, it is not always clear to complainants to whom they should direct their complaint.

A ‘central mail box’ for all complaints related to therapeutic goods has recently been created,\textsuperscript{20} to address this issue, but the TGA website still includes information that directs complainants to four different lodgement processes,\textsuperscript{21} so confusion remains and may act as a deterrent to the lodgement of complaints. Concern was also expressed that under the current complaints handling process, if the complaint is not received by the correct delegated authority it is sent back to the complainant rather than forwarded to the responsible delegated authority. This time consuming process may result in many complaints being withdrawn.

In the UK complaints may be handled by multiple bodies, depending on the nature of the issue, but consumers are able to direct their complaint to the MHRA in the first instance, with the MHRA referring the complaint onto the relevant body if required, without returning it back to the complainant. This model recognises that it may not be possible or appropriate to have a single agency manage all complaints, for example it would be inappropriate for a government regulator to investigate complaints that relate to requirements under an industry Code of Practice rather than to requirements under an act or regulation, but places the onus on government to navigate the system on behalf of complainants.
Question for consideration:

Should there be a single authority for receiving complaints about the advertising and marketing of therapeutic products? If yes, which agency would be best placed to act in this capacity?

In respect of penalties and enforcement powers, stakeholders have questioned the capacity and effectiveness of the current regulatory framework to deter and/or respond effectively to compliance breaches. For example, in a submission to the TGA the Consumer Health Forum asserts that the:

...current communication between the TGA, the respective industry bodies with responsibilities for advertising pre-approval, and the Complaints Resolution Panel (CRP), has not met the expectations of consumers in terms of accountability, transparency and effectiveness to enforce meaningful sanctions on advertisers who breach the Act or advertising requirements. 22

If, after investigating a complaint, the CRP determines that there has been a contravention of the Act, the Regulations, or the Code, it may request, in writing, that the person responsible for the advertisement does one or more of the following:

- withdraw the advertisement;
- publish a retraction;
- publish a correction; or
- withdraw a particular claim or representation made by the advertisement, and give the CRP a written undertaking not to use that claim or representation in any other advertisement.

The CRP cannot itself impose penalties, enforce sanctions, or take any other regulatory action against advertisers or sponsors who fail to comply with its requests. In 2013-14 the level of compliance following a CRP determination was 76 per cent, suggesting that the majority of sponsors/advertisers seek to do the right thing. 23 However a small, but not insignificant, minority fail to comply with such requests.

If the person responsible for an advertisement fails to comply with the CRP’s request within 14 days, or breaches an undertaking given to the CRP, then the CRP can recommend that the Secretary of the Department of Health take a range of actions, including:

- suspend or cancel the ARTG entry for the advertised goods (where the sponsor was responsible for the advertisement);
- order the advertiser to publish a retraction or correction;
- order the advertiser to remove advertising material or general information from the marketplace and/or destroy such material; and/or
- order that a particular claim or representation made by the advertisement be withdrawn, and not be used in any other advertisement unless certain conditions are met.

The timeframe for all these steps to occur can be many months, during which the advertisement generally remains in place. In addition, monetary penalties for advertising breaches of the Act,
Regulations, or Code vary from 30-60 penalty units, depending on the nature of the offence (i.e., $5,100 - $10,200). Given this, some stakeholders have suggested that the current compliance and penalty regime fails to deter advertisers/sponsors from breaching the Code.

The current sanctions and penalties for advertising breaches were introduced in 2002-03. Amendments to the Act were made in 2006 to introduce additional enforcement options to enable the TGA to deal more effectively and efficiently with various regulatory requirements. These amendments, which provided for among other things, civil penalties, did not cover advertising breaches, however. As such, civil penalties are not currently available under the Act in relation to contraventions of advertising requirements.

As a result the penalties available for advertising breaches lag well behind penalties for other breaches of the Act and are only available by way of criminal prosecution. For example, Section 9H of the Act currently provides for a civil court to impose a penalty of up to 5000 penalty units on an individual ($850,000) and up to 50,000 penalty units ($8.5 million) on a body corporate:

\[ \text{...if the person in or in connection with a request under Section 9D for the variation of an entry in the Register [ARTG] in relation to therapeutic goods, makes a statement that is false or misleading in a material particular.} \]

In contrast, as outlined above, the maximum penalty for an advertising breach is 60 penalty units ($10,200). It has been suggested that the low penalty levels may make mounting a successful prosecution for an advertising breach difficult, as the breach would be assessed by the Commonwealth Director of Public Prosecutions (CDPP) as a trivial offence under the CDPP’s prosecution policy and guidelines. These concerns feed into a perception that the TGA is a ‘toothless tiger’ when it comes to advertising breaches of the Act, Regulations, and Code.

In addition to concerns about the penalty regime for advertising offences, there have also been calls to strengthen the TGA’s enforcement powers so that immediate action could be taken if an advertisement for a product is considered to place at risk public health and safety (through for example, making unsubstantiated or misleading claims). Currently, the TGA is unable to suspend advertising campaigns while complaints are being investigated.

International comparisons

Australia appears to be lagging behind some overseas regulators in terms of sanctions and enforcement powers, and mechanisms to incentivise sponsors to comply with advertising requirements. For example, in the UK the MHRA:

- Incentivises compliance by allowing sponsors to self-regulate, but retaining the right to require pre-publication approval of new advertisements for products that have previously breached Regulations.
- Is able to commence proceedings as either a criminal or civil offence. Penalty and enforcement powers provide for a fine and up to two years imprisonment for breaches of the advertising requirements.\[24\]
Questions for consideration:

Does the current regulatory framework for advertising medicines direct-to-consumers:

- Provide adequate incentives to promote compliance with requirements? If not, why not. What additional incentives should be included?

- Contain adequate sanctions and penalties for non-compliance? If not, what additional sanctions and penalties should be available?

Should the TGA have the power to take immediate action to suspend an advertisement that it considers places at risk public health and safety?

- If yes, why and how might any risks be mitigated?

- If not, why not?

**Issue 5 – Advertising of medical devices**

Advertising of medical devices in Australia must comply with the Code, but is not subject to the pre-publication approval process. The MTAA administers an industry Code of Practice for medical technology companies which sets out the ethical framework within which they must work in their relationships with both health care professionals and (where relevant) consumers. Similarly IVD Australia administers a Code of Conduct for the *in vitro* diagnostics industry in Australia.

A number of stakeholders have expressed concern that the lack of pre-publication approval for medical devices means that consumers may be exposed to advertisements that are false, misleading or deceptive. They assert that expanding the pre-publication approval process to include medical devices would be consistent with the aim of minimising risk to consumers.

If pre-publication approval was required for all medical devices, the range of low risk devices that would be captured by this requirement would be numerous and include products such as band aids and antiseptic creams that are routinely advertised in Australia today. Some stakeholders have argued that the majority of medical devices (Class I and Class IIa) advertised to consumers are relatively low risk and present no inherent hazard to the consumer. They assert, therefore, that subjecting such devices to a pre-publication approval scheme would impose a considerable burden on industry that would not be commensurate with the risk posed to consumers by the advertising of these products. In respect of devices that are categorised as high risk, stakeholders argue that these are generally surgically invasive devices that cannot be self-administered and are, therefore, not advertised to consumers. As such, they argue, no further regulation of these products is required.

In addition, some stakeholders who are opposed to pre-approval of device advertising assert that the majority of complaints about medical devices relate to products that were not included on the ARTG. They therefore question how effective requiring pre-approval of advertisements for medical devices would be in reducing public exposure to false and misleading claims. That is, requiring pre-publication approval for devices included on the ARTG will not address the issue of advertisers of ‘devices’ that are not included on the ARTG making false and misleading claims. Rather, these sorts of breaches might better be addressed through standard consumer law.
Question for consideration:

Is the current self-regulatory scheme for advertising of medical devices effective? If not, why not? Please provide examples of where the system has failed.


10 Mintzes B. and Mangin D., (2009), op,cit., p. 1555.

11 Ibid.


Consumer Health Forum of Australia, op.cit., p. 3.


Consumers Health Forum of Australia, op.cit., p.5.

Australian Dental Industry Association, *ADIA Submission. Therapeutic Product Advertising Regulation*, p.2


Ibid. p.4.

Ibid. p. 2..

APPENDIX 1: REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION SUBMISSION COVER SHEET

Please complete all parts of this document, sign it, and attach it to your submission.

1. Contact information

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2. Consent to publish on the internet

It is the intention of the Panel to publish submissions that it receives, along with the name of the individual or organisation that made the submission, on the Review’s webpage, located on the Department of Health website. Please indicate your willingness for your details to be published on the website by checking the appropriate box below.

☐ I CONSENT to the attached submission being published in its entirety on the Department of Health website.

☐ I CONSENT to a redacted version of my submission being published on the Department of Health website. If you check this box please provide a copy of your submission with the information you do not want to be published redacted and clearly mark the submission Redacted for Publication.

☐ I CONSENT to my name (if an individual) or the name of my organisation being included in a list of submissions received on the Department of Health website but do not consent to any part of my submission being published on the site.*

☐ I DO NOT CONSENT to any information about my submission, including my name or the name of my organisation, being published on the Department of Health website. *

Signature___________________________________________ Date_________________________

*NOTE: The Panel will consider submissions in formulating its report to Government and may cite particular submissions. If your submission contains confidential information that cannot be cited, please clearly mark these parts of your submission as ‘in-confidence’.
3. **Abstract**
   
   Please provide a brief abstract (no more than one page) of your submission, highlighting the key points that you would like the Panel to consider.