Australian Government

Department of Health

Australian Government Response

to the

Review of Medicines and Medical Devices Regulation

Title: Australian Government Response to the Review of Medicines and Medical Devices Regulation
Online ISBN: 978-1-76007-261-2
Publications Number: 11475

Creative Commons Licence

Contents

Australian Government Response to the Review of Medicines and Medical Devices Regulation

Introduction

In October 2014 the Expert Panel Review of Medicines and Medical Devices Regulation was announced by the then Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash.

The Expert Panel (comprised of Emeritus Professor Lloyd Sansom AO (Chair), Mr Will Delaat AM and Professor John Horvath AO) delivered two reports[1] that assessed the regulatory framework for medicines and medical devices in Australia, and made 58 recommendations for reform.

The Review reports noted the increasing globalisation of the pharmaceutical and medical devices industries and the rapid pace of innovation, and accordingly made recommendations as to how to position the Therapeutic Goods Administration (TGA) to respond to these trends in the future. It also recognised that the TGA has an excellent reputation internationally and domestically for its role in ensuring the timely availability of safe, efficacious and high quality therapeutic goods.

The Review reports made recommendations that were significant in scale and scope. Accordingly, the Department of Health conducted a number of consultations on particular recommendations, as part of a consultative and collaborative approach to reform. The consultations were central to the formulation of this response.

This response presents a strategic and systems-based approach to achieve long-term sustainable reform to the regulation of therapeutic goods in Australia. It identifies ways to improve access to therapeutic goods for consumers and remove unnecessary red tape for industry whilst maintaining the safety of therapeutic goods in Australia.

[1] Expert Panel, Review of Medicines and Medical Devices Regulation: Report to the Minister for Health on the Regulatory Framework for Medicines and Medical Devices (31 March 2015) and Report to the Minister for Health on the Regulatory Frameworks for Complementary Medicines and the Advertising of Therapeutic Goods (31 July 2015) available at http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

The case for reform presented by the Expert Panel

The Expert Panel identified several significant trends in the regulation of medicines and medical devices internationally. In particular, the Panel noted international trends towards allowing earlier access to medicines and medical devices through the development of provisional approval pathways.

Additionally, the Panel commented on the benefits of harmonising international regulatory frameworks, noting that there are benefits for consumers and efficiencies for industry from greater harmonisation.

After considering the current regulatory framework for therapeutic goods, the Panel found that the TGA has a strong reputation as a regulator both domestically and internationally, and benchmarks well against comparable overseas regulators. However, the Panel found that while the TGA performs well there are opportunities for reform and improvement in the regulation of therapeutic goods.

The Panel concluded that allowing for greater flexibility in approval pathways for medicines and medical devices (including greater use of overseas assessment reports and provisional approvals in certain circumstances) would expedite access to market without compromising the safety, quality and efficacy or performance of medicines and medical devices.

The Panel also identified areas of regulation where a more risk-based approach could be adopted to more appropriately align regulation with the risk posed by regulated products. The Panel was also of the view that the use of data was essential in assessments of therapeutic goods, and that better utilising existing data sets could lead to system enhancements and provide greater information for the regulator to base decisions upon.

The Panel's recommendations considered the following issues: the role of the Australian Government to make sovereign decisions regarding therapeutic goods; the medicines regulatory framework; the medical devices regulatory framework; enhancements to post-market monitoring; the complementary medicines framework; and the framework for advertising therapeutic goods to the public.

The Government's plan for reform

In order to better understand the potential impact of the Review's recommendations, the Department of Health undertook targeted consultation on the recommendations with consumer, health professional and industry groups through a series of stakeholder forums held in the second half of 2015. This consultation indicated widespread support for many of the Review's recommendations, in particular the proposal to offer multiple pathways for market access for medicines and medical devices.

The Government welcomes the Review, which reinforces the important role the TGA plays in ensuring therapeutic goods sold in Australia are safe, of good quality and efficacious, and the potential benefits of utilising overseas approvals of medicines and medical devices and introducing expedited approvals of life-saving medicines and medical devices.

The Government recognises that streamlining access to medicines and medical devices, including access to novel and life-saving therapies, offers significant benefits to consumers, health professionals and industry. The proposed reforms reflect the Government's plan to boost competitiveness and lessen unnecessary regulatory burden through the Industry, Innovation and Competitiveness Agenda and encourage innovation through the National Innovation and Science Agenda.

The Panel has provided a strong case for the reform of the regulation of therapeutic goods in Australia - one that strikes a balance between supporting consumer choice, the safe and effective use of therapeutic products, creates flexibility for industry and ensures that regulatory settings are appropriately aligned to risk. The proposed programme of reform involves:

- increasing use of overseas assessments with comparable regulators, while maintaining sovereignty of regulatory decisions;
- increasing flexibility in pre-market assessment processes for medicines and medical devices, including expedited and provisional approval and allowing the operation of commercial assessment bodies in Australia for medical device assessments;
- taking a risk-based approach to variations to medicines and medical devices and access to products not listed in the Australian Register of Therapeutic Goods (ARTG);
- enhancing post-market monitoring and improving integration of administrative arrangements relating to pre- and post-market processes for subsidy and other purposes;

- simplifying processes by which advertising of therapeutic products to the public is regulated;
- working across government to consider incentives for innovation to improve the competitiveness of the Australian complementary medicines industry and increasing information available to consumers; and
- conducting further reviews on the Scheduling Policy Framework for substances in consultation with states and territories and on the appropriateness of the application of the therapeutic goods regime to a range of low-risk products.

In order to progress this important programme of reform, the Government will take a strategic and systems-based approach. This will involve implementation of recommendations in a staged approach over the next three years in order to maintain continuity of business. The Department of Health will collaborate and consult across government and with consumers, health professionals and industry in order to progress these reforms. The TGA, where necessary, will cost recover from industry so as to ensure that it is adequately resourced to implement these reforms and undertake the ongoing work without interrupting business as usual.

The Government understands that consumer, professional, and industry groups are looking for immediate action. Accordingly, the Department of Health will commence work on designing implementation of the recommendations, with a view to implementing early opportunities in 2016-2017. Implementation of this important programme of reform will deliver significant benefits for the Australian public and to the Australian medicine and medical device industries.

What these reforms mean for consumers

The reforms outlined in this response will improve access to therapeutic goods for Australian consumers, including the potential for expedited access to innovative and life-saving products, without compromising the integrity and safety of medicines and medical devices available in Australia. These benefits include:

- access to life-saving and innovative medicines and medical devices will be improved through the introduction of new, expedited pathways for approval. This will lead to earlier access to vital, life-saving therapies for patients with serious conditions;
- faster access for Australian consumers to certain medicines and medical devices that are approved based on assessments from comparable overseas regulators. This will reduce duplication of effort, leading to efficiencies, while ensuring Australian consumer protection is maintained through retention of oversight by the TGA as the final decision-making authority;
- consumer protection will be enhanced through the development of a more comprehensive system of post-market monitoring which will provide the TGA with better information about emerging safety issues. This will ensure that therapeutic goods in Australia continue to be safe for use, efficacious and of a good quality;
- access to products under the Special Access Scheme and the Authorised Prescriber Scheme will be streamlined, reducing burden for healthcare professionals and enabling ease of access to products not on the ARTG for individual patients who meet the relevant criteria;
- the process for managing complaints relating to advertisements of therapeutic goods directed at consumers will be simplified and streamlined, but with stronger compliance powers against misleading advertising;
- the regulation of complementary medicines will be reformed to provide new pathways where evidence of efficacy will be reviewed by the TGA prior to market and compliance powers strengthened, whilst recognising the low-risk nature of complementary medicines.

Recommendations and Government Response

Recommendations relating to the National Regulatory Authority role

Recommendations	*Government response*
Recommendation One: The Panel recommends that Australia maintain the capacity to undertake assessments of therapeutic goods for safety, quality and efficacy. **Recommendation Two:** The Panel recommends that the Australian Government, as a sovereign entity, retain responsibility for approving the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (ARTG).	The Commonwealth accepts Recommendations One and Two and recognises that maintenance of Australia's capacity to undertake assessments of therapeutic goods and of sovereignty of decision-making is an important assurance to consumers, and underlines Australia's strong reputation as a regulator of therapeutic goods. The Commonwealth also notes that the strong reputation of the Therapeutic Goods Administration (TGA) in performing assessments is critical to the success of Australian manufacturers in exporting therapeutic goods, particularly to Asian markets.

Recommendations relating to the medicines regulatory framework

Recommendations	*Government response*
Recommendation Three: The Panel recommends that there be three pathways to seek registration of a new chemical entity and its inclusion in the ARTG: Pathway One - Submission of a complete dossier for de novo assessment. This assessment may be undertaken in full by the Australian National Regulatory Authority (NRA) or via a work-sharing arrangement between the Australian NRA and a comparable overseas NRA. Pathway Two - Submission of an un-redacted evaluation report from a	The Commonwealth **accepts** Recommendation Three as it provides flexibility for industry by introducing two new pathways (Pathways Two and Three) to registration in the ARTG. Pathway Two will allow for a reduction in regulatory burden by allowing sponsors to utilise one overseas assessment report, rather than two, therefore reducing duplication of regulatory assessment between Australia and overseas.

Recommendations	*Government response*
comparable overseas NRA, along with a copy of the dossier submitted to that NRA and an Australian specific Module 1, for assessment by the Australian NRA. The Australian NRA to make a recommendation regarding registration of the medicine once it has considered the data within the Australian context. Pathway Three - Application for expedited approval of a medicine in certain circumstances. Any expedited approval pathway should make provision for submission of data and assessment consistent with requirements of Pathways One and Two as outlined above.	Pathway Three will provide an opportunity for novel and life-saving medicines to be fast-tracked, either through an accelerated approval process or by offering provisional (time bound) approval. This will have important benefits for consumers who are suffering from serious and life-threatening conditions. While the Commonwealth supports this recommendation, it is noted that the implementation of work-sharing with overseas regulators under the already existing Pathway One will only be achievable in the longer term.
Recommendation Four: The Panel recommends that there be two pathways to seek registration of a generic medicine or biosimilar and its inclusion in the ARTG: Pathway One - Submission of a complete dossier for de novo assessment. This assessment may be undertaken in full by the Australian National Regulatory Authority (NRA) or via a work-sharing arrangement between the Australian NRA and a comparable overseas NRA. Pathway Two - Submission of an un-redacted evaluation report from a comparable overseas NRA, along with a copy of the dossier submitted to that NRA and an Australian specific Module 1, and: A. If the product is a generic product, evidence that the reference product used by the comparable overseas NRA when assessing bioequivalence was identical to, or interchangeable with, the Australian reference product; or B. If the product is a biosimilar, evidence that the overseas reference product and the Australian reference product are the same.	The Commonwealth **accepts** Recommendation Four, as it will provide flexibility for sponsors of generic medicines and reduce unnecessary regulatory burden by allowing sponsors to provide an overseas assessment report to the TGA as part of their application for registration. While this recommendation is supported with respect to generic medicines, the Commonwealth notes that international experience with the regulation of biosimilars is still developing and, accordingly, implementation of the multiple pathways approach for biosimilars will only be viable in the longer-term.

Recommendations	*Government response*
The Australian NRA to make a recommendation regarding registration of the medicines once it has considered the data within the Australian context.	
Recommendation Five: The Panel recommends that the Australian Government develop and apply transparent criteria for identifying comparable overseas NRAs. Such criteria might include that a comparable overseas NRA must: A. Regulate for a population demographic that is broadly representative of the Australian population and has similar health outcomes; and B. Adopt ICH guidelines; and C. Have a credible and consistent track record of approving safe and effective medicines; and D. Conduct de novo evaluations of data dossiers for all types of medicines, e.g. new chemical entities, generics and biosimilars; and E. Have processes in place that require peer review or independent assessment of the evaluations that they conduct; and F. Have evaluators with the necessary technical and clinical capabilities to evaluate the data provided and make an independent regulatory decision in accordance with the ICH guidelines; and G. Provide access to un-redacted evaluation reports and, where applicable, individual patient data; and H. Communicate and prepare evaluation reports in the English language.	The Commonwealth **accepts** Recommendation Five as it will provide a transparent method for identifying comparable overseas regulators for the purposes of Pathway Two.
Recommendation Six: The Panel recommends that in circumstances where a sponsor seeks registration of a new chemical entity in Australia via Pathway Two and has submitted all necessary materials, including an un-redacted	The Commonwealth **accepts** Recommendations Six and Seven. Implementation of these recommendations will clarify for sponsors how Pathway Two will work in practice.

Recommendations	*Government response*
evaluation report from a comparable overseas NRA, to the Australian NRA: 1. The Australian NRA makes a recommendation regarding registration of the new chemical entity once it has satisfied itself that: A. The new chemical entity is identical in dosage form, strength, formulation and indications; and B. The new chemical entity will be manufactured at a plant that has received GMP certification from the Australian NRA (or from a comparable overseas NRA with whom the Australian NRA has co-recognition); and C. The manufacturing process to produce the new chemical entity will be identical to that assessed by the comparable overseas NRA for the overseas product; and D. There are no specific issues regarding applicability of the submitted data to the Australian context that need to be examined; and E. Proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements. 2. Where the new chemical entity seeking registration in Australia does not meet conditions 1A to 1D above, the Australian NRA undertakes an assessment of the extent to which the differences have the potential to impact the quality, safety or efficacy of the product. A. If the differences are assessed to have minimal impact on product quality, safety or efficacy, the Australian NRA should satisfy itself that the proposed product labelling, Product Information, and Consumer Medicine Information is appropriate and consistent with Australian requirements before	

Recommendations	*Government response*
making a recommendation regarding registration of the new chemical entity in the ARTG. B. Where differences between the new chemical entity seeking registration in Australia and that approved by the comparable overseas NRA have the potential to impact product quality, safety or efficacy, before making a recommendation regarding registration of the new chemical entity in the ARTG, the Australian NRA should: I. Undertake an assessment of the application for registration to the extent necessary to satisfy itself that any potential impact of the differences on quality, safety or efficacy have been addressed and/or taken into consideration in assessing risk and benefit; and II. Assess whether the proposed product labelling, Product Information, and Consumer Medicine Information are appropriate and consistent with Australian requirements. **Recommendation Seven:** The Panel recommends that in circumstances where a sponsor seeks registration of a generic medicine or biosimilar in Australia via Pathway Two and has submitted all necessary materials, including an un-redacted evaluation report from a comparable overseas NRA, to the Australian NRA: 1. The Australian NRA makes a recommendation regarding registration of the generic medicine or biosimilar once it has satisfied itself that: A. The generic medicine or biosimilar is identical in dosage form, strength, and formulation to the product approved by the comparable overseas NRA; and	

Recommendations	*Government response*
B. The generic medicine or biosimilar will be manufactured at a plant that has received GMP certification from the Australian NRA (or from a comparable overseas NRA with whom the Australian authority has co-recognition); and C. The manufacturing process to produce the generic medicine or biosimilar will be identical to that assessed by the comparable overseas NRA for the overseas product; and D. If the product is a generic medicine - the reference product used by the comparable overseas NRA when assessing bioequivalence was identical to, or interchangeable with, the Australian reference product; or E. If the product is a biosimilar - the overseas reference product and the Australian reference product were the same; and F. Proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements. 2. Where the generic medicine seeking registration in Australia does not meet conditions 1A to 1D above, the Australian NRA undertakes an assessment of the extent to which the differences have the potential to impact the quality, safety or efficacy of the product. A. If the differences are assessed to have minimal impact on product quality, safety or efficacy, the Australian NRA should satisfy itself that the proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements before making a recommendation regarding registration of the generic medicine in the ARTG.	

Recommendations	*Government response*
B. Where differences between the generic medicine seeking registration in Australia and that approved by the comparable overseas NRA have the potential to impact product quality, safety or efficacy, before making a recommendation regarding registration of the generic medicine in the ARTG, the Australian NRA should: I. Undertake an assessment of the application for registration to the extent necessary to satisfy itself that any potential impact of the differences on quality, safety or efficacy have been addressed; and II. Assess whether the proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements. 3. Where the biosimilar seeking registration in Australia does not meet conditions 1A to 1C and 1E above, the Australian NRA undertakes an assessment of the extent to which the differences have the potential to impact the quality, safety or efficacy of the product. A. If the differences are assessed to have minimal impact on product quality, safety or efficacy, the Australian NRA should satisfy itself that the proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements before making a recommendation regarding registration of the biosimilar in the ARTG. B. Where differences between the biosimilar seeking registration in Australia and that approved by the comparable overseas NRA have the potential to impact product quality, safety or	

Recommendations	*Government response*
efficacy, before making a recommendation regarding registration of the biosimilar in the ARTG, the Australian NRA should : I. Undertake an assessment of the application for registration to the extent necessary to satisfy itself that any potential impact of the differences on quality, safety or efficacy have been addressed; II. Assess whether the proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements.	
Recommendation Eight: The Panel recommends that the Australian NRA should develop and apply transparent criteria under which application may be made for accelerated assessment of promising new medicines (Pathway Three). Such criteria should not be inconsistent with those adopted by comparable overseas NRAs for accelerated assessment. **Recommendation Nine:** The Panel recommends that in circumstances where the Australian NRA has approved an expedited approval process utilising Pathway Two, and the sponsor has submitted all necessary materials, including an un-redacted evaluation report from a comparable overseas NRA, to the Australian NRA, the Australian NRA makes a recommendation regarding registration of the new chemical entity once it has satisfied itself that: A. The new chemical entity is identical in dosage form, strength, formulation and indications; and B. The new chemical entity will be manufactured at a plant that has received GMP certification from the Australian NRA (or from a	The Commonwealth **accepts** Recommendations Eight, Nine and Ten, noting that legislative amendments will be required to implement Recommendation Ten. These recommendations will provide clarity on how Pathway Three will be implemented for sponsors and assist in achieving earlier access to life-saving medicines for consumers. The Government will consult with stakeholders to ensure the implementation of these reforms maintains timely and sustainable access to medicines for all Australians.

Recommendations	*Government response*
comparable overseas NRA with whom the Australian regulator has co-recognition); and C. The manufacturing process to produce the new chemical entity will be identical to that assessed by the comparable overseas NRA for the overseas product; and D. There are no specific issues regarding applicability to the Australian context that need to be examined; and E. Proposed product labelling, Product Information and Consumer Medicine Information are appropriate and consistent with Australian requirements; and F. Any conditions placed on the medicine by the comparable overseas NRA are applicable to the Australian context; and G. Data provided to the comparable overseas NRA under these conditions will be available to the Australian NRA in a timely way. **Recommendation Ten:** The Panel recommends that where accelerated approval occurs following evaluation of a more limited data dossier than would be required for a submission under Pathway One, registration of the medicine in the ARTG should be: 1. Provisional and time-limited, with a requirement for the sponsor to collect and submit further data to demonstrate safety, quality and efficacy in order for the product to be granted full registration. 2. Subject to any conditions imposed by the Australian NRA (which should be consistent with those imposed by a comparable overseas NRA if relevant and applicable to the Australian context). 3. Subject to the provision of clear advice to consumers and health practitioners that the medicine has been granted provisional approval	

Recommendations	*Government response*
and the implications of that for the consumer/health practitioner.	
Recommendation Eleven: The Panel recommends that the Scheduling Policy Framework be reviewed, in consultation with State and Territory Governments, to provide for: 1. The development and adoption of a formal risk-benefit methodology to assess scheduling applications; and 2. Opportunities to enhance input from interested parties into the scheduling process. **Recommendation Twelve:** The Panel recommends that the Schedule 3 Advertising Guidelines be reviewed, in consultation with State and Territory Governments, and in concert with the review of the Scheduling Policy Framework, to: 1. Provide for the development and adoption of a formal risk-benefit methodology for assessment of Schedule 3 substances for inclusion on Appendix H of the Poisons Standard; and 2. Identify synergies between application requirements for re-scheduling and for inclusion of a Schedule 3 substance on Appendix H, so as to streamline these processes and reduce duplication.	The Commonwealth **accepts** Recommendations Eleven and Twelve, noting that the Australian Health Ministers Advisory Council (AHMAC) has overall policy responsibility for the *Scheduling Policy Framework*, and therefore would need to consider any proposed changes.
Recommendation Thirteen: The Panel recommends that Australia adopt a risk-based approach to the management of variations to medicines registered in the ARTG. This approach should provide for: 1. Notification of variations to the Australian NRA in circumstances where the variation does not impact the quality, safety or efficacy of the medicine. This approach should be harmonised with that adopted by the EU, unless there is a clear rationale not to do so.	The Commonwealth **accepts** Recommendation Thirteen. Implementing a risk-based approach to assessments of variations to registered medicines will benefit consumers through faster access to products and lessen the regulatory burden for sponsors.

Recommendations	*Government response*
2. Assessment of the variation by the Australian NRA in circumstances where the variation has the potential to impact the safety, quality or efficacy of the medicine. This assessment to be abridged in scope, so that only those aspects of the data dossier that require evaluation in order to establish the continued safety, quality and efficacy of the medicine following implementation of the proposed variation are examined (abridged assessment). 3. Reduced legislative timeframes for abridged assessments. 4. Fees for abridged assessments that reflect cost recovery principles. 5. Electronic submission of data.	
Recommendation Fourteen: The Panel recommends that the Australian Government undertake a review of the range of products currently listed in the ARTG (not including complementary medicines) and subject to regulation under the medicines framework, with a view to ensuring that: 1. Products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and 2. Goods remaining under the auspices of the Act are subject to regulatory requirements that are commensurate with the risk posed by the regulated products.	The Commonwealth **accepts** Recommendation Fourteen, noting that a review will involve consultation with consumers, industry, health professionals and other Commonwealth regulatory bodies. The review will also take into consideration agreed reforms to the National Industrial Chemicals Notification and Assessment Scheme. Implementation of this recommendation will be furthered in conjunction with that of Recommendations Twenty-Three and Forty-Eight.

Recommendations relating to the medical devices regulatory framework

Recommendations	*Government response*
Recommendation Fifteen: The Panel recommends that: 1. Class I, non-sterile and non-measuring devices, continue to be included in the ARTG on the basis of a self-assessment by the device manufacturer. NRA communications directed at consumers and health professionals should make it clear that such devices have not been subject to any independent assessment. 2. In order to provide timely access to devices that are safe, high quality and fit for purpose, there be multiple pathways to seek approval for the inclusion of other classes of medical device in the ARTG. Such pathways to provide for: Pathway One - Conformity Assessment to occur within Australia by either: A. The Australian NRA; or B. A body designated by the Australian NRA to undertake Conformity Assessments of medical devices for the Australian market. Pathway Two - Utilisation of marketing approval for the device in an overseas market in circumstances where the device has been: A. Conformity Assessed by a body that has been designated to undertake Conformity Assessments by a comparable overseas Designating Authority; or B. Approved by a comparable overseas NRA. Pathway Three - Expedited approval of medical devices in certain circumstances.	The Commonwealth **accepts** Recommendation Fifteen, noting that legal and administrative arrangements will need to be developed to support the designation by the TGA of bodies to undertake Conformity Assessments of medical devices. Implementing multiple pathways to marketing authorisation will streamline access to medical devices for consumers, provide additional flexibility for sponsors, and is consistent with the Government's regulatory reform and contestability agendas.
Recommendation Sixteen: The Panel recommends that the Australian Government develop transparent criteria that it will utilise in order to designate suitably qualified bodies within Australia to undertake Conformity	The Commonwealth **accepts** Recommendation Sixteen, noting that development of criteria will be dependent on consultation with stakeholders. Development of transparent criteria will be

Recommendations	*Government response*
Assessments of medical devices [Recommendation Fifteen, Pathway 1B]. Such criteria to: 1. Include capacity to set specific requirements for different classes of medical devices; and 2. Be developed in consultation with health care consumers, health professionals, the medical devices industry and the NRA.	critical in identifying suitably qualified bodies to be designated to undertake Conformity Assessments.
Recommendation Seventeen: The Panel recommends that: 1. The Australian Government develop and apply transparent criteria for identifying: A. Comparable overseas Designating Authorities [Recommendation Fifteen, Pathway 2A]; and B. Comparable overseas NRAs for the evaluation of medical devices [Recommendation Fifteen, Pathway 2B]. 2. These criteria are developed in consultation with health care consumers, health professionals, the medical devices industry, and the NRA and give consideration to factors such as: A. Population demographics and health outcomes. B. Adoption of International Medical Device Regulators Forum guidelines. C. The track record of the organisation in evaluating/assessing medical devices and/or oversighting the evaluation/assessment of medical devices. D. Independence and impartiality. E. Transparency of systems and processes. F. Technical competence.	The Commonwealth **accepts-in-principle** Recommendations Seventeen, Eighteen and Nineteen, noting that development of criteria will be subject to further consultation with relevant stakeholders. Development of criteria will provide transparency and clarity to consumers, health professionals and industry on how the pathways to marketing authorisation will work.

Recommendations	*Government response*
G. Utilisation of Quality Management Systems. H. Accountability, including independent review/audit. I. Reporting and communication. J. Timeliness of access to information and data. K. Compatibility of evaluation/assessment of medical devices with the Australian Essential Principles. **Recommendation Eighteen:** The Panel recommends that, where an application for inclusion of a medical device in the ARTG is made utilising Pathway Two, and all necessary documentation is provided to the Australian NRA: 1. The Australian NRA make a recommendation regarding inclusion of the medical device once it has satisfied itself that: A. The device has been correctly classified; and B. The 'marketing approval' documentation is in order and meets Australian requirements; and C. The product is identical to the one assessed by the Notified Body or comparable overseas NRA, having been made in the same manufacturing facility, of the same materials, and for the same intended purpose; and D. There are no specific issues regarding applicability to the Australian context that need to be examined, including in respect to post-market monitoring and risk management; and E. Proposed product labelling and product information/instructions are appropriate and consistent with Australian requirements; and F. Any conditions or provisions that are imposed on the	

Recommendations	*Government response*
marketing approval of the medical device under the terms of the overseas marketing approval are able to be replicated and complied with in the Australian market. 2. Where the medical device does not meet conditions 1A to 1F above, the Australian NRA should work with the sponsor to correct any deficiencies, or undertake such further assessment as is necessary to satisfy itself that the product is safe and effective, prior to making a recommendation on the inclusion of the medical device in the ARTG. **Recommendation Nineteen:** The Panel recommends that: 1. The Australian Government develop transparent criteria under which application may be made for accelerated assessment of novel medical devices for inclusion in the ARTG. 2. In circumstances where accelerated assessment is granted, the Australian NRA have capacity to place conditions on the inclusion of the medical device in the ARTG.	
Recommendation Twenty: The Panel recommends that: 1. The regulation of medical devices by the Australian NRA is, wherever possible, aligned with the European Union framework including in respect of the: A. Classification of medical devices; B. Essential Principles/Requirements. C. Adoption of a risk-based approach to variations to medical devices. 2. Should the Australian NRA seek to apply specific requirements, there must be a clear rationale to do so.	The Commonwealth **accepts** Recommendation Twenty, as harmonising regulation in line with international approaches has benefits for consumers and industry. The Commonwealth also notes the current close alignment of many areas of medical devices regulation between Australia and the European Union.
Recommendation Twenty-One: The Panel recommends that the NRA establish target timeframes that reflect international benchmarks and the	The Commonwealth **accepts** Recommendation Twenty-One, and notes that the development of target timeframes will

Recommendations	*Government response*
typical lifecycle of a medical device for: 1. Conformity assessments conducted under Pathway One; and 2. Recommendations about inclusion of a device in the ARTG following submission of an application for inclusion under Pathway 1B or Pathway Two.	provide greater certainty and clarity for sponsors of medical devices.
Recommendation Twenty-Two: The Panel recommends that: 1. All high-risk implantable devices are included in a registry that is compliant with the requirements for registries established by the Australian Commission on Safety and Quality in Health Care (ACSQHC). 2. Responsibility for ensuring that registries are operated consistent with the ACSQHC requirements should rest with the NRA. 3. Data collected by device registries should be made available to the NRA in a timely manner to inform post-market monitoring. 4. The NRA should implement an active programme of analysis and reporting on adverse events, and associated data, collected through registries or by other means. 5. The NRA should continue collaborative activities with overseas medical device regulators to actively share registry and other monitoring data, with a view to facilitating timely identification of emerging safety concerns and to inform better clinical practice.	The Commonwealth **defers** consideration of Recommendation Twenty-Two, as establishing and maintaining registries requires careful consideration of the range of registries managed by a variety of organisations and how they could be sustainably managed and funded in the future. Further consultation with stakeholders is required to adequately assess the risks and benefits of establishing registries, and to determine appropriate mechanisms to enable access to data.
Recommendation Twenty-Three: The Panel recommends that the Australian Government undertake a review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunctions.	The Commonwealth **accepts** Recommendation Twenty-Three, noting that the review will involve consultation with consumers, industry, health professionals and other Commonwealth regulatory bodies. Implementation of this recommendation will be furthered in conjunction with that of Recommendations Fourteen and Forty-Eight.

Recommendations relating to access to products not listed in the Australian Register of Therapeutic Goods (ARTG)

Recommendations	*Government response*
Recommendation Twenty-Four: The Panel recommends that: 1. The current criteria and processes for Category A SAS patients remain unchanged. 2. The Australian NRA develop and apply transparent criteria for identifying Category B applications that could be subject to automatic approval. Such criteria might include applications for products that: A. Were previously registered in the ARTG for the proposed indication and were not cancelled or withdrawn for safety reasons; B. Have been approved for the proposed indication by a comparable overseas NRA; C. Have been deemed by the Australian NRA as suitable for automatic approval for treatment of a particular indication; and D. Have been approved by the Australian NRA under Category B in response to a medicine shortage, in circumstances where there is no need to triage the use of the unapproved product. 3. The Australian NRA continue to require individual assessment and approval for certain Category B products, including products that: A. Do not have a history of safe use for the proposed indication through either the SAS scheme or in comparable overseas markets; B. Have not been approved for the proposed indication by a comparable overseas NRA; C. Were cancelled or withdrawn from the ARTG for safety reasons, or had an application for registration rejected by the	The Commonwealth **accepts** Recommendations Twenty-Four, Twenty-Five and Twenty-Six, which will streamline access to medicines and medical devices not currently in the ARTG for individual patients, and minimise the need for health practitioners to repeatedly apply to the TGA for approval to supply certain lower-risk medicines and medical devices under the Special Access and Authorised Prescriber Schemes. Development of an online system also has the potential to reduce administrative costs for health practitioners, and enable better monitoring of the use of these products.

Recommendations	*Government response*
Australian NRA for safety reasons; D. Were previously approved overseas but were withdrawn or removed from the market for safety reasons; and E. Have been approved by one comparable overseas NRA for an indication but were rejected by another comparable overseas NRA for that indication. **Recommendation Twenty-Five:** The Panel recommends that the NRA establish an integrated, online system to manage SAS notifications, approvals and reporting requirements. Such a system should have capacity to: 1. Establish a Schedule of Category B Products that are eligible for automatic approval; 2. Allow clinicians to enter a restriction code to auto-populate information relating to SAS notifications, automatic approvals and applications; 3. Utilise smart-forms to reduce unnecessary administrative burden on clinicians and sponsors; and 4. Provide data for real-time monitoring of the SAS by the Australian NRA, to identify potential trends and abuses. **Recommendation Twenty-Six:** The Panel recommends that the role of the NRA under the Authorised Prescriber Scheme be to authorise a prescriber, and the supply of an unapproved medicine or device to that prescriber, in circumstances where it is satisfied that: 1. Approval for the prescriber to use the unapproved medicine or device in the proposed patient cohort has been provided by a properly constituted ethics committee; and 2. There is no medicine or device available in the ARTG that would be suitable in the proposed circumstances; and	

Recommendations	*Government response*
3. There are no emerging safety concerns in respect of the medicine or device that may alter the consideration of risk and benefit.	

Recommendations relating to enablers and functionality

Recommendations	*Government response*
Recommendation Twenty-Seven: The Panel recommends that the Australian Government develop a more comprehensive post-market monitoring scheme for medicines and medical devices. Such a scheme to include: 1. Better integration and timely analysis of available datasets, including analysis of matched de-identified data from the Pharmaceutical Benefits Scheme, Medical Benefits Scheme, eHealth records, hospital records, private health insurance records and device and other relevant registries and datasets; 2. Establishment and maintenance of registries for all high-risk implantable devices; 3. Implementation of a scheme to alert practitioners and consumers that a drug is newly registered and to encourage reporting of any adverse events; 4. Provision for electronic reporting of adverse events; and 5. Enhanced collaboration with overseas NRAs to share information relating to safety or efficacy.	The Commonwealth **accepts** Recommendation Twenty-Seven, with the exception of part 2. Consideration of registries for high-risk implantable devices is being deferred until other work is undertaken (Recommendation Twenty-Two). The development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes.
Recommendation Twenty-Eight: The Panel recommends that: 1. The Australian Government undertake a comprehensive review of the legislative framework underpinning the regulation of therapeutic goods, including a review of the Therapeutic Goods Act 1989 (the Act) and associated Regulations in their entirety, with a view to simplifying its structure and language to achieve a more user-friendly	The Commonwealth **accepts-in-principle** Recommendation Twenty-Eight but will propose amendments to Parliament as required to implement particular recommendations. It will implement the intent of this recommendation (which is to simplify the legislative framework and ensure it is more user-friendly) when implementing agreed changes to legislation and

Recommendations	*Government response*
approach. In doing so: A. the objects clause of the Act should be amended to better reflect the public health and consumer protection outcomes that the Act aims to achieve; and B. the Act should be re-drafted in such a way as to: I. maximise transparency of both policies and processes; II. provide flexibility for the Australian NRA to appropriately modify processes to ensure a thorough analysis of safety, quality and efficacy, while avoiding unnecessary duplication; III. recognise that medicines and medical devices are very different products and should be regulated accordingly; IV. provide for graduated penalties that allow the NRA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance; V. reflect contemporary practice standards for health professionals; and VI. maximise the capacity of the Australian NRA to utilise electronic transactions and to collect information once to use for multiple purposes. 2. The Australian Government consider asking the Australian Law Reform Commission to undertake the proposed review and present a report to Government and to the Parliament.	regulations. Once legislative changes are implemented, an assessment will be made on the need for a more comprehensive review of the legislative framework underpinning the regulation of therapeutic goods, and whether the benefits of redrafting and implementing new legislation would outweigh the costs of doing so.
Recommendation Twenty-Nine: The Panel recommends that: 1. The decision making process for the inclusion of medicines and	The Commonwealth **rejects** Recommendation Twenty-Nine. In consultation on the review recommendations, all stakeholders (industry, health professionals and consumer groups) strongly

Recommendations	*Government response*
medical devices in the ARTG be changed to provide for: A. The Australian Government's Chief Medical Officer to be the delegate for decisions. B. The establishment of a statutory committee to make recommendations to the Chief Medical Officer about registration of a medicine in the ARTG (Advisory Committee on Medicines). C. The establishment of a statutory committee to make recommendations to the Chief Medical Officer about inclusion of a medical device in the ARTG (Advisory Committee on Medical Devices). 2. Both Committees be composed of experts across relevant fields and consumer representation and have the authority to: A. Consider information submitted by the product sponsor. B. Consider evaluation reports prepared by or for the Australian NRA and comparable overseas NRAs. C. Take evidence from sponsors, the Australian NRA, and any other parties which the committees consider may have a reasonable interest in the registration of the medication or medical device. D. Take into account any other information that the committees consider may be material in their deliberations.	opposed this recommendation, as there was a consensus that delegating decision-making to a single person would slow approval processes and lead to a significant backlog of applications, thus potentially undermining efficiencies gained by implementing other recommendations in the Review. The Commonwealth notes that the stated purpose of the recommendation (which is to increase dialogue between the TGA and sponsors), will be achieved through implementation of the broad range of reforms the Commonwealth proposes to adopt, such as improving transparency of decision-making, developing an SME support function to provide regulatory advice and facilitating increased engagement between sponsors and the regulator.
Recommendation Thirty: The Panel recommends that the Advisory Committee on Medicines Scheduling (ACMS) become a sub-committee of the Advisory Committee on Medicines and make recommendations to that committee about the: 1. Scheduling of medicines; and	The Commonwealth **rejects** Recommendation Thirty as the roles of medicine consideration for TGA registration and for scheduling are quite different. This recommendation was not supported by stakeholders. As part of the *Smaller Government Agenda*, the Commonwealth proposes to rationalise the number

Recommendations	*Government response*
2. Inclusion of medicinal substances in Appendix H of the Poisons Standard.	of TGA advisory committees from eleven to seven, of which the Advisory Committee on Medicines Scheduling will be retained as a standalone committee. This is due to its important role in advising the TGA on the scheduling of medicinal substances and ensuring that state and territory governments have strong input into scheduling decisions (as state law actually implements a scheduling decision).
Recommendation Thirty-One: The Panel recommends that the Australian Government give consideration to organisational structures that will facilitate improved integration of: 1. Pre-market regulation of medicines and medical devices with health technology assessment of these products for subsidy and other purposes; and 2. Post-market monitoring of medicines and medical devices for safety, efficacy and cost-effectiveness.	The Commonwealth **supports the intent** of Recommendation Thirty-One, and notes recent organisational changes within the Department of Health to address process alignment and implement collaborative mechanisms.
Recommendation Thirty-Two: The Panel recommends that the Australian Government review and enhance the NRA's funding model, with a view to providing either a dedicated annual appropriation or other appropriate budgetary arrangements on an 'as-needs' or routine capacity basis, to enable it to more effectively fulfil its mandate to act in the public interest and to ensure that genuine and systemic improvements to its capacity, expertise and operation are achieved.	The Commonwealth **defers** consideration of Recommendation Thirty-Two. The Department of Health and associated agencies are scheduled to undergo a *Portfolio Charging Review* in 2017-18. A review of the regulator's funding arrangements should not be conducted in isolation. Deferring consideration under the *Portfolio Charging Review* will ensure funding arrangements are fully considered and aligned within a whole-of-portfolio perspective.

Recommendations relating to the complementary medicines regulatory framework

Recommendations	*Government response*
Recommendation Thirty-Three: The Panel recommends that listed medicinal products, including complementary medicinal products, and the ingredients for use in such products, continue to be regulated within the	The Commonwealth **accepts** Recommendation Thirty-Three, noting the strong support from all stakeholders for complementary medicines to continue to be regulated by the

Recommendations	*Government response*
therapeutic goods framework.	TGA.
Recommendation Thirty-Four: The Panel recommends that the redrafted Therapeutic Goods Act 1989 is amended to provide the NRA with the capacity to refuse to list in the ARTG complementary medicinal products and other listed medicinal products that have the potential to undermine Australia's public health efforts.	The Commonwealth **supports the intent** of Recommendation Thirty-Four, noting that current mechanisms (such as allowing complementary medicines to contain only ingredients that have been assessed by the TGA to be safe, and targeted reviews of particular types of products immediately post-listing) can achieve the intent of the recommendation.
Recommendation Thirty-Five: The Panel recommends that the NRA continues to evaluate ingredients for use in listed medicinal products, and requires listed medicinal products to only include ingredients that have been approved for use in listed products. In undertaking an evaluation of ingredients the NRA should continue to give consideration to: A. the safety of the proposed ingredient, taking into account factors such as: proposed dosage; route of administration; frequency and duration of administration; and possible drug interactions; B. working with stakeholders to identify a broader range of appropriate sources of evidence for the quality of new ingredients, which may change over time; and C. the quality of the proposed ingredients, including proposed methodology for ensuring product purity, consistency, stability and other aspects of the PIC/S GMP.	The Commonwealth **accepts** Recommendation Thirty-Five, noting that stakeholders were in favour of the TGA continuing to evaluate ingredients for use in listed medicinal products.
Recommendation Thirty-Six: The Panel recommends that a sponsor seeking to have a new ingredient assessed by the NRA for use in listed medicinal products, including complementary medicinal products, is able to either: A. submit data relating to the safety and quality of the proposed ingredient for use in listed medicinal products for de novo assessment by the NRA; or B. submit an un-redacted evaluation report from a comparable overseas	The Commonwealth **accepts** Recommendation Thirty-Six, as it will provide additional flexibility for applicants looking to apply for assessment of new ingredients for use in listed medicines. The Commonwealth notes that take-up of Option B will depend on the availability of relevant un-redacted evaluation reports from comparable overseas regulatory agencies.

Recommendations	*Government response*
NRA, along with a copy of the dossier submitted to that NRA and data supporting specific Australian requirements, such as labelling, to the Australian NRA for assessment (refer to Recommendation Five). The Australian NRA to make a recommendation regarding use of the ingredient in listed medicinal products once it has considered the data within the Australian context.	
Recommendation Thirty-Seven: The Panel recommends that the NRA develop and maintain, in real time, a catalogue of approved ingredients for use in listed medicinal products that is readily accessible to sponsors and the general public.	The Commonwealth **accepts** Recommendation Thirty-Seven, as it will provide a single readily accessible list of ingredients for sponsors and the general public, minimising unnecessary regulatory burden.
Recommendation Thirty-Eight: The Panel recommends that the NRA establishes the list of Permitted Indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG.	The Commonwealth **accepts** Recommendation Thirty-Eight, noting that implementation of the list of Permitted Indications will require legislative change and will be subject to consultation with consumers, sponsors and health professionals.
Recommendation Thirty-Nine: The Panel recommends that there be three options by which sponsors may seek entry into the ARTG of complementary medicinal products and other listed medicinal products for supply in Australia. Option One - Listing in the ARTG following self-declaration by the sponsor of the safety and quality of the product in circumstances where: A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, comply with listing notices or similar documents issued or endorsed by the NRA; and C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and	The Commonwealth **accepts** Recommendation Thirty-Nine, noting that legislative amendments are required to implement Option Two. Implementing this recommendation would increase transparency for consumers, provide additional flexibility for sponsors and support innovation.

Recommendations	*Government response*
D. the product is manufactured in accordance with PIC/S GMP; and E. the sponsor only seeks to make claims regarding the indications for use of the product selected from the list of Permitted Indications (Recommendation Thirty Eight refers); and F. the sponsor holds evidence to support these indications, consistent with requirements outlined in the evidence guidelines issued by the NRA from time to time. Option Two - Listing in the ARTG following a self-assessment of the safety and quality of the product, and following assessment of the efficacy of the product by the NRA, in circumstances where: A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, are compliant with listing notices or similar documents issued or endorsed by the NRA; and C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and D. the product is manufactured in accordance with PIC/S GMP; and E. the sponsor seeks to make health claims that fall outside the list of Permitted Indications but which are still appropriate for listed medicinal products; and F. the sponsor can provide evidence acceptable to the NRA to support the safety and efficacy of the product for the proposed indication(s), commensurate with risk. This may include the submission of an un-redacted evaluation report(s) from a comparable overseas regulator. Option Three - Registration of a complementary medicinal product in the	

Recommendations	*Government response*
ARTG following an assessment by the NRA of the product for safety, quality and efficacy in accordance with existing requirements for registration of complementary medicines (Recommendation Forty refers).	
Recommendation Forty: The Panel recommends that where a sponsor seeks to include a complementary medicinal product in the ARTG that the sponsor is able to do so utilising registration Pathways One or Two, namely: Pathway One - Submission of a complete dossier for de novo assessment. This assessment may be undertaken in full by the Australian NRA or via a work-sharing arrangement between the Australian NRA and a comparable overseas NRA. Pathway Two - Submission of an un-redacted evaluation report from a comparable overseas NRA, along with a copy of the dossier submitted to the comparable overseas NRA and Australian specific data similar to that provided by sponsors in Module 1 of the Common Technical Document, for assessment by the Australian NRA. The Australian NRA to make a recommendation regarding registration of the complementary medicinal product once it has considered the data within the Australian context.	The Commonwealth **accepts** Recommendation Forty, as it will increase flexibility for sponsors seeking to register a complementary medicine in the ARTG. This recommendation is consistent with the Australian Government's *Regulatory Reform Agenda* and the *Industry Innovation and Competitiveness Agenda*.
Recommendation Forty-One: The Panel recommends that the NRA develops, in consultation with industry, legislative timeframes for the: A. assessment of new ingredients for use in listed medicinal products; B. publication of finalised compositional guidelines for newly approved ingredients for use in listed medicinal products, where appropriate; C. assessment of medicinal products listed under Option Two; and D. registration of medicinal products under Option Three.	The Commonwealth **accepts** Recommendation Forty-One, noting that development of legislative timeframes will be subject to further consultation with stakeholders.
Recommendation Forty-Two: The Panel recommends that, consistent with Recommendation Thirteen, the NRA adopt a risk-based approach to the management of variations to complementary medicines listed in the ARTG.	The Commonwealth **accepts** Recommendation Forty-Two. Implementing a risk-based approach to assessments of variations to listed complementary medicines will reduce

Recommendations	*Government response*
This approach should provide for: A. notification of variations to the NRA in circumstances where the variation does not impact the quality, safety or efficacy of the product; or B. assessment of the variation by the NRA in circumstances where the variation has the potential to impact the safety, quality or efficacy of the medicine. This assessment to be abridged in scope, so that only those aspects that require evaluation in order to establish the continued safety, quality and efficacy of the complementary medicine following implementation of the proposed variation are examined (abridged assessment).	regulatory burden for sponsors.
Recommendation Forty-Three: The Panel recommends that where a medicinal product is listed in the ARTG, the sponsor be required to publish on the sponsor's website or, if the sponsor does not have a website, on another website nominated by the NRA, the evidence that it holds to support all indications included in the ARTG entry.	The Commonwealth **supports the intent** of Recommendation Forty-Three, which is to better inform consumers and improve the accuracy of information available to them. Consistent with the principles of minimum effective regulation, the Commonwealth will encourage self-publishing by sponsors of relevant information.
Recommendation Forty-Four: The Panel recommends that where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use.	The Commonwealth **supports the intent** of Recommendation Forty-Four, which is to assist in educating consumers about the listing system. Noting that careful design and consultation with affected stakeholders would be required prior to any implementation, the TGA will conduct further consultation on ways to better educate consumers about the listing system, including consideration of an educative statement about the difference between listed and registered medicines to be placed on sponsors' websites. In accordance with the Government's commitment to red tape reduction, the Government will not require sponsors to place a disclaimer on product labels.

Recommendations	*Government response*
Recommendation Forty-Five: The Panel recommends that where a medicinal product is listed in the ARTG following an assessment by the NRA of an application under Option Two, the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indication(s).	The Commonwealth **accepts-in-principle** Recommendation Forty-Five, noting that the design and use of the promotional statements will require careful consideration by the TGA and further consultation with stakeholders.
Recommendation Forty-Six: The Panel recommends that the NRA develops or adopts from comparable overseas regulators, efficacy monographs for commonly used active ingredients that have been approved for use in listed medicinal products. Such monographs would document the evidence supporting the efficacy of the ingredients for specific indications and other relevant information.	The Commonwealth **accepts** Recommendation Forty-Six, as the development or adoption from comparable regulators of monographs has the potential to improve the availability and accuracy of information for consumers and to reduce time and costs for industry.
Recommendation Forty-Seven: The Panel recommends that, in revising the Therapeutic Goods Act 1989 and subordinate legislation (Recommendation Twenty Eight refers), the Australian Government provides review and appeal rights for the sponsor who has lodged an application for a new ingredient (to be approved for a listed medicine) to seek a review of an NRA decision regarding that application.	The Commonwealth **supports the intent** of Recommendation Forty-Seven. The design of potential review and appeal rights requires careful consideration of the application of administrative law principles in this context.
Recommendation Forty-Eight: The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.	The Commonwealth **accepts** Recommendation Forty-Eight, noting that the review will involve consultation with consumers, industry, health professionals and other Commonwealth regulatory bodies. Implementation of this recommendation will be furthered in conjunction with that of Recommendations Fourteen and Twenty-Three.
Recommendation Forty-Nine: The Panel recommends that the NRA develops a more comprehensive post-market monitoring scheme for listed medicinal products, including complementary medicinal products. Such a scheme should include: A. an increase in the number of products subject to random/targeted post-market review;	The Commonwealth **accepts** Recommendation Forty-Nine, as the development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes. With respect to parts B and C of Recommendation Forty-Nine, the Commonwealth notes that the intent of these parts is already

Recommendations	*Government response*
B. provisions to allow the NRA to complete a post-market review in the event that the sponsor withdraws the product from the ARTG during the course of the review; C. timely availability of information for consumers for each listed product in relation to whether the product has been subject to post-market review, and the timing and outcome of any review; D. integration and timely analysis of any available datasets, including eHealth and hospital records, to provide a more streamlined and cost-effective approach to post-market monitoring (Recommendation Twenty-Seven refers), particularly of products including newly approved ingredients; E. provision for electronic reporting of adverse events; and F. enhanced collaboration with overseas NRAs to share information relating to safety or efficacy of comparable products.	achieved through use of existing mechanisms available to the regulator such as targeted post-market audits.
Recommendation Fifty: The Panel recommends that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation.	The Commonwealth **accepts-in-principle** Recommendation Fifty, noting the cross government responsibility for innovation policy. The Department of Health will collaborate with other Departments (such as the Department of Industry, Innovation and Science) and with relevant stakeholders to consider this issue further. This reform aligns with the Australian Government's *National Innovation and Science Agenda*.
Recommendation Fifty-One: The Panel recommends that the statutory Advisory Committee on Complementary Medicines is retained, and that the committee: A. is composed of a range of experts across relevant fields and consumer representation, as required over time; B. at the request of the NRA, provides advice regarding the inclusion, variation, removal of complementary medicinal products from the	The Commonwealth **accepts** Recommendation Fifty-One. The Advisory Committee on Complementary Medicines will provide an important opportunity for TGA to receive expert advice from consumers, industry and health professionals in the complementary medicines sector.

Recommendations	*Government response*
ARTG and any other matters relating to complementary medicines; and C. takes into account any other information that the committee considers is material to its deliberations.	

Recommendations relating to the therapeutic goods advertising framework

Recommendations	*Government response*
Recommendation Fifty-Two: The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the NRA under a legislative framework which includes an advertising code.	The Commonwealth **accepts** Recommendation Fifty-Two, noting that stakeholders strongly supported continuing to regulate advertising of therapeutic goods to the public within the therapeutic goods regulatory framework.
Recommendation Fifty-Three: The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the Poisons Standard continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).	The Commonwealth **accepts** Recommendation Fifty-Three, noting that the issue of advertising of Schedule 3 (Pharmacist only) medicinal substances will be considered as part of a review of the *Scheduling Policy Framework* (Recommendations Eleven and Twelve).
Recommendation Fifty-Four: The Panel recommends that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.	The Commonwealth **accepts** Recommendation Fifty-Four and notes that increasing consistency of approach could help reduce complexity for advertisers. The Commonwealth also notes that the differences between medicines and medical devices means that consistency may not be appropriate in particular circumstances.
Recommendation Fifty-Five: The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.	The Commonwealth **accepts** Recommendation Fifty-Five, noting that the acceptance of Recommendations Fifty-Seven (enforcement powers) and Fifty-Eight (sponsor education) is critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation. Removal of pre-approval requirements could help reduce unnecessary complexity for sponsors and advertisers, and is

Recommendations	*Government response*
	consistent with the Government's commitment to minimising unnecessary regulatory burden.
Recommendation Fifty-Six: The Panel recommends that current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. The Government should consider the following options: A. establishing the function within the NRA or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or B. calling for tenders from external organisations to undertake the function.	The Commonwealth **accepts** Recommendation Fifty-Six. A single agency approach to complaints management has the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers. To progress this recommendation, the Department of Health will consult with stakeholders on the appropriate design of the new complaints-management process.
Recommendation Fifty-Seven: The Panel recommends that, further to Recommendation Twenty-Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.	The Commonwealth **accepts** Recommendation Fifty-Seven, and notes that broadening enforcement powers will benefit consumers by appropriate compliance with advertising regulatory requirements, and deter inappropriate and misleading advertising of products.
Recommendation Fifty-Eight: The Panel recommends that the NRA facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.	The Commonwealth **accepts** Recommendation Fifty-Eight, as developing sponsor education programmes to assist sponsors and advertisers in understanding their obligations will be particularly important once the reforms to the advertising regulatory framework are in place (particularly implementation of Recommendation Fifty-Five).