

# Review of Medicines and Medical Devices Regulation

Recommendations

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July 2015



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**Expert Panel**

**Review of Medicines and Medical Devices Regulation**

**Recommendations to the Minister for Health on the  
Regulatory Frameworks for Medicines, Medical  
Devices, Complementary Medicines and Advertising  
of Therapeutic Goods**

**31 July 2015**

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## FOREWORD

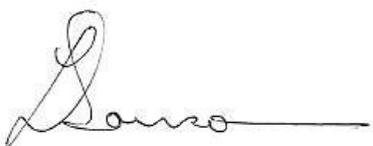
The rapid pace of innovation and change in the health sector confers both benefits and risks. The Government's deregulation agenda is based on the core principle that well-designed regulation has a role in achieving the greatest net benefit for the Australian community. In therapeutic products sectors, regulations need to support timely access by consumers to innovative products which enable them to protect their health, manage conditions and have diseases treated effectively. Regulations also need to provide adequate protections for consumers commensurate with the potential risks to health of product use, in a way that results in the benefits outweighing the risks.

In considering these tensions, the Panel is cognisant that the objectives of the Government's *National Medicines Policy* and its *Industry, Innovation and Competitiveness Agenda* are relevant to the regulation of both medicines and medical devices. The desired outcome is to balance consumers' access to, and wise use of, therapeutic products with maintaining responsible and viable industries. The Panel is mindful that there is a danger of risks being either over or under estimated. The level of risk must be carefully quantified, and regulatory controls designed accordingly, so that a business friendly environment which is conducive to industry innovation and entrepreneurship is facilitated, while fundamental public protections are retained.

Achieving that balance will result in regulation that contributes to maintaining a high standard of living, well-being, and economic productivity in the Australian community, while fostering industry competitiveness internationally.

The Report of the Independent Review of Medicines and Medical Devices Regulation makes fifty eight recommendations taking a principles-based approach to regulatory reform. The recommendations are of a high order and do not address operational, process or implementation matters. In the text of the Report's ten chapters, however, the Panel has suggested issues that would need to be considered in actioning the recommendations, and has proposed some structures and processes for the consideration of government. The recommendations do not stand alone, and should be considered in relation to the text.

The Panel's intention was to recommend enhancements to the regulatory frameworks to enable them to be dynamic and flexible, positioning Australia to effectively respond to emerging opportunities for, and manage challenges to the health and safety of the public.



Emeritus Professor Lloyd Sansom AO  
Chair

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## RECOMMENDATIONS

### RECOMMENDATIONS RELATING TO THE NATIONAL REGULATORY AUTHORITY ROLE

#### 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).

### RECOMMENDATIONS RELATING TO THE MEDICINES REGULATORY FRAMEWORK

#### Recommendation Three

The Panel recommends that there be three pathways to seek registration of a **new chemical entity** and its inclusion in the ARTG:

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|---------------|--|
| 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, 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.  |

#### 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:

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|-------------|--|
| 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, to the Australian NRA for assessment, 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 Australian NRA to make a recommendation regarding registration of the medicine 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.

### 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 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 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
  - 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.
  - 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 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; and
    - 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 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 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 the 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.

### **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.
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.

## RECOMMENDATIONS RELATING TO THE MEDICAL DEVICES REGULATORY FRAMEWORK

### 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.

### 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 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.

### 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 overseeing the evaluation/assessment of medical devices.
  - D. Independence and impartiality.
  - E. Transparency of systems and processes.
  - F. Technical competence.
  - 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 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.

### **Recommendation Twenty One**

The Panel recommends that the NRA establish target timeframes that reflect international benchmarks and the 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.

### **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.

### **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.

## **RECOMMENDATIONS RELATING TO ACCESS TO UNAPPROVED THERAPEUTIC GOODS**

### **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 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
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**

### **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.

### 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 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.

### Recommendation Twenty Nine

The Panel recommends that:

1. The decision making process for the inclusion of medicines and 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.

### **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
2. Inclusion of medical substances in Appendix H of the *Poisons Standard*.

### **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.

### **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.

## RECOMMENDATIONS RELATING TO THE COMPLEMENTARY MEDICINES REGULATORY FRAMEWORK

### Recommendation Thirty Three

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

### Recommendation Thirty Four

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

### Recommendation Thirty Five

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

- A. the safety of the proposed ingredient, taking into account factors such as: proposed dosage; route of administration; frequency and duration of administration; and possible drug interactions;
- B. working with stakeholders to identify a broader range of appropriate sources of evidence for the quality of new ingredients, which may change over time; and
- C. the quality of the proposed ingredients, including proposed methodology for ensuring product purity, consistency, stability and other aspects of the PIC/S GMP.

### Recommendation Thirty Six

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

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

### **Recommendation Thirty Seven**

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

### **Recommendation Thirty Eight**

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

### **Recommendation Thirty Nine**

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

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

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

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

### Recommendation Forty

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

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

### **Recommendation Forty One**

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

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

### **Recommendation Forty Two**

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

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

### **Recommendation Forty Three**

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

### **Recommendation Forty Four**

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

### **Recommendation Forty Five**

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

### **Recommendation Forty Six**

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

### **Recommendation Forty Seven**

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

### **Recommendation Forty Eight**

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

### **Recommendation Forty Nine**

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

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

### **Recommendation Fifty**

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

### **Recommendation Fifty One**

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

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

## **RECOMMENDATIONS RELATING TO THE THERAPEUTIC GOODS ADVERTISING FRAMEWORK**

### **Recommendation Fifty Two**

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

### **Recommendation Fifty Three**

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

### **Recommendation Fifty Four**

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

### **Recommendation Fifty Five**

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

### **Recommendation Fifty Six**

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

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

### **Recommendation Fifty Seven**

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

### **Recommendation Fifty Eight**

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







