The Complementary Medicines Industry response to the recommendations of the 'TGA Reforms – A Blue Print for TGA's Future' (the Blueprint Report)

Correlation of recommendations and responses

Recommendation relating to:	Recommendation	Government response	CHC response
Communication and Stakeholder engagement	**TR- Rec 1** The TGA to establish an Australian Therapeutic Goods Advisory Council	Agreed	**Supported.** TGA Industry Consultative Committee (TICC) to continue until this occurs. The CHC recommends current TICC representation be incorporated into the Advisory Council.
	TR- Rec 2 The TGA to define, adopt and publish consultation principals to guide regulatory transparency and accountability	Agreed	**Supported**
	TR- Rec 3 The TGA to develop and implement a comprehensive communication strategy to inform and educate. A dedicated communication team should be established within TGA to implement that strategy	Agreed	**Supported**
	TR- Rec 4 The TGA work transparently with other key providers of information to enhance the information available to the public (community and stakeholders), consistent with the principles of the quality use of medicines	Agreed	**Strongly supported.** The CHC can assist in promoting user friendly information to highlight the two tier risk based system used for therapeutic goods via the CHC Consumer Magazine, and via members' consumer email databases (capturing around 1 million consumer contacts). This would be a positive approach in supporting the TGA's strategy to inform consumers that listed medicines and some medical devices (low risk) are not required under legislation to be evaluated for effectiveness by the TGA before being made available in Australia.
	TR- Rec 5 The TGA develop a plan to ensure information on the key public access portal, the TGA	Agreed	**Supported.** This includes refreshing out-dated documents on the TGA website or noting they are

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	website, is current, accurate, relevant, timely and up to date and meets the needs of its audiences		'under revision'. The CHC supports transparency of information that is balanced against protecting commercial in confidence material.
	TR Rec 6 The TGA provide user friendly information on the risk based framework under which it operates, including detailed explanations of how this operates for different classes of therapeutic goods. As a priority the differences between registered and listed therapeutic goods, and their processes of evaluation, should be explained	Agreed	**Supported**. The CHC will not support the use of a label disclaimer to communicate regulatory messages as there is no evidence to suggest that this would be effective (consumer tested) or practical (space on multi ingredient labels and truth in labelling after post market review). If a label disclaimer is implemented it should be applied across all listed therapeutic goods. The CHC supports the TGA in communicating the risk based framework, via mediums such as advertising and the TGA website.
	TR Rec 7 The TGA implement mechanisms to educate and inform the public that listed medicines are not evaluated for effectiveness by the TGA prior to market	Agreed	**Supported.** The CHC suggests a positive communication strategy that promotes the safety and quality criteria listed medicines meet rather than what they are not evaluated for.
	TR Rec 8 The TGA provide clear information on the role of its statutory advisory committees, and adopts a consistent and transparent approach to the publication of information from those committees	Agreed	**Supported**
	TR Rec 9 The TGA improve access and quality information on the processes for regulation of advertising of therapeutic goods, including the compliant process and the outcomes of complaints	Agreed	**In Principle Support**. The CHC questions the suitability of the Complaints Resolution Panel (CRP) as the body to determine advertising complaints against the complementary medicine industry. The composition of

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			the CRP currently means that there is not the right expertise representative of CMs to provide an expert opinion. Industry is concerned with the lack of an effective appeals mechanism for the CRP. The CHC recommends the Complaints Resolution Committee (CRC) become the body to deal with all complaints related to CMs, as they represent the expertise to provide a balanced view.
	TR Rec 10 The TGA, in conjunction with key stakeholders, develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency. This may be achieved in conjunction with the proposed Australian Therapeutic Goods Advisory Council	Agreed	**Supported** - through the development of the proposed Australian Therapeutic Goods Advisory Council
	TR Rec 11 The TGA develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for each therapeutic product type. The policy should take into account the practices followed by comparable international regulators	Agreed	**In Principle Support**. The CHC recommends priority development of a TGA policy regarding commercial in confidence information as **u**nlike prescription medicines, complementary medicines are not generally patent protected, and so publishing a company's intellectual property could be very damaging to the sector and is likely to stifle innovation. The CHC therefore reiterates that documents such as supporting tables of evidence should be kept commercial- in-

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			confidence, as Industry invests substantially in the preparation of these documents. Should the policy on the disclosure of commercial in confidence information be substantially different from its current interpretation, the statement should be consulted on.
	TR Rec 12 The TGA explore mechanisms for providing explanations on its various regulatory processes, and the TGA adopt publication principles on the outcomes of application assessments using as an example the Australian Public Assessment Reports (AusPAR)	Agreed	The CHC agrees that stakeholders would benefit from the publication of the rationale for recommendations made by the TGA's statutory committees, and the final decisions on applications, including withdrawals and rejections . More information is required as to the possibility of this approach working for other types of therapeutic goods, such as complementary medicines.
	TR Rec 13 The TGA asses the reports on the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, which enables the sponsor to ascertain the progress of an application	Agreed with consultation to be undertaken with stakeholders to further develop options for consideration by the TGA	**Supported.**
	TR Rec 14 The TGA work with stakeholders to improve labelling and packaging requirements to educate and assist consumers and health practitioners to make informed decisions about the quality use of therapeutic goods	The Government considers that there is capacity to improve labelling and packaging requirements and will	The CHC is in consultation on this issue

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		further develop options in consultation with stakeholders	
	TR Rec 15 The TGA conduct, and report on, a feasibility study into the development of an early post-marketing risk communication scheme for therapeutic goods, with consideration of international models	Agreed	No comment until results of feasibility study complete
	TR Rec 16 The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers	Agreed	Relates to CMIs and PIs being kept up-to-date. The CHC encourages sponsors to inform the TGA when significant new safety information on CMs becomes available
	TR Rec 17 The TGA to explore mechanisms to maintain the currency of Consumer Medicines Information and Approved Product Information	In-principle agreement further consultation to be undertaken with stakeholders	No comment – N/A
	TR Rec 18 The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.	Agreed	The CHC supports the improvement of transparency of information to stakeholders and supports tougher penalties for repeat and serious offenders. The CHC acknowledges that the TGA has limited resources and needs to target those products and companies with the greatest risk for non-compliance. The TGA should also use its powers to deem certain foods (not subject to a food standard) making therapeutic claims to be therapeutic goods. There is

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			currently a very uneven playing field with many products being sold as foods and making claims that would not be permitted by the TGA, especially in the sports food and weight loss segments.
	TR Rec 19 The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system	Agreed	**Supported** – the CHC supports a publicly accessible national adverse event database, with online interrogation capacity for reports by health professionals. The CHC strongly recommends the publication of the revised Pharmacovigilance Guideline.
	TR Rec 20 The TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods.	Agreed	As above
	TR Rec 21 The TGA work with State and Territory governments, stakeholders, and other relevant agencies, to improve the visible management of adverse event reporting in support of consumer safety and consistent with the findings of the Horvath Review into Immunisation	Agreed	The CHC supports further information on how to lodge and adverse event report and the significance of these reports. The CHC supports an adverse event system that improves integration between jurisdictional, national and overseas reporting systems
Complementary Medicines The Auditor-General report was tabled in	**CM Rec 1** To achieve timely completion of key guidance material for complementary medicines, the ANAO recommends that DoHA: (a) provides a target date for the completion and publication of each key guidance document; and	Agreed	**Supported**. The CHC notes that many of the guidance documents are out of date and inadequate to provide industry with certainty around regulatory compliance. The CHC will work proactively in providing feedback to the TGA on

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Parliament on 12 September 2011			key guidance documents. The CHC supports priority update of the ARGCM and LoE Guidelines. The LoE Guideline requirements should be made clear and not subject to ambiguity.
	b) provide regular progress reports on the development of key guidance documents on the TGA website, to keep industry, health professionals and consumers informed.	Agreed	**Supported.** The CHC supports transparency to of this regulatory activity to all stakeholders
	CM Rec 2 To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods (ARTG), the ANAO recommends that DoHA seeks to finalise work on the 'coded indications' project so as to limit the use of inappropriate claims and indications on the ARTG.	Agreed	**In Principle Support –** The CHC are not prepared to support this proposal unless there are provisions for an extensive list of coded indications, a guaranteed turn around time of 48 hours for new indications, and broad industry consultation on the final list of coded indications. There should be consideration with regard to the interface between coded indications and the Advertising Code. Wording within the spirit of the coded indication should be allowed. The CHC strongly recommends the TGA release coded indications in groups, for example according to either the WHO Anatomical Therapeutic Chemical (ATC) or International Classification of Diseases (ICD) coding systems, or a market segment that represents most value to the industry sector. It is recommended that this process begin as soon as possible to allow sponsors to start mapping the current specific text to coded

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			indications to determine (a) the appropriateness of existing evidence to support the mapped coded indication, and (b) identify indication gaps for which a request with justification can be made to the TGA to develop additional coded indications.
	CM Rec 3 The ANAO recommends that the TGA makes information available in a timely manner to the Australian public, for each listed complementary medicine, stating whether it has been subject to post-market review by the TGA, when it was reviewed, and the outcome of that review.	Agreed	The CHC supports the improvement of transparency of information to stakeholders. The CHC considers that this recommendation relates to the conclusion of a review and that stating if a product has been subject to a review means once the sponsor as received a conclusion letter from the TGA. However, it is critical that any review of listed medicines remains confidential until the review is fully completed, to prevent harm to the reputation of Sponsors. The CHC recommends that at the end of the review, the outcomes should be either. • Reviewed - Compliant; or Reviewed - Non compliant.
	CM Rec 4 To improve compliance with the regulatory framework, the ANAO recommends that the TGA:		
	(a) use its random sampling review of listed medicines to develop risk profiles of sponsors and the most	Agreed	The CHC believes that a shared approach to the development of a risk matrix for the determination of

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	significant characteristics of medicines; and (b) use the profiles to inform its program of post-market reviews.		the risk profiles of sponsors would contribute to industry knowledge, leading to improved industry compliance within the regulatory framework. If Sponsors do not nominate an industry code of practice at the time of listing this should be flagged as a higher level of risk. Mechanisms to decrease the 'higher level of risk' could be achieved through ongoing review working on a points system for example. The sponsor's risk matrix status should be available to only the Sponsor.
	CM Rec 5 The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches. In developing the procedure TGA should incorporate: (a) appropriate timeframes for completing the investigations of advertising breaches; and (b) the provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.	Agreed	The CHC questions the suitability of the Complaints Resolution Panel (CRP) as the body to determine advertising complaints against the complementary medicine industry. The composition of the CRP currently means that there is not the right expertise representative of CMs to provide an expert opinion. The CHC recommends the Complaints Resolution Committee (CRC) becomes the body to deal with all complaints related to CMs, as they represent the expertise to provide a balanced view. The SOP for the CRP that is to be developed should be made publically available.
Informal Working	**IWG Rec 1** Provide increased information:	The Government	The CHC will not support the use of a label disclaimer to

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Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates	(a) on product labels regarding regulatory assessment undertaken by TGA of complementary medicines; and	considers that improvements in this area could increase public awareness of the regulation of complementary medicines and will work with stakeholders to develop options for consideration by Government.	communicate regulatory messages as there is no evidence to suggest that this would be effective (consumer tested) or practical (space on multi ingredient labels and truth in labelling after post market review). The CHC believes that the TGA website provides ample information around the regulatory processes used in Australia for therapeutic goods. If a label disclaimer is implemented it should be applied across all listed therapeutic goods.
	(b) on TGA website regarding regulatory assessment undertaken by TGA of complementary medicines.	Agreed	As above
	IWG Rec 2 Modify Electronic Listing Facility system, to: (a) include restriction or elimination of access by sponsors to 'free text'.	Agreed	**In Principle Support –** The CHC are not prepared to support this proposal unless there are provisions for an extensive list of coded indications, a guaranteed turn around time of 48 hours for new indications, and broad industry consultation on the final list of coded indications. There should be consideration with regard to the interface between coded indications and the Advertising Code. Wording within the spirit of the coded indication should be allowed. The CHC strongly recommends the TGA release coded indications in

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			groups, for example according to either the WHO Anatomical Therapeutic Chemical (ATC) or International Classification of Diseases (ICD) coding systems, or a market segment that represents most value to the industry sector. It is recommended that this process begin as soon as possible to allow sponsors to start mapping the current specific text to coded indications to determine (a) the appropriateness of existing evidence to support the mapped coded indication, and (b) identify indication gaps for which a request with justification can be made to the TGA to develop additional coded indications.
	(b) Provide guidance and cautionary notes for sponsors using the Electronic Listing Facility, regarding the consequences of misleading and unsubstantiated claims.	Agreed	**Strongly Supported**. The CHC supports the amending of the ELF to include warnings/alerts at the time of validating a listing, to increase sponsor awareness of and compliance to the relevant parts of the regulations being undertaken. The CHC continues to progress its work on providing for a sponsor accreditation program, including initiatives to increase sponsors awareness of relevant parts of the Act, and the requirements that are being undertaken at the time of validating a listing. This is part of our commitment to further enhance credibility and compliance in industry.

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	IWG CM Rec 3 Update 'Guidelines for levels and kinds of evidence' and include 'Guidelines for levels and kinds of evidence' in regulation.	In-principle agreement with further consultation to be undertaken with stakeholders.	**Supported**. The CHC notes that the LoE guidance document is out of date and inadequate to provide industry with certainty around regulatory compliance. The CHC has worked proactively to provide an industry review of the LoE Guideline in the lead up to formal consultation.
	IWG CM Rec 4 Review current 'coded indications' project based on the document Guidelines for levels and kinds of evidence' and either restrict or eliminate access by sponsors to 'free text' in the Electronic Listing Facility.	Agreed	**In Principle Support –** The CHC are not prepared to support this proposal unless there are provisions for an extensive list of coded indications, a guaranteed turn around time of 48 hours for new indications, and broad industry consultation on the final list of coded indications. There should be consideration with regard to the interface between coded indications and the Advertising Code. Wording within the spirit of the coded indication should be allowed. The CHC strongly recommends the TGA release coded indications in groups, for example according to either the WHO Anatomical Therapeutic Chemical (ATC) or International Classification of Diseases (ICD) coding systems, or a market segment that represents most value to the industry sector. It is recommended that this process begin as soon as possible to allow sponsors to start mapping the current specific text to coded indications to determine (a) the appropriateness of existing evidence to support the mapped coded

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			indication, and (b) identify indication gaps for which a request with justification can be made to the TGA to develop additional coded indications.
	IWG CM Rec 5 Apply, enforce and publicise sanctions and penalties, including for advertising breaches, including recalling products from the market that are removed from the ARTG as a result of regulatory action, where circumstances warrant	Agreed	The CHC supports the improvement of transparency of information to stakeholders and supports tougher penalties for repeat and serious offenders.
	IWG CM Rec 6 Enhance sanctions and penalties for repeated breaches of non-compliance (as well as strengthening sanctions and penalties for advertising).	Noted with further consultation with stakeholders to consider appropriate sanctions and penalties.	As above
Advertising of therapeutic products	**Advert Rec 1** Publish the report on advertising reform on the website, once finalised	Agreed	**Supported**
	Advert Rec 2 Reforms to advertising framework	The TGA will further consult with stakeholders on appropriate reforms to the advertising framework.	**Supported**

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	Advert Rec 2a Modify pre-approvals process to include medical devices and pay TV (advertising claims about the efficacy of a product to be assessed by the TGA)	In-principle agreement with further consultation to be undertaken with stakeholders and development of options for consideration by Government.	In principle support with further consultation to occur
	Advert Rec 2b Establish a single entry point for all complaints, with some handled by TGA (complaints about the efficacy of a product to be assessed by the TGA).	Agreed	The CHC notes that recommendations concerning the advertising of therapeutic goods and the associated complaints system will be addressed in the context of broader advertising reforms. And would like to see more information about this proposal before providing a formal response. The CHC notes high levels of industry dissatisfaction with the operation of the Complaints Resolution Panel (CRP), inadequate penalties and sanctions and its lack of power to enforce rulings, especially for repeat offenders. The CHC supports responsible advertising claims and recognises that a small number of 'cowboys' make claims which are not supported by the evidence and reduce the credibility of the industry. Industry is concerned with the lack of an effective appeals mechanism for the CRP. The CHC recommends the Complaints Resolution

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			Committee (CRC) become the body to deal with all complaints related to CMs, as they represent the expertise to provide a balanced view.
	Advert Rec 2c Develop a more effective approach to sanctions and penalties (including use of the infringement notice provisions)	The Government will look at options to introduce more effective approaches to sanctions and penalties in consultation with stakeholders.	As above
Promotion of therapeutic products working group	**PTP Rec 1** The artificial difference in the Position Paper between 'high risk' and 'low risk' products be set aside, with application of a sector specific industry code to be determined by coverage of the relevant therapeutic sector to a specific product	Supported	The CHC considers there is a greater need to encourage non-members of industry associations to sign up to an industry code. In particular, the CHC is in favour of a mechanism for the nomination of an industry code at the time of listing a product on the ARTG.
	PTP Rec 2 Consistency of therapeutic sector industry codes of practice be facilitated by each therapeutic industry association, incorporating in its code the high level principles, operational coverage areas and governance provisions developed by the working group	Supported	**Strongly supported**. As above The CHC is currently reviewing it code of practice inline with the high level principles, operational coverage and governance provisions.
	PTP Rec 3 Each industry association must determine the steps required to be taken to implement the	Supported	**Supported** and timelines communicated.

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	working group's recommendation 2, and the time by which these steps will be completed. Each industry association will advise the Government of the anticipated completion date for implementation	Noting that industry associations have indicated that the target timeline for completion of code revisions is 2014.	
	PTP Rec 4 Information on therapeutic industry codes be made available to the public via the internet, with access to the complaints processes and links to each of the applicable codes. The industry associations will work with the Government to identify the most appropriate vehicle to make the information available.	Noted Improves access to information responds to consumer concerns and will strengthen self-regulation	**Supported**
	PTP Rec 5 TGA include on its application forms (whether electronic or paper) a requirement for an applicant to nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing on the ARTG.	Not supported as currently proposed. Departs from self-regulatory model. The Government's preference is to maintain the current self-regulatory focus. If after industry codes have been updated, further encouragement is required for non-	**Strongly supported.** The CHC considers there is a greater need to encourage non-members of industry associations to sign up to an industry code. In particular, the CHC is in favour of a mechanism for the nomination of an industry code at the time of listing a product on the ARTG. This initiative should be incorporated as part of the proposed fees and charges increase for 2012-13, which take into account the cost of implementing the Blueprint recommendations over the next 3-4 years.

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		members to nominate a code, the Government will consider further legislative measures including the TGA seeking this information	
	PTP Rec 6 TGA provide on the ARTG public summary for each product, information on the nomination of an industry code, in a searchable format	Noted Cannot be implemented separately to Recommendation 5	**Strongly supported.** As above
	PTP Rec 7 Industry associations work with TGA to develop a process for notification to an association when an applicant nominates that association's code of practice	Not supported as currently proposed. Departs from self-regulatory model as TGA is co-opted as an intermediary between industry associations and product sponsors	**Strongly supported.** As above
	PTP Rec 8 Industry associations develop comprehensive training programs on the codes to ensure that non-members (as well as members) are educated on the requirements of the relevant code.	Supported	**Strongly supported.** The CHC has a strong commitment to the ongoing professional development of its members and non-members in industry.

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	PTP Rec 9 The effectiveness of voluntary registration be evaluated annually and that consideration be given to mandatory nomination of a code if voluntary registration proves ineffective to achieve the Government's objectives	Noted Evaluation prior to 2014 may be premature given industry's advice on when their codes may be revised and operational. Further work with industry associations will be required to identify the most appropriate evaluation methodology	**Supported** with the provision of evaluation post 2014. The CHC considers there is a greater need to encourage non-members of industry associations to sign up to an industry code
	PTP Rec 10 AHPRA and AHMAC be encouraged to advocate changes to health professional codes to more closely reflect the mutuality of obligations between industry and healthcare professionals, to ensure ethical promotion of therapeutic products	The Government will refer this matter to AHPRA and National Boards	No comment at this stage, further information required.
	PTP Rec 11 The healthcare professional colleges and associations actively pursue alignment of their professional codes and/or guidelines to be consistent with the principles and areas of operational coverage	The Government will refer this matter to National Boards and professional colleges	**Supported.** The CHC agrees with a consistent approach across industry with regards to codes of practice/ethics.
	PTP Rec 12 Education on relationships with the	The Government will	**Strongly supported**. The CHC encourages greater

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	therapeutic industry be included in the training of healthcare professional students, in addition to education on the healthcare professional codes and guidelines	refer this matter to healthcare professional associations and/or education bodies.	awareness and understanding of the regulatory environment for healthcare professional students, in addition to healthcare professional and industry codes.
	PTP Rec 13 An educative complaints portal be established as a mechanism to assist channelling complaints to the appropriate industry association. The industry associations will work with the Government to identify the most appropriate vehicle for this purpose	Noted Strengthens access to information, communication and universal adherence to consistent industry-wide codes. Further work by industry associations will be required to identify options, expectations regarding lines of responsibility and mechanisms for effective implementation	**Supported**. The CHC will work to identify options for suitable mechanisms in consultation.
	PTP Rec 14 Each industry association provides on its website, a link to the complaints mechanism for each other therapeutic industry sector	Supported	**Supported**. Proposed wording for each association is being considered.

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	PTP Rec 15 The industry associations actively engage in the education on and dissemination of the outcomes of the deliberations of the working group, with assistance from the Government as appropriate.	Noted Further work by industry will be required to identify the need and scope for Government assistance and the capacity to fulfil within existing resources	**Supported**. The CHC is actively engaged in providing outcomes of this working group to its membership and will highlight where further assistance may be required.
	PTP Rec 16 The establishment of a process to evaluate, on an ongoing basis, the implementation of the recommendations of the working group	Noted Further work by industry will be required to identify mechanisms for evaluation	**Supported**, in progress.
	PTP Rec 17 The Government form a permanent advisory group, similar in composition to the working group, with responsibility for the oversight of implementation of the working group's recommendations, and with a mandate to regularly report to Government on the effectiveness of the implementation against the evaluation criteria set out above	Noted Proposal for continuing involvement of government departs from a self-regulatory approach. Further work will be required to identify an appropriate role, membership and	**Noted**, resourcing to be identified.

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		source of resourcing of such a group	
	PTP Rec 18 The Government review the National Medicines Policy (NMP) and consider replicating its policy coverage through the development of analogous policies for other therapeutic product sectors.	Not supported as currently proposed	The CHC supports the NMP Policy objectives of consumers access to, and quality use of medicines and maintaining a responsible and viable medicines industry.