Chapter 2

Key issues

2.1 This chapter focuses on key issues raised in relation to particular provisions of the TGA Bill. The committee did not receive evidence outlining concerns about the proposed changes in Schedules 4, 5, 8 and 9 of the TGA Bill, while very little evidence addressed the TGCA Bill, and so these are not discussed here.[1]

2.2 The concerns that submitters raised included:

- The nature and extent of consultation on the TGA Bill;
- The importance of public education and safety surrounding the proposed provisional approval pathway for promising new medicines;
- The development of the list of permitted indications and evidence required to support complementary and traditional medicines listed under a particular indication;
- Medicines that had passed the proposed new assessment pathway being able to indicate this in promotional material;
- The Therapeutic Good Administration (TGA) taking sole responsibility for the proposed new complaint system;
- Abandonment of the pre-approval system for advertisements; and
- Increased and harsher penalties for industry occurring in tandem with the abolishment of the pre-approval system that had ensured their compliance previously.

Consultation on the provisions of the TGA Bill

2.3 Several submitters stated their concern about the nature and extent of consultation that had been carried out on the TGA Bill prior to it being introduced into Parliament.[2]

2.4 PharmaCare Laboratories submitted that industry had been consulted on each phase of the reform 'separately and in stages, meaning that it is difficult for the industry to clearly understand the full impact of the regulatory reform in totality'. They contended that consultation had not yet occurred on some elements at the time the draft bills were provided for consultation, despite these being 'directly relevant' to

---

1 Dr Jon Wardle in *Submission 41*, p. 4, argued in relation to the TGCA Bill that: 'Cost-recovery initiatives in the regulation of health products and practices in Australia and other countries has generally resulted in regulators poorly serving the public interest…It is my opinion that it is in the public interest to move the TGA away from being reliant on cost-recovery, to being funded by governments based on the degree required to uphold its public duties'.

2 For example, Mr Allan Asher submitted that there had been 'almost no public debate' on the Bill with the community, writing that 'Multiple industry forums have been held but civil society views have not been encouraged'. *Submission 31*, p. 5.

the provisions of the TGA Bill.[3] They further asserted that stakeholders were given only two and a half business days to give feedback on the exposure draft of the two bills, despite the TGA Bill being 200 pages long and its explanatory memorandum being 152 pages. They argued that the period of time given for feedback was inconsistent with the Guidance Note on Best Practice Consultation released by the Department of Prime Minister and Cabinet's Office of Best Practice Regulation, which recommends a consultation period of between 30 to 60 days.[4]

2.5 However, other submitters were of the opinion that the TGA Bill was backed by 'a rigorous and inclusive review and consultation process'.[5] Medicines Australia emphasised that 'significant public consultation' had occurred on the issue of provisional registration since the MMDR Review:

> The TGA has conducted numerous consultations and workshops; with respect to the provisional approval reforms, these consultations have occurred over more than 12 months. We are confident that the TGA will continue to consult with relevant stakeholders, including Medicines Australia and its members, on implementation aspects of provisional approval, once the reforms are enacted by Parliament.[6]

2.6 The Department of Health (the department) noted that the MMDR Review involved a broad range of consultations with consumers, health professionals and industry stakeholders, and that the Australian Government had chosen to conduct further stakeholder consultation on some of the MMDR Review's recommendations before implementing them.[7] The department outlined in its submission that it had carried out a range of consultations on the government's response to the MMDR Review and on specific schedules of the TGA Bill.[8]

Schedule 1: Provisional approval pathway

2.7 Much of the evidence provided to this committee expressed support for the establishment of a provisional approval pathway for promising new medicines. For example, GlaxoSmithKline wrote that '[t]his important measure will ensure earlier

---

3 PharmaCare Laboratories Pty Ltd, *Submission 40*, pp. 5, 9. Examples they gave of elements that had not yet been subject to public consultation were Minimum Data Requirements and Evidence Guidelines that would be required under the proposed new assessment pathway in Schedule 3.

4 Office of Best Practice Regulation, Department of the Prime Minister and Cabinet, *Best Practice Consultation Guidance Note*, p. 6, https://www.pmc.gov.au/sites/default/files/publications/best-practice-consultation.pdf (accessed 19 January 2018); PharmaCare Laboratories Pty Ltd, *Submission 40*, p. 8.

5 NICM, *Submission 44*, p. 1; Medicines Australia, *Submission 42*, p. 1.

6 Medicines Australia, *Submission 42*, p. 3.

7 Department of Health, *Submission 46*, pp. 4, 5.

8 Department of Health, *Submission 46*, pp. 11, 12, 18, 19, 23, 26, 29.

access for patients to innovative medicines without compromising standards of quality, safety or efficacy'.[9]

2.8 However, the Royal Australasian College of Physicians expressed its concern about the provisional pathway and emphasised that 'maintaining patient and public safety in the use of therapeutic goods must be of paramount priority'.[10]

2.9 The Consumers Health Forum of Australia suggested that consumers might not understand the status of provisionally registered medicines. They proposed that there should be 'a well-constructed patient information/education package that explains what a provisional registration means so that consumers understand that the medicines have not been through the full TGA assessment process'.[11]

2.10 The department outlined the measures that it intended to take to ensure that there would be sufficient protections in place for patients, and patients would be aware that a medicine was provisionally approved:

> The Bill provides that provisionally registered medicines are, for the most part, to be treated the same as fully registered medicines under the Act. This is intended to enable all of the requirements and safeguards which currently apply to fully registered medicines to also apply to provisionally registered medicines. The main difference is that provisional registration is time-limited and there will be additional post-market monitoring processes. For example, the product information of all provisionally approved medicines will carry a prominent black triangle with accompanying wording, to alert health professionals and patients to the fact that the medicine is newly (and provisionally) approved and that any adverse events should be reported to TGA to allow for prompt assessment.[12]

2.11 The department also stated that the anticipated benefits of the medicine must outweigh its potential risks, and that the sponsor must report '[a]ny new information that changes the benefit-risk profile of the medicine' to the TGA. The Secretary, under the proposed amendments, would be able to vary the Register entry of provisionally registered medicines if new information called into question its quality, safety or efficacy. The department further explained that the provision would allow:

---

9 GlaxoSmithKline (GSK), *Submission 12*, p. 1. See also Research Australia, *Submission 3*, p. 1; Pharmaceutical Society of Australia, *Submission 7*, p. 2; Rare Voices Australia Ltd, *Submission 8*, p. 1; Centre for Research in Evidence Based Practice, *Submission 13*, p. 1; Novartis Pharmaceuticals Australia, *Submission 17*, p. 1; Consumers Health Forum of Australia, *Submission 19*, pp. 3, 5; Pfizer Australia, *Submission 20*, p. 1; Bristol-Myers Squibb Australia Pty Ltd, *Submission 27*, p. 1; Medicines Australia, *Submission 42*, p. 1; NICM, *Submission 44*, p. 1.

10 Royal Australasian College of Physicians, *Submission 10*, p. 1.

11 Consumers Health Forum of Australia, *Submission 19*, p. 5.

12 Department of Health, *Submission 46*, p. 7.

> …the Secretary to reduce the class of persons for whom the medicine is suitable, change the directions for use of the medicine, or add a warning or precaution in relation to the medicine.[13]

Schedule 2: List of permitted indications

2.12 Some submitters raised questions about the proposed list of permitted indications provided for under Schedule 2.

2.13 One line of argument against the list was that there had been a lack of consultation concerning Item 5 of Schedule 2, in which the Minister may specify, by legislative instrument, evidence requirements for medicines, and applicants would be required to certify that they held evidence meeting the requirements of the legislative instrument.[14] Vitaco Health (NZ) Limited argued that '[a] legislative instrument for evidence was not recommended by the MMDR Panel. There has not been consultation or a Regulatory Impact Assessment, therefore it should not be included'.[15]

2.14 Another submitter stated his concern that while the legislative instrument proposed in Item 5 would require the sponsor to hold evidence of claims for a product, the proposed changes did not 'specify that this evidence must be supplied to the TGA'.[16]

2.15 A number of submitters who had viewed the TGA's proposed permitted indication list contended that many of the permitted indications appeared to lack scientific evidence to back them.[17]

2.16 Several academics argued that '[t]he national pharmaceuticals and medical devices regulator should not be providing legitimacy to products that are inherently non-efficacious'.[18] The basis of their argument was that over the past three decades, successive studies and inquiries by regulatory bodies and parliamentary committees had been unable to 'substantiate claims by adherents of homeopathy that those products are therapeutically efficacious', including the department's review of private

13 Department of Health, *Submission 46*, p. 9.

14 TGA Bill Explanatory Memorandum, pp. 2–28.

15 Vitaco Health (NZ) Limited, *Submission 24*, pp. 1–2. See also Complementary Medicines Australia, *Submission 34*, p. 15.

16 Mr Chris Guest, *Submission 33*, p. 1.

17 Associate Professor Ken Harvey, *Submission 2*, p. 3.

18 Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 3.

health insurance for natural therapies, and a study by the National Health and Medical Research Council.[19]

2.17 The Royal Australian College of Physicians were of the opinion that the inclusion of indications on the list as medicines backed by tradition would encourage industry to avoid providing scientific proof of efficacy of its products, as well as endorse 'pseudoscience and…mislead and confuse consumers'.[20] The College suggested that even if a particular product (product X) has no benefit to health at all:

> the proposed Bills will allow the manufacturer to claim that X nourishes or rejuvenates, or assists weight reduction or jet lag. Manufacturers can simply state that X is a traditional product that has at some point been recommended by various alternative practitioners.
>
> This justification is so vague that it is hard to see any product failing to meet that low bar. It would be extraordinarily difficult to refute the statement that some tradition has recommended product X for whatever therapeutic benefit the manufacturer chooses to advertise.
>
> To base the regulation process merely on manufacturer claims about tradition entirely ignores the question 'Does it work'?[21]

2.18 Research Australia contended that '[t]here is a real risk that consumers will infer that, because a complementary medicine refers to an indication that is allowed by the TGA, the TGA is asserting the medicine is effective for this indication'.[22] They argued that the MMDR's expert panel had shared this concern and had proposed Recommendation Forty Four of the MMDR Review to address it, requiring a sponsor to include a disclaimer on all promotional materials 'to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use'.[23]

2.19 A number of submitters expressed concern that anti-complementary medicine activists had pushed to limit 'the number, strength and specificity of particular indications'.[24] These submitters and others called for sponsors not to be required to

---

19 Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, pp. 3–4. See also Australian Skeptics, *Submission 18*, p. 1. See Department of Health, *Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance*, 2015, p. 9. One submission, however, argued that the report from this review 'did not review any original research studies, excluded subject experts, appointed anti-CM [complementary medicine] activists…did not declare conflicts and did not conduct any targeted cost-benefit analysis'. Your Health Your Choice, *Submission 49*, p. 7.

20 Royal Australasian College of Physicians, *Submission 10*, p. 1.

21 Royal Australasian College of Physicians, *Submission 10*, p. 2.

22 Research Australia, *Submission 3*, p. 1.

23 Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation – Stage Two: Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods*, July 2015, p. xii.

24 Vitaco Health (NZ) Limited, *Submission 24*, p. 1.

draw from the permitted indications on the list but, rather, for the list to be retained as guidance.[25]

Disclaimer

2.20 Many submissions called for the committee to request that the TGA require all indications based on traditional evidence to include a disclaimer stating that the product had no scientific evidence of efficacy.[26] Some proposed drawing on the disclaimer required by the United States Federal Trade Commission accompanying over-the-counter homeopathic products, which states that these have not been substantiated by scientific evidence and are not accepted by most modern medical experts.[27]

2.21 However, the committee also received evidence arguing against the proposed disclaimer put forward in other submissions.[28] For example, the National Institute of Complementary Medicine stressed that in the majority of cases, scientific evidence has been used to prove the efficacy of traditional medicine, and argued that sponsors may choose 'to refer to traditional usage as a positive statement of safety and effectiveness precisely because of a product's long history of safe and repeated use'.[29]

2.22 Dr Jon Wardle, from the Australian Research Centre in Complementary and Integrative Medicine, emphasised that traditional medicine terminology is currently being standardised by the World Health Organisation (WHO) for inclusion in the *International Classification of Diseases*. He noted that Australia is an active partner in the International Standards Organization's Traditional Chinese Medicine Technical

---

25 Vitaco Health (NZ) Limited, *Submission 24*, p. 1; Complementary Medicines Australia, *Submission 34*, pp. 3, 9.

26 Associate Professor Ken Harvey, *Submission 2*, p. 4; Ms Wendy Logan, *Submission 4*, p. 2; Australian Skeptics Victoria Branch, *Submission 6*, p. 3; Royal Australasian College of Physicians, *Submission 10*, pp. 2–3; Centre for Research in Evidence Based Practice, *Submission 13*, p. 1; Gold Coast Skeptics, *Submission 15*, p. 2; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 4; Australian Skeptics, *Submission 18*, p. 3; Consumers Health Forum of Australia, *Submission 19*, pp. 5–6; Mr Michael Dong, *Submission 28*, p. 2; Miss Amy Mustac, *Submission 30*, p. 2; CHOICE, *Submission 38*, pp. 3–4; Mordi Skeptics, *Submission 52*, p. 3; Ms Beverley Snell, *Submission 53*, p. 3.

27 Associate Professor Ken Harvey, *Submission 2*, p. 4; Australian Skeptics Victoria Branch, *Submission 6*, p. 3; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 3; Mr Michael Dong, *Submission 28*, p. 2; CHOICE, *Submission 38*, pp. 3–4 ; Royal Australasian College of Physicians, *Submission 10*, pp. 2–3. United States of America Federal Trade Commission, *Enforcement policy statement on marketing claims for OTC homeopathic drugs*, November 2016, https://www.ftc.gov/system/files/documents/public_statements/996984/p114505_otc_homeopathic_drug_enforcement_policy_statement.pdf (accessed 17 January 2018).

28 BioMedica, *Submission 21*, p. 1; Complementary Medicines Australia, *Submission 34*, pp. 3, 20–21; Dr Jon Wardle, *Submission 41*, p. 2; ASMI, *Submission 43*, pp. 10–11; NICM, *Submission 44*, p. 2; Your Health Your Choice, *Submission* 49, pp. 6–7.

29 NICM, *Submission 44*, p. 2.

Committee. He argued that by including the type of disclaimer outlined above, Australia would not be in accordance with recent international developments that were moving towards recognising the value of traditional medicine:

> …[A]s part of its *Traditional Medicine Strategy*…the WHO has… recommended that all member states appropriately include traditional medicine terms in their regulatory, legislative and policy initiatives around traditional and complementary medicine products and practices.
>
> Beyond this formal work, legitimate traditional evidence claims (i.e. those that are verified as having come from a legitimate tradition of use and being compliant with that tradition of use) have also been held up in Australian and international law. These legal developments and the policy work by WHO would make a negative advisory statement or restriction of use of traditional medicine terms problematic, and most likely inconsistent with national and international law and new global regulatory norms and recommendations.[30]

2.23 Dr Wardle further argued that standardising traditional indications in regulatory and policy tools would provide the following benefits:

- Incorporating traditional indications offered regulatory guidance around how traditional claims could be used appropriately, and placed the burden of proof on sponsors to show that their traditional claims are based on legitimate and recognised traditional medicine systems;
- Traditional indications could be used as outcomes in research projects in a more effective and rigorous way, and their use would likely bridge the current evidence gap between traditional and conventional diagnoses;
- The use of traditional indications could lead to acknowledgement and legal action against people co-opting or misrepresenting indigenous intellectual property; and
- Regulating traditional indications would also provide consumers with assurances that the product they are buying is equivalent to the traditional medicine with a documented history of traditional and safe use.[31]

2.24 The Public Health Association of Australia submitted that while regulators need to find ways to incorporate traditional medicines in line with international developments, there needs to be further investigation into whether the claims made about these products do indeed align with traditional usage:

> International developments, such as the development of a traditional medicine chapter in the update of the International Classification of Diseases, necessitate that regulators begin to identify ways in which to ensure claims based on traditional knowledge do in fact have a legitimate basis to make those claims. However, some of the claims in the proposed list would be unlikely to be supported by established texts in those

30 Dr Jon Wardle, *Submission 41*, p. 2.

31 Dr Jon Wardle, *Submission 41*, pp. 3, 4.

> traditions...In some cases the product making traditional claims may not reflect the product that was traditionally used...The PHAA [Public Health Association of Australia] suggests that traditional indications should be reviewed to ensure that they do align with the traditions from which they are purported to come, so that the use of traditional indications is not used as a pathway to entrench inappropriate claims.[32]

2.25 In its submission, the department stated that it intended to require a statement regarding traditional use:

> The Government supported the intent of [Recommendation Forty-Four of the MMDR Review], and it is proposed that a label statement regarding traditional use will be required. However it will not require sponsors to place a disclaimer on product labels that the products have been independently assessed.

2.26 The reasons the department gave for not mandating a disclaimer on traditional medicines were:

- The additional regulatory burden that this requirement would impose;
- The experience in the US indicating that these disclaimers are ineffective in influencing consumers' beliefs about the efficacy or safety of these products;
- A number of independent studies published in major consumer research and health policy journals that also concluded that such disclaimers are ineffective; and
- Face-to-face meetings between senior TGA and US Food and Drug Administration (FDA) officials that confirmed this view, based on additional in-house FDA research that the US disclaimer had little or no effect.[33]

2.27 The department committed to the TGA conducting further consultation on how consumers could be better educated about the list, including the difference between listed complementary and registered medicines.[34]

Support for the list of permitted indications

2.28 A number of submissions were supportive of the proposed list of permitted indications, albeit with conditions.

2.29 The Public Health Association of Australia stated that 'in principle' it supported the changes, but had concerns about the extent of the list, and proposed that it 'be tightened significantly and focused on modest indications (e.g. “may be helpful...”, “may assist…”, etc.)'.[35]

---

32 Public Health Association of Australia, *Submission 22*, pp. 6–7.

33 Department of Health, *Submission 46*, p. 12.

34 Department of Health, *Submission 46*, p. 12.

35 Public Health Association of Australia, *Submission 22*, p. 6.

2.30 The Australian Self-Medication Industry expressed support for the list, though requested that:

- The list not include claims, only indications;
- The list be clearly worded, comprehensive and appropriate;
- Processes for amending the list be reasonable and subject to review; and
- Products matched to particular indications not be considered in terms of their efficacy, but rather their suitability.[36]

2.31 The joint submission from the National Boards and the Australian Health Practitioner Regulation Agency was unreserved in its support for the list, suggesting that the current system would 'be greatly strengthened by the removal of the free text field for indications and replaced by a more controlled approach to permitted indications'.[37]

2.32 The department argued that the TGA Bill would 'provide transparency on what indications are suitable for listed medicines to help prevent non-compliance', as well as 'greater protection for consumers from misleading and inappropriate claims'. By introducing a permitted indications list and removing the option of a free-text field for sponsors, it suggested, the TGA would be able to better identify trends in non-compliance.[38]

2.33 It further contended that the proposed list 'provides an additional layer of control to limit listed medicines…provided appropriate evidence is held by the medicine sponsor', including evidence of traditional use.[39] Sponsors would no longer be able to use the term 'may' in their labels (such as 'may relieve symptoms of…'), because:

> it can imply that the sponsor does not have evidence of sufficient quality to demonstrate that their medicine is effective. This is not consistent with the legal requirement for sponsors to hold evidence for the indications they make for their medicine.[40]

2.34 In relation to the number and content of the permitted indications, the department emphasised the level of consultation the TGA had undertaken in the development of the list:

> The TGA has…undertaken significant consultation to develop the final proposed list of permitted indications and is satisfied that it is commensurate with the low risk nature of listed products and appropriately balances consumer and industry concerns. People will be able to apply to the Secretary for a recommendation that the Minister add another permitted

36 ASMI, *Submission 43*, p. 9.

37 National Boards and AHPRA, *Submission 47*, p. 2.

38 Department of Health, *Submission 46*, p. 13.

39 Department of Health, *Submission 46*, pp. 10–11.

40 Department of Health, *Submission 46*, p. 12.

> indication to the list. The legislative instrument specifying the list of permitted indications will be required to be tabled in Parliament and be subject to disallowance.[41]

2.35 The department clarified that it would introduce 'greater clarity about the evidence base for listed complementary medicines' by requiring listed medicine products to identify their evidence base in the Register and on the medicine's label. This could include statements such as 'traditionally used in Chinese medicine'. A new mandatory requirement would be introduced for these products to include an advisory statement on their label, recommending that the consumer seek the advice of a practitioner before using the medicine.[42]

2.36 The department advised that it intended to make labelling requirements stricter. It further stated that under the proposed amendments, the TGA would have the power 'to immediately cancel a medicine from the Register', particularly if the product's advertising and label suggested that the product could 'be used to treat a serious form of a disease, condition or ailment'.[43]

Schedule 3: New assessment pathway

2.37 The committee received evidence outlining some concern about the proposed new assessment pathway, based on an assessment of the medicine's claims and indications. The Australian Self-Medication Industry's main source of concern was that successful sponsors would be able to indicate in advertising that they had passed this assessment:

> A claimer is likely to be taken as TGA endorsement for a product (which would be in breach of the current Advertising Code). This TGA endorsement will likely be interpreted by consumers as applying to the product, its labelling and all the product advertising. Any advertising to consumers, no matter how misleading, will therefore be likely to be taken to be accurate since the product has the TGA's endorsement…
>
> For products that use the same label in other markets (e.g. New Zealand) the claimer on the label may not be acceptable in the other market. A significant proportion of ASMI members' products are packaged in harmonised Australian/New Zealand labelling (with individual member portfolios ranging from about 50% harmonised to as high as 95% harmonised).[44]

2.38 However, other submitters welcomed the proposed new pathway. The National Boards and the Australian Health Practitioner Regulation Agency suggested the new approach would provide an incentive for industry to move towards

---

41 Department of Health, *Submission 46*, p. 11.

42 Department of Health, *Submission 46*, p. 13. However, some evidence to this inquiry found this proposed requirement 'deeply unsatisfactory' for a number of reasons. See CHOICE, *Submission 38*, p. 4.

43 Department of Health, *Submission 46*, pp. 12–13.

44 ASMI, *Submission 43*, p. 10.

independent assessment of product efficacy.[45] Vitaco Health (NZ) Limited echoed this assertion, writing that '[t]he new "listed assessed" pathway will provide our business with the opportunity to research, innovate and expand the range of therapeutic use'.[46]

2.39 Complementary Medicines Australia anticipated that the new pathway and the ability of sponsors to indicate that their product had passed the assessment would lead to further investment into research by industry into complementary medicines:

> If implemented successfully, this represents a ground-breaking and unique opportunity for complementary medicine products to gain recognition for undergoing rigorous scientific assessment. By incentivising expansion of the clinical research base for non-patentable naturally occurring substances, it will encourage increased investment by industry into Australian research bodies. Consumers, both locally and globally, would be able to access complementary medicines for an increasing range of health benefits.[47]

2.40 The department in its submission outlined a number of anticipated advantages to the proposed new assessment pathway, such as:

- Access for consumers to a broader range of evidence-based products to self-manage their health;
- Increased evidence for the effectiveness of products, which would build confidence in the sector amongst consumers and health professionals; and
- The provision of a regulatory framework and market advantage for sponsors.[48]

2.41 The department also noted that careful consideration and consultation with stakeholders would be required before deciding on the design and use of promotional statements.[49]

Schedule 6: Changes to advertising of therapeutic goods

2.42 Many submissions to this inquiry raised concerns about the proposed new advertising framework put forward in Schedule 6 of the TGA Bill. The issues that submitters discussed fell broadly into three categories:

- The TGA taking sole responsibility for the complaint system;
- Abandonment of the pre-approval system of advertisements; and
- No mention of a self-regulatory regime.

---

45 National Boards and AHPRA, *Submission 47*, p. 2.

46 Vitaco Health (NZ) Limited, *Submission 24*, p. 1. See also Consumers Health Forum of Australia, *Submission 19*,

47 Complementary Medicines Australia, *Submission 34*, p. 7.

48 Department of Health, *Submission 46*, p. 15.

49 Department of Health, *Submission 46*, p. 15.

TGA given sole responsibility for complaints

2.43 A number of submitters stated that they were concerned about the TGA being given sole responsibility for resolving complaints about advertising. Professor Jon Jureidini stated that the source of his concern was the TGA's 'unenviable reputation of not providing an outcome on hundreds of complaints sent to them'.[50]

2.44 Associate Professor Ken Harvey and Professor John Braithwaite stated that 'there are concerns about the current operation of the TGA which must be addressed. The most important is a lack of transparency in dealing with complaints'.[51]

2.45 Submitters further highlighted that they were worried that the shift to the TGA would lead to a loss of stakeholder involvement.[52] Associate Professor Bruce Baer Arnold and Associate Professor Wendy Bonython argued that the TGA was viewed poorly outside industry because of its reluctance to engage with stakeholders:

> The TGA has been reluctant to meaningfully engage with stakeholders outside industry, fostering perceptions that it has experienced regulatory capture (ie incorrectly considers that the interests of the businesses that it regulates are the same as the interests of the organisation and of the community at large). It is regarded with disquiet by health practitioners, academics and others over its failure to anticipate and/or prevent harms.[53]

2.46 To overcome this perception, several submitters requested that the TGA explain publicly how it intended to involve stakeholders in the new advertising system.[54]

2.47 In its submission, the department outlined that the new system would involve improved stakeholder input, and suggested that the costs involved in running the current system would be used to enhance compliance and undertake enforcement in the new system:

> At present, as Prof Jureidini describes in his submission to the Committee, transparency around the handling of certain advertising complaints can be significantly constrained… The changes in the Bill will correct this as the routine publication of notices and directions has been incorporated into transparency provisions built into the Bill.
>
> Improved consultation mechanisms will enhance stakeholder input on the new system. While stakeholder involvement is currently provided by the Complaints Resolution Panel (CRP) and the Therapeutic Goods Advertising

---

50 Professor Jon Jureidini, *Submission 1*, p. 1.

51 Associate Professor Ken Harvey, *Submission 2*, p. 2.

52 Associate Professor Ken Harvey, *Submission 2*, p. 3; Ms Wendy Logan, *Submission 4*, p. 2; NewsMediaWorks, *Submission 26*, p. 3.

53 Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 1.

54 Public Health Association of Australia, *Submission 22*, p. 6; Centre for Research in Evidence Based Practice, *Submission 13*, p. 1; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 3.

> Code Council (TGACC), which are to be abolished, these committees have a number of deficiencies and cost about $ 600,000 per annum to support – which could alternatively be directed towards increased compliance and enforcement activities.[55]

2.48 A group of submitters proposed that one way to overcome perceptions of a lack of transparency on the part of the TGA would be to require the Secretary to take action (instead of allowing the Secretary the option) in instances where there had been advertising contraventions.[56]

2.49 The department argued that changing this language 'would significantly limit [the] TGA's ability to take proportional and appropriate responses to regulatory non-compliance'. It further contended that flexibility in the wording of the legislation was necessary, because in some instances, 'it may be more appropriate to take other action…including education and guidance…'[57]

2.50 Regarding the issue of transparency of complaint handling within the TGA, the department stated that:

> New section 42DY empowers the Secretary to issue written public warning notices about therapeutic goods if the Secretary…is satisfied that it is in the public interest to issue the notice. These provisions will give the Secretary or her delegate the authority to publish and will also require publication of complaint outcomes as soon as practicable where a breach has been substantiated and where the person responsible for the advertisement is required to take some action...
>
> As well as routine publication of notices and directions, other complaint outcomes will be published, including where compliance has been achieved following TGA's interaction with the advertiser.
>
> Key performance indicators for the new system will be published on a quarterly basis.[58]

2.51 The Pharmacy Guild of Australia suggested 'there are significant challenges' inherent in establishing the TGA as an effective single point for handing and resolving advertising complaints, and recommended that 'the TGA must be given adequate financial and workforce resources to investigate and respond to complaints in a timely manner'.[59]

---

55 Department of Health, *Submission 46*, pp. 21–22.

56 See TGA Bill, Division 6, 42DKB(1) and 42DV (1) and (2). Professor Jon Jureidini, *Submission 1*, p. 2; Associate Professor Ken Harvey, *Submission 2*, p. 3; Ms Wendy Logan, *Submission 4*, p. 2; Centre for Research in Evidence Based Practice, *Submission 13*, p. 1; Gold Coast Skeptics, *Submission 15*, pp. 1–2; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 3; Mordi Skeptics, *Submission 52*, p. 1.

57 Department of Health, *Submission 46*, p. 21.

58 Department of Health, *Submission 46*, p. 22.

59 The Pharmacy Guild of Australia, *Submission 45*, pp. 3–4. See also Public Health Association of Australia, *Submission 22*, p. 5; Consumers Health Forum, *Submission 19*, p. 6.

2.52 Some submitters argued that the current system of resolving advertising complaints should not be abolished at all.[60] Others emphasised the difficulties presented by the current system.[61] The Medical Technology Association of Australia stated that they welcomed 'the implementation of a more transparent and efficient complaints management process with [the] TGA as the sole point of contact and decision-making authority'.[62] Complementary Medicines Australia was of the opinion that the proposed amendments would lead to 'an excessively cumbersome advertising system' being replaced 'with a streamlined and centralised mechanism that includes tougher sanctions, but reduces red-tape and improves fairness of complaint-handling'.[63]

Abandonment of the pre-approval system for advertisements

2.53 A number of submitters outlined concerns about the abandonment of the TGA's current system of pre-approval of advertisements to move towards a post-market monitoring scheme.[64] These concerns were spread across a range of submissions, from consumer and advocacy groups to industry.

2.54 Mr Allan Asher contended that it was predominantly industry and consumer interest groups that were in favour of removing the current system of pre-approvals which take, on average, seven days to be approved.[65] Similarly, the Public Health Association of Australia argued that the current system of pre-approvals was working, and support for the shift came predominantly from industry and the media.[66]

2.55 CHOICE, among other submitters, stressed that the pre-approval process provided important protections for consumers, and emphasised that most

60 See, for example, Mr Allan Asher, *Submission 31*, pp. 2–3.

61 Complementary Medicines Australia, *Submission 34*, p. 18.

62 Medical Technology Association of Australia (MTAA), *Submission 25*, p. 5. See also Vitaco Health (NZ) Limited, *Submission 24*, p. 1.

63 Complementary Medicines Australia, *Submission 34*, p. 3. See also National Boards and AHPRA, *Submission 47*, p. 2.

64 Associate Professor Ken Harvey, *Submission 2*, p. 2; Research Australia, *Submission 3*, p. 2; Ms Wendy Logan, *Submission 4*, p. 1; Australian Skeptics Victoria Branch, *Submission 6*, p. 1; Centre for Research in Evidence Based Practice, *Submission 13*, p. 1; Gold Coast Skeptics, *Submission 15*, p. 1; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 2; Consumers Health Forum, *Submission 19*, pp. 6–7; Public Health Association of Australia, *Submission 22*, p. 5; NewsMediaWorks, *Submission 26*, pp. 2–3; Mr Robin Brown, *Submission 29*, p. 3; Mr Allan Asher, *Submission 31*, p. 2; Mr Chris Guest, *Submission 33*, p. 1; Ms Amy Vaux, *Submission 35*, p. 3; CHOICE, *Submission 38*, pp. 5–6; PharmaCare Laboratories Pty Ltd, *Submission 40*, pp. 5, 7; ASMI, *Submission 43*, p. 2; The Pharmacy Guild of Australia, *Submission 45*, p. 2; Mordi Skeptics, *Submission 52*, p. 3.

65 Mr Allan Asher, *Submission 31*, p. 5.

66 Public Health Association of Australia, *Submission 22*, p. 5.

advertisements in the current system were determined to be in breach of the Therapeutic Goods Advertising Code.[67]

2.56 The Pharmacy Guild of Australia suggested that the enhanced sanctions and penalties and post-market monitoring proposed in the TGA Bill to offset the risks of a post-market monitoring scheme would not be:

> sufficient protection for consumers compared to the current process. Advertising campaigns generally only run for a relatively short period of time and misleading health messages can have a lasting impact on consumer beliefs and behaviour. Investigations to determine whether an advertising breach has taken place often take several months, by which time many advertisements will have finished. It is far better if consumers are not misled in the first place rather than trying to mitigate the effects of an irresponsible advertisement after it has reached the public domain.[68]

2.57 Research Australia was of the opinion that the success of the proposed system 'remains to be seen' and would 'depend on how quickly and effectively the TGA responds to complaints about advertising'. It questioned whether the TGA would be adequately resourced to implement the complaints process.[69]

2.58 NewsMediaWorks, a peak organisation representing Australia's major news media publishers[70], argued that:

> Unless there is ongoing and consistent market review, a framework for complaints handling and sanctions in place prior to the dismantling of the pre-approval system there is significant potential for increases in the number of advertisements which breach the Code resulting in consumer detriment.[71]

2.59 However, several submitters welcomed the proposed shift to post-market surveillance. For example, the Pharmaceutical Society of Australia argued that abolishment of the vetting and pre-approval of therapeutic goods 'was felt to be a logical option given the [MMDR] Review outlined that complexities and inconsistencies existed in the pre-approval arrangements'.[72]

2.60 Similarly, Accord Australasia emphasised that the provisions in the TGA Bill for harsher penalties would offset any negative impacts on consumers brought about by abolishing the pre-approval system:

---

67 CHOICE, *Submission 38*, p. 5. See also the Pharmacy Guild of Australia, *Submission 45*, p. 3; ASMI, *Submission 43*, p. 5.

68 The Pharmacy Guild of Australia, *Submission 45*, p. 3.

69 Research Australia, *Submission 3*, p. 2.

70 NewsMediaWorks, *About us*, http://newsmediaworks.com.au/about-us/ (accessed 18 January 2018).

71 NewsMediaWorks, *Submission 26*, p. 3. See also Free TV Australia, *Submission 51*, p. 3.

72 Pharmaceutical Society of Australia, *Submission 7*, p. 2. See also Vitaco Health (NZ) Limited, *Submission 24*, p. 1.

> Accord does not hold the same reservations as other submitters have expressed, in that we do not believe that the removal of pre-approval for certain therapeutic goods advertisements will necessarily result in consumer detriment. It is important to note that the Bill introduces a number of additional changes which will strengthen rather than diminish consumer protection and enhance consumer access to information.[73]

2.61 A number of submissions called for a transition period to adapt to the proposed post-market surveillance system, for varying reasons. Some asked for a transition period until a government-proposed formal three-year review of the reform package has been completed[74]; while several industry bodies asked for a transition period that would allow industry to adjust to the absence of a pre-approval system, particularly in light of the proposed stricter penalties and the number of breaches noted to have occurred via the vetting system.[75]

Departmental response

2.62 The department in its submission outlined the measures that it had undertaken to date to ensure that post-market surveillance would be effective:

> Changes to enable more comprehensive post-market monitoring of therapeutic goods have…been introduced. These include implementation of new and enhanced analytics capabilities and a new adverse events reporting system; the launch of the Pharmacovigilance Inspection Program in September 2017; and work with sponsors to reformat Product Information documents to ensure important prescribing information is easily accessible. Further reviews into the medicines scheduling process and the appropriate regulation of low-risk therapeutic goods have been carried out.[76]

2.63 It also clarified that it would implement measures to ensure that the shift to the new system would be smooth, including by providing detailed guidance for advertisers to understand the new penalties regime:

> [T]he introduction of a broader range of sanctions and penalties would commence on the day after the Bill receives Royal Assent, and an industry education program will commence in the second quarter of 2018 to ensure that these measures are in place before the pre-approval system is removed. Subject to the passage of the Bill there will also be detailed guidance material available on the TGA website to assist advertisers with their understanding of the new advertising sanctions and penalties regime.[77]

---

73 Accord Australia, *Submission 5*, p. 2.

74 Associate Professor Ken Harvey, *Submission 2*, p. 2; Centre for Research in Evidence Based Practice, *Submission 13*, p. 1; Gold Coast Skeptics, *Submission 15*, p. 1; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 2; Consumers Health Forum, *Submission 19*, p. 6; Public Health Association of Australia, *Submission 22*, p. 5; CHOICE, *Submission 38*, p. 1.

75 ASMI, *Submission 43*, p. 2; NewsMediaWorks, *Submission 26*, p. 3.

76 Department of Health, *Submission 46*, p. 6.

77 Department of Health, *Submission 46*, p. 20.

2.64 In response to concerns that the TGA would not react quickly enough to non-compliant advertisements, the department emphasised that the new regulatory system proposed under the TGA Bill would 'allow the TGA to take speedy enforcement action in response to serious non-compliant advertising, such as seeking a Court injunction to prevent an advertisement being aired'.[78]

2.65 The department acknowledged that under the current system, most pre-approved advertisements are found to need changes so that they are compliant. However, it contended that the system encourages advertisers to use 'the mandatory pre-approval system as a form of editing consultancy for the content of their advertisements', and so is not an accurate representation of how many advertisements would not be compliant under the new, stricter system requiring industry to ensure its own compliance.[79]

2.66 The department acknowledged that although most stakeholders from the MMDR Review agreed that the current advertising system was ineffective, there were divergent views about what a new system should look like. It outlined that it would implement a review of the proposed complaint handling system after three years:

> Following a public consultation process, the Government has decided that the TGA will assume responsibility for handling all complaints about therapeutic goods advertisements directed to the public from 1 July 2018, and that this model will be independently reviewed after three years of operation to determine whether it is the most effective solution.[80]

2.67 In relation to the call for a transition period, the department argued that delaying the removal of the pre-approval system until the three year review would be problematic for several reasons:

- It would require amendments to the Bill and its reconsideration in the House, thereby delaying other important measures in the Bill;
- Delaying the removal of the current pre-approval system would be unlikely to provide useful data on which to judge the new advertising system, because the new advertising system would not be in place during that period;
- There would also be greater costs as elements of both the new and former advertising regulatory systems would be in place, with the cost of the current pre-approvals system being about $1.4–1.5m annually; and
- Delaying the abolition of pre-approval would severely limit the actions that the TGA could take against advertisements found to be non-compliant.[81]

78 Department of Health, *Submission 46*, p. 24.

79 Department of Health, *Submission 46*, p. 20.

80 Department of Health, *Submission 46*, pp. 18–19.

81 Department of Health, *Submission 46*, p. 20.

No mention of a self-regulatory regime

2.68 The Australian Self-Medication Industry (ASMI) drew attention to the fact that while the proposed amendments in Schedule 6 addressed the first part of Recommendation Fifty Five of the MMDR Review, the Bill 'provides no incentive or guidance' on the second part of the recommendation, regarding a self-regulatory regime.[82]

2.69 ASMI further argued that the removal of the pre-approval system for 'product sponsors to have marketing claims pre-approved for compliance' would cause problems for industry because of the introduction of 'much harsher criminal and civil penalties'.[83] They outlined that because of this situation, they intend to offer from 1 July 2018 a 'voluntary, self-regulatory, advisory service' for industry to 'reduce the likelihood of breaches and the potentially (new) severe penalties and sanctions'. The intended effect of this service would be a reduction in the level of non-compliance, thereby 'reducing the resource impact on the TGA', and would mean that 'those advertisements not subject to self-regulation will be easily identifiable by the TGA'.[84]

2.70 ASMI proposed that a due diligence provision be included in the TGA Bill to:

> specifically identify an advertiser's use of a self-regulatory service as a factor to be considered when assessing whether that person took reasonable steps to ensure compliance and when assessing what penalty (if any) should be applied.[85]

Schedules 6 and 7: Penalties and sanctions

2.71 Some concerns were raised in evidence regarding the proposed amendments in Schedules 6 and 7 that would broaden and strengthen penalties and sanctions for misleading and inappropriate advertisements.

2.72 PharmaCare Laboratories argued that '[i]n the interest of avoiding bias and to facilitate fair and even-handed treatment of sponsors, no one body should monitor, regulate and adjudicate on any one issue'.[86] They were also concerned about a lack of clarity about the circumstances in which an infringement could be issued.[87]

2.73 While the Pharmacy Guild of Australia expressed their support for expanded enforcement powers and increased sanctions and penalties, they contended that 'the

---

82 ASMI, *Submission 43*, p. 4. See also Lloyd Sansom, Will Delaat and John Horvath, *Review of Medicines and Medical Devices Regulation – Stage Two: Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods*, July 2015, p. xv.

83 ASMI, *Submission 43*, p. 5.

84 ASMI, *Submission 43*, pp. 7–8.

85 ASMI, *Submission 43*, p. 6.

86 PharmaCare Laboratories Pty Ltd, *Submission 40*, p. 7.

87 PharmaCare Laboratories Pty Ltd, *Submission 40*, p. 11.

funding and resources currently dedicated to post-market monitoring in this context are inadequate'.[88]

2.74 Free TV Australia was concerned that under Schedule 6, broadcasters could be held liable for the content of advertisements that are non-compliant.[89] They also proposed that news and public interest or entertainment programs should not be considered to be 'advertising', submitting that:

> Excluding these programs from the scope of the legislation is critical to ensuring broadcasters can fulfil the important role they play in disseminating public health information, promoting the free flow of information to the public on matters of public interest and to ensure freedom of speech isn't impeded.
>
> The *Therapeutic Goods Advertising Code* already recognises this and excludes these from the definition of 'advertisement' in the Code. The Draft Bill should be consistent with this.[90]

2.75 Other submitters supported the proposed increases to penalties and sanctions.[91] The Australian Dental Industry Association emphasised that the current regulatory framework has deficiencies in how compliance can be enforced, and was of the opinion that:

> these reforms will act to enhance confidence in the Australian market for medical devices, something achieved as a result of the TGA's ability to more effectively enforce the illegal supply provisions within the legislation.[92]

2.76 Complementary Medicines Australia, while recognising that '[t]he vast majority of industry' tries to comply with the advertising regulations, welcomed the increased penalties and sanctions, submitting that in conjunction with post-market monitoring, it would 'set the stage for an effective deterrent regime'.[93]

2.77 The department emphasised in its submission that the proposed amendments in Schedule 6 of the TGA Bill would 'be accompanied by an education program to assist advertisers [to] understand and comply with the new advertising requirements'.[94] It also highlighted that the new provisions would allow routine publication of directions and notices of complaints.[95]

---

88 The Pharmacy Guild of Australia, *Submission 45*, p. 2.

89 Free TV Australia, *Submission 51*, p. 2.

90 Free TV Australia, *Submission 51*, p. 2.

91 Research Australia, *Submission 3*, p. 3; National Boards and AHPRA, *Submission 47*, p. 2.

92 Australian Dental Industry Association, *Submission 9*, p. 5.

93 Complementary Medicines Australia, *Submission 34*, p. 18.

94 Department of Health, *Submission 46*, p. 24.

95 Department of Health, *Submission 46*, pp. 21–22.

Other issues raised

2.78 Several other issues were raised regarding the provisions in the TGA Bill:

- That, because of the structure of the current regulatory framework, some sponsors are able to reformulate their products as food to avoid the requirements of the Therapeutic Goods Advertising Code[96];
- That the proposal for industry education about the changes introduced by the bill does not include a proposal for consumer education[97]; and
- That the TGA Bill does not explicitly address the issue of economic harm to consumers caused by misleading advertisements.[98]

Committee view

2.79 This inquiry received a broad range of submissions with strong arguments both in favour and against some of the provisions of the TGA Bill, reflecting the strength of stakeholder engagement in the regulation of therapeutic goods and the diversity of opinions on issues related to complementary and traditional medicines.

2.80 The committee acknowledges the significant amount of consultation involved in the years leading up to the introduction of this bill, including through the MMDR Review, as well as the time and detailed work undertaken to ensure that the proposed reforms are appropriate. The committee is of the opinion that the bill introduces a number of essential reforms to the regulatory framework for complementary and traditional measures that are in the public interest.

2.81 Given the urgency of the passage of a number of provisions of the bill to public health, particularly provisional approval for potentially life-saving medicines, and the benefits that the TGA Bill will provide consumers with regard to advertising compliance and enforcement, it is imperative that both bills are passed. Further, given the varying evidence provided to the committee on the provisions of the TGA Bill, the committee considers that no matter the changes proposed, there would be stakeholders who propose a different path to reform. The bill in its current form provides the best way forward to monitor advertising, improve compliance, provide members of the

---

96 Associate Professor Ken Harvey, *Submission 2*, p. 5; Centre for Research in Evidence Based Practice, *Submission 13*, p. 2; Gold Coast Skeptics, *Submission 15*, p. 2; Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, *Submission 16*, p. 4; Public Health Association of Australia, *Submission 22*, pp. 4–5; Ms Amy Vaux, *Submission 35*, p. 1; The Royal Australian College of General Practitioners, *Submission 39*, p. 3. The Department of Health in its submission responded to this concern, writing that: 'it is beyond the scope of advertising provisions of the Therapeutic Goods Act (even if they were extensively amended) and potentially beyond the Commonwealth's constitutional powers for the TGA to be able to manage complaints related to foods that make health claims' (*Submission 46*, p. 24).

97 Mr Allan Asher, *Submission 31*, p. 3. However, the Department of Health stated its commitment to introducing educational programs for consumers once the final legislation introducing changes to the system is passed. Department of Health, *Submission 46*, p. 12.

98 Mr Robin Brown, *Submission 29*, pp. 1–2; ACCESS 2: Foundation for Effective Markets and Governance, *Submission 32*, p. 8.

public with potentially life-saving medicines earlier than would otherwise be the case, and encourage the complementary and traditional medicines industry to provide an evidence base for their products.

2.82 However, the committee is of the opinion that a number of issues raised to this inquiry need to be addressed. Some evidence contained concerns that several provisions of the bill involved only limited stakeholder consultations, sometimes with only limited time given for feedback. Given the importance of continuing stakeholder engagement to the therapeutic goods regulatory framework, the committee suggests that the government ensure that the Therapeutic Goods Administration carries out comprehensive, appropriate and timely consultations with industry and other stakeholders.

Recommendation 1

2.83 The committee recommends that the government ensure that the Therapeutic Goods Administration continues to carry out comprehensive, appropriate and timely consultations with industry and other key stakeholders, particularly in relation to legislation and regulations affecting the Therapeutic Goods Administration regulatory framework.

2.84 The committee supports the proposed stronger and expanded penalties for advertisements deemed to be non-compliant. The committee welcomes the Department of Health's assurances that it will commit the TGA to increased transparency by providing outcomes of decisions and information for industry regarding the new penalties regime. The committee notes concerns held by industry that with the removal of the pre-approval process for advertisements, it would be subject to stronger penalties and may struggle to adjust to a new regime that does not identify problematic advertisements before they are published. The committee is aware that some members of industry would be willing to implement their own self-regulatory model to ensure that their advertisements are compliant with the relevant advertising regulations. This approach has merit. The committee recommends that the TGA investigate ways to further encourage industry to take this step.

Recommendation 2

2.85 The committee notes the importance of self-regulatory models and recommends that the Therapeutic Goods Administration investigate ways to better support the effective functioning of self-regulatory models by industry, including the potential for further strengthening of the penalties regime if needed.

2.86 Although many submitters to the inquiry were strongly in favour of the enhanced compliance and enforcement provisions contained in the bill, they also expressed concern that the Therapeutic Goods Administration would not be adequately resourced to conduct a strong and comprehensive post-market surveillance regime to ensure that advertisements comply with advertising regulations. The committee urges the government to ensure that the Therapeutic Goods Administration has sufficient resources and funds to carry out its new functions.

Recommendation 3

2.87 The committee recommends that the government ensure that the Therapeutic Goods Administration is adequately resourced in accordance with its cost-recovery framework so that it is able to carry out its surveillance and monitoring functions in relation to advertising compliance.

2.88 The committee supports the proposed list of permitted indications and is of the view that this list will lead to increased compliance and protections for consumers. We note that evidence to this inquiry questioned whether this list would go far enough in ensuring that medicines listed under traditional indications do align with the traditions from which sponsors claim they originate. The committee suggests that in the future, the Therapeutic Goods Administration investigate ways in which to monitor compliance in this area.

2.89 Finally, the committee welcomes the government's commitment to conduct a three-year review of the bill's provisions, and considers, on balance and in light of the broad range of evidence and opinions provided to this inquiry, that this review will be the best method to consider whether the proposed reforms to the therapeutic goods regulatory framework have had a positive impact and are working. The committee was not persuaded that essential reforms should be delayed until this review has taken place, as the purpose of the review is to examine the effectiveness of the reforms.

Recommendation 4

2.90 The committee recommends that the Senate pass the bills.

Senator Slade Brockman

Chair