2

Agreement with New Zealand concerning the establishment of a Joint Scheme for the Regulation of Therapeutic Products

2.1 The proposed *Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the regulation of Therapeutic Products* (the Agreement) aims to safeguard public health and safety. It will achieve this through the establishment and maintenance of a joint regulatory scheme (the joint Scheme) between Australia and New Zealand for the regulation of the quality, safety and performance of therapeutic products, and the manufacture, supply, import, export and promotion of therapeutic goods.[1] The joint Scheme will be administered by a single regulatory Agency.[2]

Background

2.2 The Agreement gives effect to the intention of the Trans Tasman Mutual Recognition Arrangement (TTMRA), namely, that Australia and New Zealand cooperate to resolve the special exemption for therapeutic products under the TTMRA.[3] According to Mr Terry Slater of the Department of Health and Ageing (the Department):

> The agreement addresses Australia's obligation under the TTMRA to work with New Zealand to develop a more

1 Regulatory Impact Statement (RIS), p. 24.
2 National Interest Analysis (NIA), para. 4.
3 NIA, para. 5.

> integrated trans-Tasman economy by removing regulatory impediments between the two countries, to enable goods to be traded freely between them. The agreement provides a framework for the joint regulatory scheme and also sets out the governance and accountability arrangements for the new regulatory agency.[4]

2.3 The National Interest Analysis (NIA) states that the Agreement is in the national interest because it will:

> Continue the development of a more integrated trans-Tasman economy, an aim of the Australia New Zealand Closer Economic Relations Trade Agreement [ANZCERTA], whilst delivering public health benefits for Australia by providing Australia with an enhanced and sustainable regulatory capacity for therapeutic products.[5]

2.4 The Committee understands that the objectives of the Agreement are to:

- resolve the TTMRA special exemption for therapeutic products regulated under the Joint Scheme;
- meet the overall objectives of the ANZCERTA by facilitating trans-Tasman trade;
- ensure sustained capacity for the regulation of such products in Australia in the present and in the future;
- reduce industry compliance costs by increasing regulatory cost efficiency;
- benefit consumers by increasing the timely availability of therapeutic products potentially at a reduced cost; and
- provide Australia, together with New Zealand, with greater capacity to influence international regulatory policy and standards.[6]

2.5 Therapeutic products include medical devices, prescription medicines, over-the-counter medicines and complementary medicines.[7]

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4 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 2.

5 NIA, para. 5.

6 RIS, p. 25.

7 RIS, p. 24.

Benefits of the Agreement

2.6 The NIA outlines the economic and consumer benefits that will flow to Australia and New Zealand as a result of the Agreement.

2.7 Harmonisation under the Agreement is expected to reduce costs for firms wishing to export to the other country through the reduction or elimination of differences in regulatory standards.[8] Further, the Agreement will eventually lead to consideration of Australia and New Zealand as a 'single market', contributing to the aims of the ANZCERTA.[9] Additionally, the creation of a single regulatory agency for both countries will ensure that:

> Australia remains a regional centre of excellence for therapeutics regulation by maintaining regulatory capacity in the face of emerging technologies, and enabling Australia and New Zealand to better influence global and regional standard setting.[10]

2.8 The Committee notes the support for harmonisation under the Agreement expressed by Australian industry groups. For example, ACIL Tasman, on behalf of the Australian Self-Medication Industry (ASMI) stated:

> the joint agency proposal affords Australia an opportunity to iron out minor but annoying idiosyncratic differences between the States and the Commonwealth, presenting industry with further market efficiencies.[11]

2.9 Similarly, Medicines Australia noted that:

> The formation of the joint agency provides an excellent opportunity for evaluation processes to be improved so that approval timelines meet or exceed international best practice (6-8 months).[12]

8 NIA, para. 8.

9 NIA, para. 10.

10 NIA, para. 10.

11 Australian Self-Medication Industry, *Submission*, p. 2.

12 Medicines Australia, *Submission*, p. 2.

2.10 The Department advised the Committee of the benefits to Australian consumers and the therapeutics industry as follows:

> The key benefit for Australian consumers will be an enhanced and sustainable specialist regulatory capacity through the establishment of the single agency. Our therapeutic products industry will benefit from reduced regulatory compliance costs due to the replacement of separate regulatory controls in both countries with a single set of controls under which products can be supplied in Australia and New Zealand. This means that a therapeutic product sponsor will need to apply only once for a product licence to supply a product in both countries and then will need to comply with only one set of pre- and post-market regulatory requirements to continue to be able to supply that product in both markets.[13]

Key obligations

2.11 As discussed in paragraph 2.1, the Parties will establish a 'joint Scheme' to regulate the quality, safety, efficacy and performance of therapeutic products, and particularly, for the regulation of the manufacture, supply, import, export and promotion of therapeutic products.[14] Existing therapeutic product regulatory systems in both Australia and New Zealand will be integrated under the joint Scheme.[15]

2.12 As part of its obligations under the Agreement, Australia will establish an Agency to administer the joint Scheme in both countries.[16] The Agency is to be established as a body corporate under Australian legislation. According to the Department:

> the new scheme will apply international best practice in the regulation of therapeutic products and will be based on the current regulatory scheme operated by the [Therapeutic Goods Administration] TGA. The agency will regulate the manufacture, supply, import, export and promotion of therapeutic products. Its activities will include: the setting of

13 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 2.

14 NIA, para. 11.

15 NIA, para. 11.

16 NIA, para. 12.

> standards with which all products must comply; pre-market activities, including the evaluation of products; controls over manufacturing, including licensing of manufacturers and auditing; post-market activities, including monitoring, surveillance and recalls; and enforcement activities[17]

and,

> This new agency will be given the power to approve products on the markets of both countries, to set standards for both countries, to enforce those standards, to issue recall notices and to have review processes and governance commitments.[18]

2.13 Mr Slater outlined for the Committee the administration arrangements for the new Agency:

> Once established, the new agency will replace the Australian Therapeutic Goods Administration—the TGA—that is within the Department of Health and Ageing and the New Zealand Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health. The agreement will establish a new ministerial council comprising the Australian and New Zealand health ministers to oversee the agency and ensure its accountability for the operation of the scheme to the Australian and New Zealand governments. The agreement will also establish a five-member board for the agency, which will be responsible for the governance of the agency.[19]

2.14 The Ministerial Council will make Rules that will contain many of the regulatory requirements of the joint Scheme. The Agency's Managing Director will make Orders for the more technical requirements.[20] Australia and New Zealand will both be obliged to legislate to give effect to parliamentary scrutiny of the Rules and Orders. If such Rules or Orders are disallowed by the parliament of either country, they will have no effect.[21] The Agency will be accountable to the Parties for the performance of its functions.[22]

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17 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 2.
18 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 10.
19 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 2.
20 NIA, para. 14.
21 NIA, para. 15.
22 NIA, para. 16.

Key impacts of the Agreement

Regulatory differences

2.15 The Committee understands that currently there are similarities in the approaches of Australia and New Zealand to pharmaceutical regulation.[23] For example, Mr Slater noted the similarity in approach to prescription medicines and over-the-counter medicines.[24] However, according to the Regulation Impact Statement (RIS), there are 'some significant differences in the scope and detailed operation of their current regulatory regimes'.[25] These differences relate primarily to:

- the limited coverage of New Zealand's existing regulation
- differences in regulatory processes.[26]

2.16 A major divergence occurs in the regulation of complementary medicines and medical devices. The Committee is aware of the concerns of the Australian Medical Association (AMA) Therapeutics Committee over 'the inadequate regulation of complementary therapies, substances and devices'.[27]

2.17 In reference to complementary medicines, ASMI has expressed concern that all therapeutic products may not be covered by the Scheme as a result of differing views between Australia and New Zealand over the classification of some substances (such as dietary supplements in New Zealand) as food rather than medicines, despite the fact that they make therapeutic claims.[28] The Committee understands that it is ASMI's assertion that either the Rules or Orders will declare whether a substance is a therapeutic product or not.[29]

2.18 Mr Slater advised the Committee that:

> New Zealand essentially do not regulate medical devices and have no regulatory scheme. In the area of complementary medicines, they do not regulate them as therapeutic goods. So the new scheme will need to introduce a regulatory

23 RIS, p. 6.
24 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 7.
25 RIS, p. 6.
26 RIS, pp. 6-7.
27 Australian Medical Association Therapeutics Committee, *Submission*, p. 4.
28 Australian Self-Medication Industry, *Submission*, pp. 6-7.
29 Australian Self-Medication Industry, *Submission*, p. 6.

> framework for medical devices and complementary medicines.[30]

2.19 The Committee was advised that the new regulatory framework will be based upon current Australian standards.

> Australia has adopted the global harmonisation recommendations on medical devices. So the current state of play is that New Zealand has agreed that those recommendations would be the framework for regulating medical devices. As Australia is leading in the area of complementary medicines, the Australian regulatory framework for complementary medicines would certainly be the regulation starting point for negotiations around what will be the regulatory framework.[31]

2.20 The Committee is thus reassured that the Agreement will not result in a 'diminution in standards' in either Australia or New Zealand.[32]

Dual country licences

2.21 Under the Agency it is proposed that there will be only one application and licence necessary to cover a therapeutic product in both Australia and New Zealand (a 'dual country licence').[33] The Committee is aware of concerns regarding how such licences would interact with differences in patent terms between the two countries:

> the granting of a dual country licence for a medicine that is off-patent in one country but still covered by a patent in the other country may re-open demands / opportunities for weakening of Australia's current Intellectual Property regime.[34]

2.22 Medicines Australia submitted to the Committee that the granting of dual country licences could:

30 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 7.
31 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 7.
32 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 7.
33 NIA, para. 10; RIS, pp. 16, 25.
34 Medicines Australia, *Submission*, p. 2.

> once again stimulate arguments to change the Australian legislation to permit manufacture in Australia for export of products that are protected by a current patent.[35]

Further,

> The dual country licence may also exacerbate patent infringements that some of our members have experienced with products protected by patent being supplied by a generic company in contravention of the Patents Act.[36]

2.23 Medicines Australia proposed that patent infringements could be prevented if a patented product's sponsor was notified by the Agency when it received an application to register a generic product. The Committee understands that a similar measure was taken in the proposed Australia-United States Free Trade Agreement.[37]

2.24 In response to a question from the Committee regarding the concerns of Medicines Australia, Mr Jeffrey Ibbotson from the Department stated:

> We are focusing our attention on the regulatory aspects of the quality, safety and efficacy of therapeutic products rather than on the patent aspects, but we think that some of the measures that we will have in place that will deal with the safety issues in particular will meet some of the needs and concerns of Medicines Australia. We are looking at it from the aspect of being able to trace products that are on the market in both countries. I think that will have the same effect of ensuring that medicines that are patented in Australia are still protected by patent law in Australia.[38]

Parallel importation

2.25 Medicines Australia also expressed concern that the issuing of dual country licences would increase the likelihood of parallel importation of products, particularly from New Zealand to Australia. Importation of cheaper New Zealand products would undermine the local Australian industry. Further, parallel importation would make it

35 Medicines Australia, *Submission*, p. 3.

36 Medicines Australia, *Submission*, p. 3.

37 Medicines Australia, *Submission*, p. 3.

38 Mr Jeffrey Ibbotson, *Transcript of Evidence*, 10 May 2004, pp. 3-4.

easier for counterfeit products or products that had not been properly stored to enter the market.[39]

2.26 Medicines Australia proposes a solution to avoid the problems arising from parallel importation:

> The current provisions whereby the authority to supply a product is solely vested in the product's sponsor must continue to apply under the joint agency regime, so that only authorised and regulated export can occur. Any other legislation, such as the New Zealand legislation relating to wholesalers, must be amended to similarly prohibit parallel importation.
>
> In addition, we consider that sponsors must be permitted to have differently labelled products for supply in either country. The labelling would be required to comply with all regulatory requirements applicable under the joint agency, but additional elements that would differentiate product supplied in one country from the other should be permitted. We understand that such differential labelling is expressly prohibited in the European Union, which we do not support.[40]

Freedom of Information

2.27 The Committee notes Medicines Australia's comments regarding the impact of the proposed treaty action on Freedom of Information (FOI).[41] Given that FOI legislation and standards differ between Australia and New Zealand, the Committee was concerned about the handling of FOI requests by the new joint Agency.

2.28 The Committee was reassured to hear that:

> The freedom of information legislation in each country will be available. Each country has exemptions in place to protect business affairs including commercial-in-confidence information, and we are working through those arrangements at the moment to ensure that confidential information will be

39 Medicines Australia, *Submission,* p. 3.

40 Medicines Australia, *Submission,* p. 3.

41 Medicines Australia, *Submission,* pp. 3-4.

> protected in both countries and there will not be a divergence of outcomes.[42]

Clinical trials process

2.29 The Committee is aware of the differences in the processes for clinical trials for therapeutic products in Australia and New Zealand. According to Medicines Australia:

> Australia and NZ have 2 different mechanisms for approving the conduct of clinical trials. The industry in each country is strongly in favour of retaining their own current system … The Australian industry believes that the adoption of the NZ system (which has been canvassed by the TGA and NHMRC) will lead to a significant decrease in clinical R&D activity as approval timelines may increase. This would lead to Australia being excluded from international studies for new medicines, which will seriously disadvantage sick Australians. We are proposing that the separate mechanisms be retained.[43]

2.30 In response to a question from the Committee on whether Australia would be maintaining its separate clinical trials process, Mr Slater stated:

> The clinical trials process for Australia is currently under review. That review incorporates New Zealand input. The desire is to produce a clinical trials regime for Australia and for New Zealand. That will be considered when the report comes to hand.[44]

Merits review

2.31 The NIA states that the Parties will be required to legislate to provide for the merits review of regulatory decisions of the Agency by an independent tribunal. Decisions of the Agency will be subject to review by the tribunal in either jurisdiction. For Australia, that tribunal will be the Administrative Appeal Tribunal (AAT). [45]

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42 Mr Jeffrey Ibbotson, *Transcript of Evidence*, 10 May 2004, p. 4.

43 Medicines Australia, *Submission*, p. 4.

44 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 4.

45 NIA, para. 17.

2.32 The current appeal mechanism for regulatory decisions consists of three separate stages: an internal appeal within the Department of Health; application to the AAT for merits review of the decision of the Minister for Health; and finally, application for review of the AAT decision by the Federal Court.[46]

2.33 With regard to the merits review of decisions made by the new Agency, the Committee understands the concerns of Medicines Australia over whether the option of appeal to the Federal Court will be maintained.[47] In response to these concerns, the Committee sought clarification from the Department. When asked by the Committee whether merits review decisions by both the AAT and the Federal court will be retained, Mr Slater replied:

> Yes, they will. There will be a special merits review process set up to enable merits review in each country. There will be a panel from which a principal panellist will chair the merits review process in either country. In Australia, that is anticipated to be conducted by the AAT, and the principal panellist who will chair that tribunal will be the President of the AAT. The process will enable each tribunal to refer a matter for review in the other country if justice will be best served.[48]

2.34 The Committee recognises that Mr Slater's comments did not adequately outline the role of the Federal Court in the appeals process.

Advertising

2.35 Advertising of therapeutic goods is noted by the RIS as an area where Australian and New Zealand policy diverges.[49] Currently, direct-to-consumer advertising (DTCA) of prescription medicines is banned in Australia but is allowed in New Zealand. However, Australia does permit DTCA for non-prescription medicines.

2.36 The Committee notes concerns that harmonisation of Australian and New Zealand practices may allow DTCA in Australia.[50] When asked

46 Medicines Australia, *Submission,* p. 4.

47 Medicines Australia, *Submission,* p. 4.

48 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 4.

49 RIS, p. 6.

50 Australian Medical Association Therapeutics Committee, *Submission,* p. 3.

whether any provisions in the Agreement would permit DTCA in Australia, Mr Slater stated:

> That is an issue of difference between Australia and New Zealand. The New Zealand government is currently examining that issue. There has been a press release from the New Zealand Minister for Health which says that it is the intention of the New Zealand government to harmonise with Australia in this area.[51]

Drugs and Poisons Scheduling Committee

2.37 The National Drugs and Poisons Scheduling Committee (NDPSC) includes representatives of all States and Territories, the Commonwealth and New Zealand. The NDPSC's policy making body, the National Coordinating Committee on Therapeutic Goods 'facilitates the harmonisation of legislative and administrative controls on therapeutic goods and poisons in both countries.'[52]

2.38 The Department advised the Committee of the implications of the proposed treaty action for the scheduling process:

> The scheduling process will involve the new agency, as it involves the TGA at present. I should point out that drugs and poisons scheduling are given legislative effect through state and territory legislation and, in the case of the joint agency, through New Zealand legislation. New Zealand has its own legislative framework for regulating access to medicines by citizens. The new arrangements for the agency to adopt are being discussed at the moment with the states and territories and New Zealand. There is no intention to change the legislative means of effect for drugs and poisons scheduling. It will still be up to the Australian states and territories and the New Zealand government to implement the recommendations of the agency.[53]

51 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 9.

52 ACT Government, *Submission*, p. 1.

53 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 9.

Entry into force

2.39 The Agreement will enter into force upon the exchange of diplomatic notes confirming the passage of implementing legislation in each country. According to the NIA, this is scheduled to occur as soon as possible after both Australia and New Zealand have completed their parliamentary processes. The NIA states that 1 July 2005 has been identified as a target date for commencement of the joint regulatory Scheme.[54]

Implementation

2.40 The joint Scheme will be implemented by legislation in both Australia and New Zealand, and by the Rules and Orders. The NIA states that an exposure draft of the proposed Bill will be released for public consultation before its introduction into Parliament.[55] It is anticipated that the legislation will provide for:

- the establishment and corporate personality of the Agency
- the Rules and Orders to have the force of law in Australia
- Parliamentary scrutiny of the Rules and Orders
- administrative and judicial review of Agency decisions
- Agency functions and powers
- securing compliance.[56]

2.41 The implementation process was outlined to the Committee by Mr Slater:

> The treaty is the first step in setting up the scheme. It sets out the key elements of the scheme, including the governance arrangements and the intent between the parties. That will be translated into legislation to be introduced in both countries. That legislation will have wide consultation before it is introduced into the parliaments of both countries and will be

54 NIA, para. 2.
55 NIA, para. 21.
56 NIA, para. 22.

> debated and considered by the parliaments of both countries.[57]

2.42 Under the Agreement, Australia will establish the Agency that will administer the joint Scheme in both countries. It is intended that Australia introduce the parts of the legislation that establish the Agency only with the Agreement of New Zealand, thus ensuring that New Zealand retains some control over the way the Agency is established, and that the Agency is established as intended by the Agreement. Any amendment to the establishment provisions must also follow this arrangement.[58]

2.43 An interim Ministerial Council will be established prior to entry into force to facilitate establishment of the Agency and matters relating to the regulatory scheme.[59]

Costs

2.44 The Agency, like the current TGA, will operate on a full cost recovery basis for all activities undertaken in relation to the regulation of therapeutic products.[60] The Australian Government has provided funding for the establishment and implementation of the Scheme. It is anticipated that most of the funding will be recovered from industry within five years of the commencement of the Scheme.[61] New Zealand will also contribute to the financial requirements of the new Agency.[62]

2.45 ASMI advised the Committee that there will be financial savings as a result of the establishment of the Agency

> the joint agency is expected to bring about cost savings because it will eliminate a lot of 'double-doing' in both Wellington and Canberra, when, in the past, the same product has been up for approval under both regimes.[63]

2.46 However, industry members have also expressed some concerns over the maintenance of full cost recovery. In a submission to the Committee, ASMI took issue with the cost recovery principle:

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57 Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 10.

58 NIA, para. 13.

59 NIA, para. 24.

60 NIA, para. 25; Mr Terry Slater, *Transcript of Evidence*, 10 May 2004, p. 2.

61 NIA, para. 25.

62 NIA, para. 26.

63 Australian Self-Medication Industry, *Submission*, p. 2.

> The Productivity Commission enquired extensively into Commonwealth agencies' cost-recovery policies and preferred 'fee for service' rather than 'whole of agency' schemes. In our view, the TGA performs a variety of functions which are of a 'policy' or 'public health' nature and from which industry receives no direct benefit. Industry should not fund these activities which benefit all taxpayers.[64]

2.47 Similarly, the AMA Therapeutics Committee stated

> The AMA strongly advocates that there must be a 'public policy' component of post-harmonisation agency funding, with budgetary funding from both governments, as there should be now for the TGA … It is neither reasonable nor appropriate to expect self-funded participation for a government council established to discuss and recommend on vital issues of public policy.[65]

2.48 The Committee notes that a Cost Recovery Impact Statement will be released prior to determination of the final level and structure of fees and charges. This Statement will address the impact of changes to cost recovery on the industry.[66]

Consultation

2.49 The NIA states that consultations were undertaken with Australian and New Zealand stakeholders including representatives from the medicines and medical device industries, healthcare professional associations, consumers and key government agencies.[67] Consultations consisted of two consultation papers (released in June 2002) and numerous meetings.[68] Forty submissions were received from Australian organisations, of which three opposed the joint Agency.[69]

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64 Australian Self-Medication Industry, *Submission,* p. 9.

65 Australian Medical Association Therapeutics Committee, *Submission,* pp. 3-4.

66 NIA, para. 27.

67 NIA, para. 30.

68 RIS, pp. 21, 41.

69 RIS, p. 41.

State and Territory Governments

2.50 The NIA states that State and Territory Governments were involved in consultations through the Standing Committee on Treaties (SCOT). Issues that were raised during this process include:

- the capacity for the Agency instead of State and Territory authorities to regulate sole traders under the joint Scheme, and
- the need for an exemption from the operation of the TTMRA for departures from the joint Scheme.[70]

The NIA states that there was no significant concern raised in relation to these issues.[71]

2.51 The Committee notes that State and Territory Governments did express concern over the possibility that the Agreement would allow the Commonwealth Government to use the external affairs power to eliminate the role of the States and Territories in the regulation of scheduled drugs and poisons.[72] According to the NIA, the Agreement will not be used to vary the existing roles and responsibilities of States in this area.[73]

2.52 ASMI notes with concern the statement in the NIA in relation to the above matter that 'consultation will continue with States and Territories through the exposure draft of the legislation':

> ASMI has strongly supported the joint agency at least in part because we expected its regulatory activities within Australia to "cover the field"... Any provision in that legislation that would extend to the States an entrenched discretion to vary scheduling decisions in often minor or subtle ways will be of serious concern to ASMI.[74]

2.53 The Committee notes the support for the proposed Agreement by the ACT Government. [75]

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70 NIA, para. 28.

71 NIA, para. 28.

72 RIS, p. 41.

73 NIA, para. 29.

74 Australian Self-Medication Industry, *Submission*, p. 8.

75 ACT Government, *Submission*, p. 1.

Conclusion and recommendation

2.54 The Committee considers that the proposed Agreement will enhance the protection of public health and safety. The Committee notes the role of the proposed Agreement in furthering trans-Tasman cooperation.

Recommendation 1

The Committee supports the *Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the regulation of Therapeutic Products* and recommends that binding treaty action be taken.