International treaty examination of the

Trans-Pacific Partnership Agreement (TPPA)

New Zealand Medical Association

Submission to the Foreign Affairs, Defence and Trade Committee

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"One particularly disturbing trend is the use of foreign investment agreements to handcuff governments and restrict their policy space…In my view, something is fundamentally wrong in this world when a corporation can challenge government policies introduced to protect the public from a product that kills" [1]
– Dr Margaret Chan,
Director-General of the World Health Organization

About the NZMA

1. The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. The NZMA is a member of the World Medical Association (WMA), which represents 10 million physicians worldwide

2. The key roles of the NZMA are to:
   - provide advocacy on behalf of doctors and their patients
   - provide support and services to members and their practices
   - publish and maintain the Code of Ethics for the profession
   - publish the *New Zealand Medical Journal*.

Focus of our submission

3. The NZMA acknowledges the highly technical nature of the TPPA. It is a complex legal document with 6,000 pages, 30 chapters, and multiple annexes and side letters. Accordingly, our feedback is focused on the potential implications of the agreement on health (including the determinants of health). Our main concerns relate to possible risks to public health posed by the inclusion of investor state dispute settlement (ISDS) provisions and the impact of the agreement on access to pharmaceuticals. We elaborate on these concerns in the following paragraphs. We request the Government to commission a formal, comprehensive, independent Health Impact Analysis before New Zealand ratifies the agreement.

[1] Address to the Sixty-seventh World Health Assembly, Geneva, 19 May 2014. Available from http://www.who.int/dg/speeches/2014/wha-19052014/en/

Concerns relating to ISDS provisions

4. We note that ISDS provisions in other international trade and investment agreements have enabled investors (generally large multinational corporations) to challenge government policies on public health in arbitration tribunals. The most well-known instance in this part of the world was the dispute between tobacco giant Philip Morris Asia and the Government of Australia regarding that Government's decision to legislate for standardised plain packaging of tobacco. The dispute appeared to have a 'chilling effect' on the introduction of standardised plain packaging of tobacco in New Zealand, despite overwhelming public health evidence in support of this measure.

5. While the National Interest Analysis accompanying the TPPA suggests that the agreement has been developed with built-in safeguards to protect public health, concerns have been expressed that these safeguards could still expose the Government to challenge at investor-initiated arbitration tribunals over measures to protect public health. While we welcome the specific provision in the TPPA that allows the Government to rule out ISDS challenges over tobacco control measures (as well as the Government's stated intent to exercise this provision), tobacco control is only one of many public health challenges. Others include, for example, the obesity epidemic, alcohol-related harm, and the health impacts of climate change.

6. The carve-out for tobacco in the TPPA has heightened concerns about whether or not the agreement's generic safeguards are adequate to protect the right of the Government to regulate for health purposes (via legislation, regulation and/or policy). If negotiators deemed the generic public health safeguards in the agreement sufficient, such a carve-out for tobacco would not have been considered necessary. We have been made aware that the exemptions / safeguards for health may not necessarily apply to the two rules that have been used most often as the basis for ISDS claims, namely 'fair and equitable treatment' (under 'minimum standard of treatment') and 'indirect expropriation'. We suggest that the Committee test the adequacy of these safeguards using the various scenarios we outline in paragraphs 11 to 13 below.

7. A number of structural flaws with ISDS tribunals and the processes that interpret rules such as 'fair and equitable treatment' have been described.[2] While the TPPA contains several minor procedural improvements, most of these major structural flaws remain. For example, the tribunal process is inherently asymmetric; cases can be initiated only by investors, not host states. Furthermore, conflicts of interest among arbitrators have not been addressed. ISDS tribunal panellists frequently rotate between adjudicators and paid corporate litigators; OECD estimates suggest that over 50% of adjudicators act as counsel for investors whereas just 10% act for states.[3] There is still no appeal mechanism, nor any system to ensure that decisions are based on precedent, to address inconsistency in rulings. Finally, ISDS tribunals lack direct public health expertise/representation.

8. While ISDS provisions are already present in many of New Zealand's existing investment agreements, a number of additional considerations are needed. The TPPA would for the first time expose the New Zealand Government to claims from United States-based companies, which have historically been the most litigious. They have initiated over twice as many claims as every other home state combined.[4] The signing of the TPPA coincides with a sharp increase in the number of ISDS cases being initiated worldwide.[5] Furthermore, under the TPPA, investors would have the

[2] Fooks G, Gilmore AB. International trade law, plain packaging and tobacco industry political activity: the Trans-Pacific Partnership. Tob Control. 2014 Jan;23(1):e1. Available from http://tobaccocontrol.bmj.com/content/23/1/e1.full.pdf+html
[3] OECD Investor-State Dispute Settlement Public Consultation: 2012. p43–4. Available from http://www.oecd.org/investment/internationalinvestmentagreements/50291642.pdf
[4] United Nations Conference on Trade and Development. Recent Trends in IIAS and ISDS. February 2015. Available from http://unctad.org/en/PublicationsLibrary/webdiaepcb2015d1_en.pdf
[5] Ibid

right to initiate ISDS claims on the basis of *alleged* breaches of contract. This is something New Zealand has never agreed to before in previous agreements. Finally, the Most Favoured Nation clauses in previous agreements mean that—where the terms of the TPPA are more favourable to signatories than previous agreements—they can generally be accessed by parties to those earlier agreements.

> *"The new obligations [in the TPPA] would, however, place new limitations on the Government's ability to modify New Zealand's policy settings to ensure they are appropriate for our domestic circumstances"*
> – MFAT National Interest Analysis on the TPPA[6]

9. We consider that the precautionary principle should apply to provisions in the agreement that could have an impact on health. It is not possible to predict future public health issues and/or effective future policy responses with absolute certainly. As such, we submit that any international trade and investment agreement should not restrict a government's ability to regulate for public health issues, including future unanticipated ones. It is therefore a matter of serious concern that New Zealand's own National Interest Statement, developed by MFAT, acknowledges that "the new obligations [in the TPPA] would, however, place new limitations on the Government's ability to modify New Zealand's policy settings to ensure they are appropriate for our domestic circumstances". We contend that the Government needs to retain the maximum flexibility and scope for policy innovation to meet current and future health challenges.

10. We draw the Select Committee's attention to a report by the Australian Senate following its inquiry into the Korea-Australia Free Trade Agreement[7] that recommended the Australian Government should not agree to include ISDS mechanisms in future trade agreements. The Australian Productivity Commission also recommended in 2010 that Australian governments should not accept ISDS provisions because they carry unacceptable risks and there is little evidence that they increase investment.[8]

Selected examples of public health policy measures for examination

11. We ask that the Committee test the robustness of the safeguards in the TPPA against various possible future measures to address some of the major public health issues in New Zealand. For example, several policy options are being mooted to tackle the obesity epidemic. Our association has recommended greater protection from the marketing of unhealthy food to children, with a more stringent statutory regulatory regime that addresses all forms of marketing, including product packaging and sponsorships.[9] A future measure to tackle obesity and tooth decay could include the requirement for hard-hitting, graphic health warning labels for sugary drinks, similar to those on tobacco products. Concerns have been raised that the TPPA could hinder the implementation of such measures, with the Government facing a challenge (or threat of challenge) at an ISDS or a state-to-state dispute level. While the Government could refer to the 'general exceptions' provisions, it would need to argue for, and establish, how such measures are

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[6] Available from https://www.tpp.mfat.govt.nz/assets/docs/Trans-Pacific%20Partnership%20National%20Interest%20Analysis,%2025Jan2016.pdf

[7] Commonwealth of Australia Senate. Foreign Affairs, Defence and Trade References Committee. Korea-Australia Free Trade Agreement. October 2014. Available from http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Foreign_Affairs_Defence_and_Trade/Korea-Australia_Free_Trade_Agreement/~/media/Committees/fadt_ctte/Korea-Australia_Free_Trade_Agreement/report/report.pdf

[8] Productivity Commission 2010, Bilateral and Regional Trade Agreements, Research Report, Canberra. Available from http://www.pc.gov.au/inquiries/completed/trade-agreements/report/trade-agreements-report.pdf

[9] NZMA. Tackling Obesity Policy Briefing. May 2014. Available from http://www.nzma.org.nz/publications/tackling-obesity

both necessary, and the least trade-restrictive, to protect health. This exception has rarely succeeded where it has been invoked.

12. It has also been suggested that the example of advertising restrictions for unhealthy food may also trigger an investor-state dispute by invoking the 'fair and equitable treatment' concept, which is the most commonly relied-on basis for investor-state disputes. Investors insist on a stable regulatory environment that does not change to their disadvantage after investment. As the safeguards available under non-conforming measures do not apply to 'fair and equitable treatment' provisions, concerns have been raised that the only protection available to the Government if an ISDS process is triggered would depend on a particular tribunal's interpretation of the various 'clarifications' in the agreement. Even the threat of a dispute may have a chilling effect on Government decisions around restricting the advertising of junk food to children.

13. We have similar concerns around the implications of the TPPA on the Government's ability to respond to various other major public health issues including alcohol-related harm and the health impacts of climate change. The NZMA has recommended a suite of measures to reduce alcohol-related harm including minimum unit pricing, phasing out of marketing, and restrictions on outlet density.[10] Future measures could include a requirement for graphic health warnings on alcohol bottles and cans. We seek clarification on whether the TPPA may permit challenges to any of the above measures through the ISDS process claiming breaches of 'minimum standard of treatment' and/or 'indirect expropriation'. Unlike tobacco, there is no carve-out from ISDS for alcohol.

Incoherence between trade and climate change policy

14. Climate change has been identified by the *Lancet* as the greatest global threat to public health in the 21st century.[11] Tackling climate change could be the greatest global health opportunity of the 21st century.[12] At the recently concluded Paris Climate Agreement, New Zealand agreed to limit global warming to "well below 2 degrees" and to net zero greenhouse gas emissions by the second half of the century. The NZMA has also called for a rapid, whole-of-society-transition to a low greenhouse gas-emitting nation.[13] It is disappointing, therefore, that climate change is not afforded a single mention anywhere in the entire 6,000 pages of the TPPA (including the Environment Chapter). We contend that a greater coherence between trade and climate policy is needed.

15. We note that, under existing international trade and investment agreements, fossil fuel and extractive industries have launched a disproportionately high number of ISDS claims.[14] Based on concerns about the use of ISDS claims to obstruct action on climate change, the EU Parliament has recommended a carve-out to ISDS for actions on climate change in the Transatlantic Trade and Investment Partnership (TTIP), the European equivalent of the TPPA. We draw the Committee's attention to a recent ISDS claim for US$15 billion initiated under the North American Free Trade Agreement by a Canadian fossil fuel company in response to the Obama

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[10] NZMA. Reducing Alcohol-Related Harm Policy Briefing. May 2015. Available from http://www.nzma.org.nz/publications/reducing-alcohol-related-harm

[11] Costello A, et al. Lancet; 2009 May 16;373:1969–1733. Available from http://www.ucl.ac.uk/global-health/project-pages/lancet1/ucl-lancet-climate-change.pdf

[12] Watts et al. Health and climate change: policy responses to protect public health. Lancet; 2015 June 23;386:1861–914. Available from http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60854-6.pdf

[13] NZMA. Health and Climate Change Position Statement. August 2015. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0010/16984/NZMA-Position-Statement-on-Health-and-Climate-Change-FINAL_August-2015.pdf

[14] UNCTAD, "World Investment Report 2015: Reforming International Investment Governance", 2015, chapter III, p. 115, http://unctad.org/en/publicationchapters/wir2015ch3_en.pdf

administration's rejection of the Keystone XL pipeline.[15] The pipeline would have carried tar sands crude oil from Alberta to refineries in Texas. It is noteworthy that President Obama specifically cited the need for leadership on climate change as the reason to block the proposed pipeline.

16. Meeting New Zealand's commitments under the Paris Climate Agreement is likely to require innovative policy responses that may conflict with fossil fuel industry objectives to maximise profits. The NZMA has a longstanding view that public health considerations should prevail when there are conflicts between protecting the public health of New Zealanders and protecting private commercial interests. This view extends to the determinants of health, including the environment. Accordingly, we ask the Committee specifically to examine whether the TPPA might constrain New Zealand's flexibility in future policy making to achieve the Government's own commitments on mitigating climate change.

The relationship between the TPPA and other international agreements

17. It is of concern that the relationship is not acknowledged between the TPPA and other international agreements designed to meet fundamental goals relating to health and wellbeing. This appears to be a systemic issue. The only health-related international agreement explicitly supported in the TPPA is the Montreal Protocol on Substances that Deplete the Ozone Layer. While support for this Protocol is welcome, the specific inclusion of ozone protections in the TPPA suggests that, as with the tobacco carve-out, generic protections for other environmental issues including climate change (and the associated health risks) are insufficient. A recent article in the *New Zealand Medical Journal* identifies the following health-protecting UN/WHO agreements that the TPPA is totally silent on:[16]

- 1948 Universal Declaration of Human Rights (including the right to health — progressively attaining conditions that enable people to be healthy)
- 2010 WHO Global strategy to reduce harmful use of alcohol
- WHO Global action plan for the prevention and control of non-communicable diseases 2013–2020
- 1981 WHO International Code of Marketing of Breast-milk Substitutes
- 2007 UN Declaration on the Rights of Indigenous Peoples
- 1992 UN Framework Convention on Climate Change (UNFCCC) and subsequent international agreements
- 2015 UN Sustainable Development Goals.

The same article also noted with concern that nutrition is mentioned only once in the TPPA (in the Intellectual Property Chapter) but as separate from public health.

18. We note the recent ruling by the World Trade Organization (WTO) on a US-initiated claim against India's domestic solar energy programme. Though India argued that the programme helps the country meet its climate commitments under the UNFCCC, the WTO rejected that argument. This is a clear contemporary example of how trade and investment arguments appear to take priority over international agreements pertaining to the environment and health. In the context of the TPPA, this is a concerning development because the TPPA rules extend beyond those of the WTO in many aspects of the agreement.

[15] http://www.ft.com/cms/s/0/550060b0-b4c6-11e5-b147-e5e5bba42e51.html#axzz42HG5GTNN
[16] Keating G, et al. TPPA should not be adopted without a full, independent health assessment. N Z Med J. 2016 Feb 19;129(1430):7–14. Available from https://www.nzma.org.nz/__data/assets/pdf_file/0004/47191/Monasterio-2220-NZMJ-1430-FINAL.pdf

Impact on access to medicines

19. We are pleased that the fundamentals of PHARMAC appear to have been protected in the TPPA. However, we note that PHARMAC would be required to meet new requirements aimed at promoting transparency and good process in decisions to fund pharmaceuticals and medical devices. For example, PHARMAC will need to introduce a statutory timeframe for considering applications and a new review process. While this is not necessarily bad, and indeed may be welcomed by some clinicians, we are concerned that these provisions could ultimately provide more leverage for the pharmaceutical industry. For example, industry could use these provisions to influence PHARMAC's decision making on pricing, reimbursement and other decisions that affect market share, such as the range of therapeutic indications for which a product is subsidised. This would have the net effect of undermining the health agenda and the public interest goals of PHARMAC.

20. We note that the administrative costs of implementing the obligations in the transparency annex ($4.5 million initial establishment costs and $2.2 million annually in ongoing costs) are substantial, given that PHARMAC reported spending approximately $28.7 million in operating costs in the financial year. In addition to these costs, PHARMAC may also face pressure on its pharmaceutical budget resulting from commitments in the intellectual property chapter (see paragraphs 20 and 21).

21. We are concerned that various provisions in the transparency annex may be used to support claims by the pharmaceutical industry that investment chapter obligations have been breached. For example, we note that a new Therapeutic Products Regime is under development, and that this is likely to re-evaluate direct-to-consumer advertising (DTCA) of pharmaceuticals, currently permitted in New Zealand and in only one other OECD country (the United States). DTCA is a biased source of health information that favours representation of benefits over harms, and is associated with unnecessary prescribing, drug harms and increased costs to the taxpayer.[17] It has been suggested that New Zealand could face a challenge by the pharmaceutical industry via the ISDS process if it decides to prohibit or limit DTCA of pharmaceuticals.[18] We ask the Committee to specifically consider this scenario during examination of the treaty.

22. With regard to the transparency annex, we are concerned at the implications of footnote 11 under Article 3: Procedural Fairness, which states "This Annex shall not apply to government procurement of pharmaceutical products and medical devices". This suggests that the protections afforded to PHARMAC against recourse to dispute settlement apply only to activities relating to the Community Pharmaceutical Schedule. PHARMAC's other major activities, such as managing hospital formularies (including most high-cost medicines and biologics) and medical devices are examples of government procurement, and are therefore excluded from the annex. As such, PHARMAC may be open to challenge by state-to-state or investor-to-state mechanisms for arguably the major volume of its most contentious work. Furthermore, the whole annex refers to **new** pharmaceutical listings, not to widening of access to pharmaceuticals already listed on the Community Pharmaceutical Schedule. We ask the Committee to consider the above situations as part of a comprehensive Health Impact Analysis of the treaty. We also request the Committee to examine what scope there will be in the enabling legislation around changes to PHARMAC to mitigate the potential above risks. For example, could the enabling legislation ensure that the

[17] Every-Palmer S, Duggal R, Menkes DB. Direct-to-consumer advertising of prescription medication in New Zealand. N Z Med J. 2014 Aug 29;127(1401):102–10.

[18] Gleeson D. Preliminary analysis of the final TPP Healthcare Transparency Annex:Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices, School of Psychology and Public Health, La Trobe University, 12 December 2015. Available from http://infojustice.org/wp-content/uploads/2015/12/Gleeson-Preliminary-Analysis-Transparency-Annex-12-Dec-2015-1.pdf

definition of new pharmaceutical listings include amendments to access to existing pharmaceuticals?

23. With respect to the intellectual property obligations relating to pharmaceuticals, we note that these would require New Zealand to provide extensions to the patent term for pharmaceuticals for delays in regulatory approval processes in certain circumstances. The National Interest Analysis suggests that, given the efficiency of New Zealand's processing times, very few unreasonable delays are expected to occur in New Zealand. The average cost of any delay is estimated at $1million. It is important to note, however, that these obligations are likely to dramatically reduce access to affordable medicines by millions of people living in developing countries. In May 2014, Dr Margaret Chan, Director-General of the WHO, articulated the concerns expressed by several developing countries that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines.[19] Furthermore, there is currently wide academic debate on patent terms; the agreement would 'lock' New Zealand's ability to modify patent terms to meet future needs.

24. Of particular concern is the requirement relating to data protection for biologics, a recent and hugely expensive category of medicines. We note that the TPPA would require New Zealand to provide either eight years' data protection for biologic pharmaceuticals, or five years, along with 'other measures to provide additional effective market protection'. New Zealand currently provides five years' data protection. We seek clarification and confirmation about the claim that the second option can be met by current New Zealand policy settings and procedures. We also seek an explicit commitment that the Government would not, in the future, elect to extend the period of data protection for biologics from five to eight years. It has been estimated that a longer monopoly for just the seven main biologics already used in New Zealand (let alone those in the pipeline) would translate into an additional cost of $25-$50 million annually.

World Medical Association resolution

25. We draw the Select Committee's attention to the World Medical Association's (WMA) emergency resolution on Trade Agreements and Public Health, adopted last year in Oslo.[20] This resolution is closely aligned with our recommendations above. For example, recommendation #2 in the WMA resolution calls on national governments and national member associations to "*ensure that trade agreements do not interfere with governments' ability to regulate health and health care, or to guarantee a right to health for all. Government action to protect and promote health should not be subject to challenge through an investor-state dispute settlement (ISDS) or similar mechanism".* The WMA resolution also covers specific areas of particular relevance to the TPPA (eg, access to medicines). We request that its recommendations be taken into consideration during the scrutiny of this trade and investment agreement.

Recommendations

26. We reiterate our request for the Government to commission a formal, comprehensive, independent Health Impact Analysis **before** New Zealand ratifies the agreement. This analysis should be based on the actual text of the agreement and include input from sector experts. It must also take into account all broad possible impacts on our health system. These include short- and long-term impacts as well as direct and indirect impacts, including social and environmental determinants of health and health equity. The Health Impact Analysis should also consider New

[19] Address to the Sixty-seventh World Health Assembly, Geneva, 19 May 2014. Available from http://www.who.int/dg/speeches/2014/wha-19052014/en/

[20] WMA Council Resolution on Trade Agreements & Public Health. Adopted by the 200th WMA Council Session, Oslo, April 2015. Available from http://www.wma.net/en/30publications/10policies/30council/cr_20/index.html

Zealand's ability to continue its current policies, and to develop and implement future policies, for the protection of public health. We request that this Health Impact Analysis be released for full public review, before New Zealand ratifies the agreement.

27. Given the current absence of a comprehensive and independent Health Impact Analysis, we ask that the New Zealand Government urgently puts forward a side letter calling for the exclusion of the ISDS provisions in relation to all health policies, regulations and decisions from the TPPA.

We hope that our feedback on this treaty is helpful. We would like to have the opportunity for an oral hearing before the Committee to support our written submission.

Yours sincerely

Dr Stephen Child
NZMA Chair