

Acceptance of a Protocol Amending the TRIPS Agreement to Implement the Doha Declaration on TRIPS and Public Health: Summary of Submissions

Profile of Submissions

1. Four submissions were received. The submitters were:
 - The Researched Medicines Industry Association of New Zealand (RMI)
 - GlaxoSmithKline (GSK);
 - The New Zealand Council of Trade Unions (CTU);
 - Sarah Meads (who describes herself as “an independent submitter with no political or commercial interests or affiliations”).
2. The Ministry of Health also made a formal submission.

Questions

3. The discussion document posed a number of questions to aid respondents in making submissions. The questions, and the responses, are set out below.

Acceptance of the Protocol

4. Submitters were asked to indicate whether or not they agreed with the proposition:

Given the WTO Membership’s unanimous support for the Doha Declaration and New Zealand’s role in drafting the waiver that later became the Protocol, there appears to be no reason why New Zealand should not accept the Protocol.

5. The RMI submission, which did not directly address any of the questions, stated that the RMI saw no reason why the New Zealand should not join with those other countries that have accepted the Protocol. GSK agreed that New Zealand should accept the Protocol.
6. The CTU submission argued that the proposed amendment to the TRIPS Agreement sets up compliance barriers that severely undermine its effectiveness. It is suggested by the CTU that New Zealand should not accept the Protocol until the underlying waiver has been adequately tested in practice.
7. Sarah Meads agreed that New Zealand should accept the Protocol. In addition to the moral imperatives and potential economic benefits mentioned in the discussion document, Ms Mead gave two other reasons for acceptance. These were New Zealand’s human rights obligations under the International Covenant on Economic, Social and Cultural Rights, and the contribution that the Protocol would make to economies of scale in the global generic pharmaceutical industry.
8. The Ministry of Health also supported acceptance of the Protocol.

New Zealand as an exporting member

9. Submitters were asked to indicate whether or not they agreed with the proposition:

Acceptance of the Protocol by New Zealand without legislative amendment to become and exporting member would appear to render acceptance meaningless. Acceptance without such amendments does not seem a viable option.

10. GSK did not disagree with this proposition. Their submission noted though, that the potential commercial benefits of becoming an exporting member should not influence how New Zealand implements the Protocol. This argument is based on the statement of the Chair of the WTO General council that the system is not to be an instrument to pursue industrial or commercial objectives.

11. The CTU, although opposed to acceptance of the Protocol, considered that, if New Zealand were to accept, that any implementation ought to be as broad as possible, pushing the boundaries of the constraints.

12. Sarah Meads and the Ministry of Health agreed with the proposition.

Legislative Changes: Purpose of the License

13. Three questions were posed. They were:

- i. Should New Zealand's legislation specifically list the public health problems for which licenses can be granted under the Protocol?*
- ii. If you think New Zealand's legislation should list the public health problems, which ones should be specified?*
- iii. If you think that New Zealand's legislation should not list the public health problems, what definition of "public health problem" could be used?*

14. Only Sarah Meads and the Ministry of Health specifically addressed these questions. Ms Mead considered that prescriptive systems, such as Canada's, suggest that developing countries lack the ability to judge for themselves what drugs should be eligible for compulsory licenses, which undermines their right to self-determination. Ms Meads favours a broad definition of "public health problem", such as that used by Norway¹.

15. The Ministry of Health considers that any legislative implementation of the Protocol should not be prescriptive. Any regime should be simple and flexible. The approach taken by Norway is considered the most suitable for New Zealand. It is suggested that the amendment should ensure access to medicines, not only to deal with current health problems in developing countries, but also public health issues that may arise in the future.

Products for which a license should be granted

16. Two questions were asked here:

¹ Norway's legislation refers to "a state's current need for the product for health purposes as described in the notification".

- i. *The Protocol contains a definition of “pharmaceutical product”. Should this definition be adopted “as is” by New Zealand?*
- ii. *If the answer to the preceding question is “no”, and bearing in mind that any alternative definition must not be inconsistent with the Protocol, what alternative definition should be adopted?*

17. Sarah Meads supported using the Swiss definition², and broadening this definition further if this is not inconsistent with the Protocol. The Ministry of Health also supports using the Swiss definition, and considers this definition would be more consistent with New Zealand’s potential obligations to Pacific nations and other poor countries in the event of a pandemic or other public health emergency.

Eligible Countries of Importation

18. The questions on this topic were:

- i. *Should non-WTO members be included as eligible countries of importation?*
- ii. *If your answer to this question is “no”, why should non-WTO members countries be excluded?*
- iii. *Should any or all of the countries that have indicated that they will not use the Protocol as importing Members be excluded as eligible countries of importation?*

19. GSK considered that countries that indicated that they will not use the Protocol should be excluded as eligible countries of importation. They argue that New Zealand’s laws should not facilitate the breach by other countries of their international obligations. It was also considered that by excluding these countries, New Zealand would be indicating its political support for the Protocol.

20. Sarah Meads considered that non- WTO members should not be excluded as importing members. She also indicated that countries that may not have indicated that they will use the Protocol as importing members should not be excluded. The reasons given relate to the responsibility, of developing countries, to the well-being of the people in developing countries.

21. It should be noted that the Protocol does not require countries to indicate that they will use the Protocol as importing members. Some countries (all of them developed countries) have indicated that they would not use the Protocol.

22. The Ministry of Health agreed, for the reasons advanced in the discussion paper, that non-WTO members should not be excluded. The Ministry also considered that those countries (which include New Zealand) that have indicated that they would not use the Protocol as importing members should not be excluded.

² “Any medicine, active ingredient, diagnostic kit or vaccine which is patented or produced on the basis of a patented process and which is necessary to remedy public health problems such as HIV/AIDS, tuberculosis, malaria or other epidemics in the country of importation may be the object of a compulsory license.”

23. The Ministry of Health argued that exclusion of New Zealand as an importing member would not allow for the possibility that New Zealand may need to use the system to import in the case of national emergency or other public health crisis, or in cases of public non-commercial use. They also note that such an exclusion is not required by the Protocol, and that New Zealand should not assume any obligations or restrictions beyond those required by the Protocol.

Voluntary Licenses

24. Submitters were asked to consider the following statement and questions:

The requirement, in s46 of the Patents Act 1953, for applicants for compulsory licenses to take “all reasonable steps” to obtain a voluntary license may be stricter than the “make efforts” requirement of Article 31 (b) of the TRIPS Agreement.

- i. Should New Zealand amend its legislation to require applicants for compulsory licenses to “make efforts” to obtain a voluntary license?
- ii. If your answer to this question is “no”, why?

25. The Ministry of Health considers that the present legislative threshold for compulsory licenses imposes a higher test than is required by the TRIPS Agreement. Sarah Meads also took the same view.

26. GSK, on the other hand, takes the opposite view. They consider that the terms of Article 31(b) of TRIPS, by requiring applicants for compulsory licenses to have offered reasonable terms and conditions, over a reasonable period of time, are the equivalent of the New Zealand requirement take “all reasonable steps”.