JSCOT: TRIPS Amendment: Clarification Note

The Department of Foreign Affairs and Trade wishes to clarify and expand on certain points raised at the Joint Standing Committee on Treaties public hearing of 22 June (The Protocol Amending the TRIPS Agreement).

DFAT would like to reiterate that during our consultations with government agencies and the public, all stakeholders agreed that Australia should accept the Protocol. And we note that no witness at the hearing suggested that Australia should not accept it.

During the hearing, the Committee asked the whether Australia had a choice in accepting the Protocol. A fuller answer is that upon acceptance by two-thirds of WTO Members, the Protocol will enter into force and will apply to all WTO Members, including Australia. To that extent, Australia may not have an option about whether the Protocol will apply to Australia. However, it is important to note that the Protocol represents a flexibility, not an obligation. Australia need take no action as a result of the entry into force of the Protocol, and it will result in no substantive change to Australia's domestic settings unless Australia agrees to assist another country to access pharmaceuticals by using the compulsory licensing system under the Protocol. Furthermore, the Protocol does not represent a substantive change. Australia is already a party to the TRIPS Waiver, just as it might become a party to the Protocol, and the existing TRIPS waiver operates in essentially the same way as the Protocol that may replace it.

An issue raised during the hearing was that there have been no compulsory licence notifications under the TRIPS waiver since it was adopted in 2003. This does not, however, mean that the TRIPS waiver or Protocol are flawed. There are several good reasons for the absence of notifications. One of these is that least-developed countries have a transition period (until 2016) where TRIPS they are not bound by TRIPS. As they don't have to protect patents, they have no need to use the waiver. Need for recourse to the TRIPS waiver may also been substantially reduced by the option of parallel importation, particularly from India where many drugs are not covered by patent. Governance and capacity issues within developing and least-developed countries also impact on the use of the waiver.

A criticism was made of the Protocol during the hearing that it "has made permanent a burdensome drug-by-drug, country-by-country decision-making process, which does not take into account the fact that economies of scale are needed to attract the interest from manufacturers of medicines". In the department's view, the requirements stipulated within the Protocol are not overly burdensome, but rather comprise important steps to prevent leakage of pharmaceutical products made under the Protocol into developed country markets. We regard the case-by-case basis upon which the amendment will operate to be an important measure to ensure that the system operates appropriate to the needs of each country. In this way, the Protocol maintains an appropriate balance of rights in the TRIPS Agreement between the innovators and the users of technology.

Another issue raised was the need for economies of scale to interest drug manufacturers. This, in the department's view, is irrelevant to the issue of compulsory licensing. Governments use compulsory licenses to mandate the production of pharmaceuticals at marginal cost and, as a result, no commercial incentive exists for the involvement of pharmaceutical companies.