Improving the regulatory capacity of developing countries to manage risks associated with trade agreements

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Introduction

- Modern bilateral/regional preferential trade agreements (PTAs) involve more than just a change to tariff schedules.
  They now affect non-tariff areas of state regulation, incl. intellectual property, investment, services, government procurement, technical standards, sanitary and phytosanitary standards.
- Thus, they place demands on states to strengthen their regulatory capacities.
- Regulatory capacity for negotiating/management of PTAs is expensive, skill-intensive and requires infrastructure.
- Smaller/poorer states struggle to find this capacity, yet if they do not, PTAs may further drive health inequities.

Aim

- We assess the importance of regulatory capacity and coordination for managing risks to public health from PTAs, and suggest ways developing countries can improve this capacity.

The problem

- Managing the risks of PTAs is generally underestimated.
  e.g. At time of negotiation, it is difficult to know the real costs and benefits for public health due to difficulties predicting effects of specific rules in dynamically changing markets.
- There is a risk in entering into agreements where business interests have disproportionate influence on PTA text.

For developing countries

- Risk management problem exacerbated for most developing countries by inequality of bargaining power.
- Studies of PTAs between large developed countries and small developing countries find small countries give up a lot to gain a little. For example:
  The developing country takes on developed country regulatory standards without having the capacity of the developed country to manage the risks of those standards.

Examples

- Affordability of medicines and health equity in New Zealand threatened by provisions in Trans Pacific Partnership, a PTA currently under negotiation.
- WTO's Sanitary and Phytosanitary Agreement draws developing countries into complying with international standards set by e.g. Codex Alimentarius Commission.
  Many lack capacity needed to evaluate the public health costs /benefits of these food standards or influence the technical meetings that produce them.
- The most recognised example presently is WTO litigation of Australia's plain packaging legislation for tobacco products
  **In 1970s/80s, tobacco and other multinational companies (MNCs) pushed an international trademark agenda.*
  ** In 1988 a coalition of MNCs presented its IP draft text to govt players involved in negotiating Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Included was wording on the principle 'unjustified encumbrance of a trade mark', which 25 years later is the subject of WTO proceedings in which some countries argue Australia's plain packaging law breaches the principle*.

Understanding the full costs of TRIPS would have been difficult in the 1980s – this is precisely the point.

How might developing countries improve capacity to manage the risks of PTAs?

1) Recognize PTAs carry risks and costs that must be managed.
2) Not confuse this risk management task with compliance capacity and donor aid objectives – not accept institutional aid from those with compliance objectives.
   Accepting donor assistance packages for patent offices (as in the case with those provided by the EU to Southeast Asia) that do not address well-known problems of pharmaceutical patents will increase public health risks.
3) As resources are scarce, pick capacity targets, giving priority to creating nodes of excellence in public health regulation.
4) Creating these nodes of excellence might be easier by learning from regulatory experience of other countries.
   ** Brazil, China and India are developing countries fairly advanced in regulation.*
   ** E.g, Brazil's National Sanitary Surveillance Agency (ANVISA) is involved in examination/grant of pharmaceutical patents rather than the Brazilian patent office having all regulatory power over grant of patents. This provides some power to a public health perspective, and a safeguard against regulatory capture of a patent office. ANVISA is a node of excellence with which other developing countries might form ties – sharing experiences, data, perhaps emulating.*
5) Intensify collaboration and networking regarding a regulatory approach to PTAs.
   US private enforcement of public regulation depends on a legal culture not found in most developing countries. An African country is as likely to gain insights from studying South Africa's experience in regulating pharmaceutical companies that are as valuable as studying that of US.

Discussion

- States must manage the risks that PTAs pose to public health through regulation and not rely on others doing it for them.
- Developing countries in particular have to recognize the importance of this risk-management task.
- Not doing so has vast inequity implications.

A copy of the reference list is available on request – helen.walls@lidc.bloomsbury.ac.uk