

C3 | TRADE AND HEALTH

Health professionals generally see trade as a political issue, which is furthermore complex and removed from immediate concerns of providing affordable health care to a large numbers of people. Thus, traditionally, the health sector has generally kept away from debates related to trade.¹ It is, however, a fact that trade, directly and indirectly, has a profound effect on the health of the global population.

Neoliberal economic policies lead to the subservience of national policies to the influence of global conditions, institutions, and policies. It is manifested in national policies of trade liberalisation, deregulation of capital movements, privatisation of public services and enterprises, monetarism, elimination of, or cutbacks in, social welfare programmes, and reduction of taxes.

Trade liberalisation operates through policies that countries adopt as part of public policy (autonomous liberalisation), or it could be routed through multilateral and bilateral agencies, bilateral or regional trade, and plurilateral agreements. The remit of multilateral and bilateral trade agreements can extend beyond trade to the health sector. In exchange for proposed trade concessions or market access, these agreements include commitments on privatisation of health care, liberalisation of health services, health insurance, and protection of intellectual property rights (IPR). In addition, of course, the WTO agreement signed in 1994 contains several multilateral trade agreements that have an impact on health: Agreement on Trade Related Intellectual Property Rights (TRIPS), General Agreement on Trade in Services (GATS), Agreement on Technical Barriers to Trade (TBT), and Agreement on Application of Sanitary and Phytosanitary Measures (SPS).

After the signing of the WTO agreement, developed countries have used other avenues, as well, to push up the standard of intellectual property protection through bilateral and regional trade agreements. They have also initiated several initiatives for the enforcement of intellectual property rights, which have an impact on access to affordable medicines.

In this chapter we discuss some of the more recent global developments related to trade liberalisation, especially with reference to the impact on the health sector.

Use of public health safeguards in TRIPS

The TRIPS agreement was premised on the logic that strengthening intellectual property protection is essential for innovation in pharmaceutical



26 Demonstration by HIV+ve groups against Indo-EU FTA, New Delhi (Amit Sengupta)

sector to take place, thereby improving access through availability of new medical products. This is clearly a false premise, and the rate of innovation and development of new medicines has slowed down since the signing of the TRIPS agreement in 2004. On the other hand, there is mounting evidence that the strengthening of patent regimes will lead to an increase in medicine prices.²

When the TRIPS agreement was signed, developing countries were assured that public health safeguards, available to them in the agreement, could be used to ensure access to medicines.³ However, the post-TRIPS period is testament to the fact that these safeguards have rarely been used. There are several reasons why this is so: a) lack of technological capabilities, in the pharmaceutical sector in most low- and middle-income countries (LMICs); b) lack of capacity in many LMICs to incorporate the public health safeguards available under TRIPS in domestic laws; c) weak institutional and administrative mechanisms in LMICs to make use of public health safeguards, after their incorporation in domestic laws; d) political pressures exercised by developed countries to prevent use of public health safeguards available in the TRIPS agreement.⁴



27 Free trade or unfair trade? (Indranil Mukherjee)

As a consequence the use of public health safeguards in the form of compulsory licence has largely been limited to HIV/AIDS medicines. Only two countries have issued compulsory licences for products that treat other conditions – for avian flu in Taiwan⁵ and for cancer and hypertension in Thailand.⁶

The lack of manufacturing capacity in many LMICs was explicitly recognised as a hurdle to the use of compulsory licences by LMICs, as such licences could not be used to produce cheaper generics in the absence of domestic manufacturing companies. Paragraph 6 of the Doha Declaration on Public Health and the TRIPS Agreement in 2003⁷ had directed the TRIPS council to find a way out of this problem. The TRIPS council, subsequently, issued a waiver that allowed compulsory licences to be issued for export. This meant that countries with manufacturing capacity (developed countries as well as LMICs such as India, Brazil, China, etc.) could issue a compulsory licence to export a generic version of a patented drug to a country that did not have manufacturing capacity. However, the waiver included a large number of procedural hurdles and was, in practice, virtually unusable.⁸ As a consequence the provision has been used only once – to export HIV/AIDS medicine from Canada to Rwanda.

TRIPS plus measures in ‘free’ trade agreements

While the use of TRIPS safeguards remains important as regards efforts to secure access to medicinal products, another concern has taken centre stage in recent years. Through a large number of mechanisms, the terrain of intellectual property protection has shifted to include what are called ‘TRIPS plus’ measures. These measures are defined as those which require higher levels of intellectual property protection than those provided for in the TRIPS agreement. They would, thus, act as a larger barrier to access to medicines



28 The counterfeit confusion (Indranil Mukherjee)

than the TRIPS agreement as they nullify most of the public health safeguards nominally available in the TRIPS agreement. TRIPS plus measures, now being proposed through a number of mechanisms, including prominently the bilateral and multilateral ‘Free’ Trade Agreements, include measures such as: patent term extension; data exclusivity; linkage between the regulatory agencies and the patent office; limiting the use of TRIPS public health safeguards; and higher levels of IP protection (see Box C3.1).

From 1990 to 2007, the number of ‘Free’ Trade Agreements (FTAs) notified to the GATT or the WTO increased from 20 to 159. At present, over 250 regional and bilateral trade agreements govern more than 30 per cent of world trade.⁹ Most developed countries, including the US, the EU, Japan, Australia, Canada and New Zealand, are engaged in negotiating FTAs (or have concluded such agreements) with developing countries. A major driver of the proliferation of regional and bilateral trade agreements has been the perceived failure of the WTO to govern global trade. This, in large measure, has been a consequence of the intransigence of the powerful trading blocs (the US, EU, Japan, etc.) to accommodate the legitimate concerns of developing nations, and also because of differences between the EU and the US in some major areas (especially related to agricultural subsidies). As a result, ever since the WTO ministerial meeting in 1999 in Seattle, virtually every WTO ministerial meeting has concluded without a clear road map. The other driver of the new bilateral and regional agreements is the perception in developed countries that

they need to go beyond the WTO agreement and ratchet up the demand for binding commitments from developing countries.

Most of these FTAs are being negotiated in secrecy (with very little scope for civil society to intervene), and most have some or all of the ‘TRIPS plus’ measures we describe. Impact assessment studies of FTAs that are already in place paint a grim picture as regards access to medicines. A study by IFARMA of the EU-Andean FTA estimates that introduction of ‘data exclusivity’ and ‘patent term extension’ would lead to ‘an increase of 459 million USD in Peru’s total pharmaceutical expenditure in 2025 and a cumulative increase in expenditure of 1267 million dollars for the same year’.¹⁰ Another study on the EU-Canada FTA finds: ‘Payers – consumers, businesses, unions and government insurers – would face substantially higher drug costs as exclusivity is extended on top-selling prescription drugs, with the annual increase in costs likely to be in the range of \$2.8 billion per year.’¹¹ An impact study of the Central American Free Trade Agreement (CAFTA) anticipates huge rises in medicine prices in Guatemala.¹²

‘Free’ Trade Agreements also contain other provisions that have an impact on health. These include provisions in the ‘investment chapter’ of such agreements and provisions related to ‘government procurement’. (See Box C3.2.)

Enforcement of intellectual property rights

Several initiatives are now under way to enhance the standard of intellectual property enforcement. These initiatives widen the scope of the definition of counterfeit (which originally refers to a particular type of trademark infringement) to include infringement of all types of intellectual property rights and also criminalise IP infringements. Further, these initiatives also broaden the scope of border measures and allow customs authorities to seize goods in transit for the suspected infringement of all types of intellectual property rights. These initiatives stand to contravene the TRIPS agreement, by which states are obligated to treat only counterfeit trademark infringement and copyright piracy as criminal offences. Similarly, countries are also obliged to apply border measures only in cases of importation of counterfeited trademark or pirated copyright goods.

The application of border measures on goods in transit has already resulted in denial of access to medicines to people in developing countries. For instance, under the Council Regulation 1383/2003, the EU allows its member-country customs authorities to seize goods in transit citing suspected IP infringement. Using this regulation, customs authorities in the Netherlands and Germany have repeatedly seized medicines on their way to Latin America and Africa. Except one, all seizures were on consignments originating from India. Subsequently, India and Brazil approached the WTO Dispute Settlement Mechanism (DSM) in May 2010¹³ but there is no clear information with regard to the current status of the complaint.

Box C3.1 'TRIPS plus' measures in FTAs

FTAs incorporate provisions that demand higher standards of IP protection, not contained in the TRIPS agreement. Thus developing countries stand to lose the limited public health safeguards that are contained in the TRIPS agreement. Some of the key 'TRIPS plus' measures include:

Patent terms extension: Many FTAs contain provisions that provide for extension of the patent term beyond the 20 years mandated by TRIPS, in cases of what are called 'delays' in granting a patent. Operationally, such provisions extend patent terms beyond 20 years and delay the introduction of cheaper generic medicines.

Limitations on compulsory licensing: The compulsory licensing provision is a key safeguard in the TRIPS agreement. It allows countries to draft laws that allow generic manufacturers to manufacture and sell medicines, even if the medicines are under patent protection. Countries have the freedom to choose the grounds for such licences (for generic manufacture of patented drugs) to be issued. Grounds that can be used to issue a compulsory licence can include high prices of patented medicines, non-availability, non-working of the patent (that is, a patentee does not manufacture after it is granted a patent), etc. Such licences on patented medicines can be issued for non-commercial use as well as for commercial use. There are specific provisions for such licences to be issued in situations of national emergency/extreme urgency, but they can also be issued without such a situation being in existence. However, provisions in many FTAs restrict the grounds and the situations in which a compulsory licence can be issued.

In order to widen the net, the EU has also started providing support in third countries to enhance IP enforcement. It is widely assumed that the EU is primarily responsible for initiatives to introduce anti-counterfeit legislations in many African countries – for example, in Kenya,¹⁴ Uganda,¹⁵ and Zambia.¹⁶ The East African Community (EAC) came up with a regional draft anti-counterfeit policy/bill in 2009. The EU is understood to have funded the Ugandan trade ministry to draft specific IP enforcement legislation, which threatens access to medicines in Uganda.¹⁷ The EU is also using the medium of bilateral and regional trade agreements to enhance IP enforcement standards.

Misuse of 'anti-counterfeit' trade measures

The conclusion of the Anti-Counterfeiting Trade Agreement (ACTA) poses a major threat to access to medicines. ACTA is a secretly negotiated treaty among governments of the United States, the European Commission, Japan,

Limitations on parallel imports: The TRIPS agreement also allows countries to import cheaper patented medicines from another country. FTAs can restrict such importation by providing that such imports will be allowed only if the patent holder agrees (which is tantamount to preventing such imports as a patent holder would never allow import of a cheaper version of its drug).

Providing for data exclusivity: Many FTAs include data exclusivity provisions, though it is not a TRIPS requirement. Data exclusivity refers to a practice whereby, for a fixed period of time (usually 5–10 years), drug regulatory authorities do not allow the data that the originator company files to get marketing approval to be used to register a generic version of the same medicine. It means that if a patent holder gets marketing approval for a drug based on data of clinical trials, the same data cannot be used to register a drug by a generic company. In practice this provides a patent-like monopoly, as the alternative available to generic companies is to duplicate expensive clinical trials in order to get marketing approval. Data exclusivity allows monopoly powers to companies even in situations where a country is not required to provide patent protection. This is true for all Least Developing Countries (LDCs), which do not need to allow patents in medicines till 2016. Further, the US is also pressing for data exclusivity for new use of an existing drug, which can push the monopoly enjoyed by the originator company beyond the 20-year patent period if the new use is ‘discovered’ just when a patent is about to expire. Data exclusivity provisions, in situations where medicine patents are allowed, delay the entry of generic manufacturers when a compulsory licence is issued.

Switzerland, Australia, New Zealand, South Korea, Canada, Mexico and Morocco.¹⁸ The agreement goes beyond the traditional concept of ‘counterfeit’ and includes a wide range of intellectual property enforcement issues. The specific details of ACTA were kept secret until April 2010. On 9 March 2010, the European Parliament passed a resolution¹⁹ seeking transparency on ACTA negotiations. It called on the European Commission and the Council to grant public and parliamentary access to ACTA negotiation texts and summaries. However, it also called on the European Commission to continue the negotiations on ACTA to improve the effectiveness of the IPR enforcement system against counterfeiting.

The ACTA text allows customs authorities in countries to seize goods ‘suspected’ of infringing trademarks, copyrights and other IPRs. It allows for seizures even when there is only a ‘prima facie’ case of IPR infringement. The agreement (ACTA) thus seeks to institutionalise mechanisms that could

lead to a spate of seizures of generic drugs in transit, of the kind described earlier. Further, ACTA's application of border measures to goods in transit negates provisions of the Doha Declaration on Public Health aimed at making effective use of compulsory licensing for countries with insufficient or no manufacturing capacities.

The WTO argues that the TRIPS agreement allows members to establish levels of protection that are more extensive than those it prescribes, provided they do not contravene the Agreement on TRIPS (Article 1.1).²⁰ However, enforcement measures conceived under ACTA clearly violate Article 41.1 of the TRIPS agreement, which spells out the general obligation on IP enforcement. According to Article 41.1, '... These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.'

Another recent development has been the creation of 'public-private partnerships' within multilateral organisations such as the World Customs Organisation (WCO), the World Health Organisation (WHO), and the International Police Organisation (INTERPOL), to enforce intellectual property rights. These include: Standards to Counter Intellectual Property Rights Infringements (SECURE) within WCO, International Medical Products Anti-Counterfeiting Task Force (IMPACT) within WHO (see Chapter D1 for a detailed discussion on IMPACT and its possible consequences), and the Pharmaceutical Crime Initiative within INTERPOL. All three initiatives attempt to conflate IP with quality, safety and efficacy of medicines.

While it is possible for a product to be both counterfeit and substandard, these are nevertheless different problems. Medicines of poor quality, i.e. substandard medicines, represent a threat to public health. However, by confusing the issues of counterfeit and quality, access to legitimate generic medicines (of good quality but which may infringe the patent laws in some countries) is curtailed.

Trade in health services

The importance of trade in health services is reflected in the fact that liberalisation of health and social services has been on the international trade agenda for many years.^{21, 22} According to WTO estimates for 2008, services represented more than two-thirds of the world gross domestic product (GDP).²³

The General Agreement on Trade in Services (GATS) came into force in 1995, as part of the WTO agreement. It aims to eliminate barriers to trade in the services sector, including financial, information technology (IT) and legal services, telecommunications, transportation, construction, and retail, as well as educational, environmental, health, and social services.²⁴ The GATS negotiations cover four types of international activities that pertain to health care: the delivery of health services across national borders, e.g. the outsourcing of telemedicine (mode 1); patients travelling abroad to receive treatment (mode

Box C3.2 FTAs: the devil lies in the details

The devil, as they say, lies in the details. Health activists often miss out on key areas of concern in FTAs that are buried in different ‘chapters’ (FTAs have different chapters dealing with different areas, such as IP, manufacturing, services, investment, agriculture, etc.)

Appropriation clause in investment chapters: A major area of concern related to investment chapters in most FTAs is that they allow private companies to file cases against governments. So they subject countries to the risk of litigation by corporations from or based in another country. This might be based on a company’s objections to the host government’s environmental, health, social or economic policies, if these are seen to interfere with the company’s ‘right’ to profit. The biggest issues relate to the provisions for compensation for ‘expropriation’, which can be direct (as in cases of nationalisation) or indirect (policies or actions that impinge on the profitability of the company concerned).³⁹

These are not imagined consequences. For example, in November 2000 the multinational water infrastructure company AdT filed for arbitration and sought \$25 million from the Bolivian government as compensation for its lost investment, including expected profits, after the government was forced to reverse a disastrous water privatisation attempt in Cochabamba. Similarly, in 2010 Philip Morris International – the world’s second-largest cigarette company and manufacturer of brands such as Marlboro and Red & White – sued the Uruguayan government for its regulation that requires tobacco companies to cover 80 per cent of their cigarette packs with pictorial tobacco-warning labels.⁴⁰

Government procurement: The EU has been prominent in pushing for an agreement on ‘government procurement’ in FTAs. This was one of the ‘Singapore issues’ that were rejected by developing countries in the Cancun ministerial meeting of the WTO in 2003. In a Government Procurement Agreement (GPA) all members have an equal right to bid for tenders in whatever the government of another member country of an FTA procures. So, for example, in an FTA with the EU and a developing country where a GPA is signed, the latter will have to allow companies to bid for contracts for all government procurements. This could mean that when tenders are floated to procure medicines for public health facilities, companies based in the EU would have the right to bid for such contracts. Such a situation can also affect the ability of governments to determine how food for public distribution systems (PDS) would be procured. In addition to such direct impact on the health sector, a GPA affects different sectors of the economy, and hinders the efforts by developing-country governments to plan for the growth of its domestic industry.

2); the presence of a foreign provider in a health services market (mode 3); and health professionals working in a foreign country (mode 4).²⁵

The commitments to liberalise under GATS are made in successive rounds, with each country making individual commitments, rather than agreeing to a collective ‘single undertaking’ to carry out reforms. Theoretically, this gives countries more scope to refrain from making commitments on topics or areas that are domestically sensitive. But the way in which GATS is negotiated – that is, in successive rounds – means that peer pressure can be applied on countries to liberalise in new areas.²⁶

Concerns abound that application of GATS to the health sector will result in inappropriate policies being applied to health services, thereby leading to suboptimal health outcomes,^{27, 28, 29, 30, 31} There is concern that GATS may affect future policy options by pre-empting or preventing reforms that are aimed at providing publicly funded health services^{32, 33, 34}

Here it may be underlined that while the WTO recognises essential government services as lying outside GATS, according to GATS Article 1.3, a government service is one which ‘is supplied neither on a commercial basis, nor in competition with one or more service suppliers’. This creates a definitional problem of exactly what a government service is.^{35, 36, 37}

Conclusion

Trade policies adopted by national governments have profound public health implications. Yet trade negotiations are seldom undertaken by those with a proper understanding of these links. If health policy is subject to trade law, and if it must work within the constraints of trade law, in the absence of health sector engagement, the health policy-makers will have less influence over the policies they make. They will become ‘policy-takers’ who must adapt to the effects of trade law. In this situation, health policy will be made through trade agreements.³⁸

Notes

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