

Effect of TRIPS on Pricing, Affordability and Access to Essential Medicines in Bhutan*

DR. TANDI DORJI**

Abstract

Health care in Bhutan is free and the Essential Drugs Program under the Ministry of Health has been able to provide high quality effective medicines for the people. The bulk of these medicines is imported from generic companies in India, where based on its 1970 patent laws, copies of patented drugs were manufactured using different processes which made it cheap and affordable for many developing countries. However with the enactment in India of its new patent laws in 2005 and with Bhutan becoming a member of the WTO, the affordability of those medicines developed post-1995 will become severely limited. With both India and Bhutan becoming TRIPS compliant, we will have to incorporate and amend our national laws and review how best we can utilize the flexibilities in TRIPS, afforded by the Doha Declaration and the Decision of the General Council. We need to address these issues if we are to safeguard public health and to continue to access affordable high quality medicines for our people.

Introduction

With the small population of approximately 700,000, Bhutan has made significant strides in health since 1961, when the health department and the first hospital were established.¹ Health care is free for all citizens, delivered through public hospitals and dispensaries. Access to health care is good with 90 % of the population having access to a health center within 3 hours walking distance.² The Drugs, Vaccines and Equipments division (DVED) is responsible for the purchase and supply of all medicine, throughout the country.

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** Pediatrician, JDWNR Hospital, Thimphu.

¹ Planning Commission (1999). Bhutan 2020. A vision for peace, prosperity and happiness., Thimphu: Royal Government of Bhutan.

² Department of Health Services (2000). A Report: National Health Survey 2000, Thimphu: Royal government of Bhutan.

In the 9th five year plan (2002-06) the ministry of health received 6.4 % of the total budget outlay, which is one of the highest in the region.³ Like most developing countries procurement of pharmaceuticals accounted for the second highest expenditure.⁴ The Essential Drug Program (EDP), which began in 1987, distributes medicines to different levels of care and is considered exemplary by the World Health Organization (WHO).⁵ It noted that 90 % of people had access to high quality essential drugs, and only 0.75 % of the overall budget was wasted on expiry drugs. The National Drug Policy guides the procurement and supply of medicines usually from pre-qualified suppliers and through central procurement. The government was thus able to negotiate and purchase these essential medicines at a price that was 50% below the world market prices.⁶

Regular prescription and drug utilization surveys enable pharmacists to interact closely with doctors and ensure that the medicines are put to their best use with minimum waste. The people thus benefit from these policies, with access to health care made available by the government and the EDP ensuring timely availability of high quality drugs. However with Bhutan on the verge of becoming a member of the World Trade Organization (WTO), we will have to comply with the TRIPS (Trade related aspects of intellectual property rights) agreement and this poses several challenges to accessing and being able to afford essential medicines. To aggravate the situation, India who is our biggest source of essential drugs, enacted its new patent laws and like other least developed countries (LDC), Bhutan will find it difficult to maintain the present system of providing free, cheap, high quality medicines.

There have been several discussions from various sectors on the advantages and disadvantages of becoming a member of the WTO here in Bhutan, however very little has been discussed or written from the health perspective. This paper will therefore discuss the issue of access and

³ National Statistical Bureau (2004). Statistical Yearbook of Bhutan, 2003, Thimphu: Royal Government of Bhutan.

⁴ Hogerzeil, H.V. (2005). "The concept of essential medicines: lessons for rich countries," British Medical Journal, 329.

⁵ Organization WH. Bhutan: Health infrastructure. In; 2002. Available at <http://w3.who.sea.org/ehp/pdf/books/bhu-2003/resources.pdf>

⁶ Group TFW (2004). Millennium project: Access to Essential medicines, Geneva: United Nations Development Fund (UNDP).

affordability of medicines in relationship to TRIPS, which is the major consequence for health on Bhutan becoming a member of the WTO.

Background to TRIPS and its challenges to developing countries

In 1994, when the WTO was formed, its member states adopted TRIPS as a means for securing intellectual property protection for pharmaceuticals and other technologies. The reason for this was to encourage funding and to provide incentives for big pharmaceutical companies to continue to research and develop new drugs. It costs between US \$402-793 million,⁷ and takes 10-15 years of research to put new medicines into the market. TRIPS enabled these major R&D pharmaceutical companies to recover their costs by way of patents. As per article 27 of the TRIPS agreement, patents on these new drugs provided exclusive rights to the producer and prevented others from “making, using, offering for sale, selling or importing” the new product for a period of 20 years, during which time they not only regained their cost but also made huge profits. Developing countries were given until 2000 to comply with TRIPS provisions and LDC’s were given six additional years until 2006, which was subsequently extended to 2016 with respect to medicines.

Although theoretically this seems fair, in reality this puts developing countries at a huge disadvantage.

Drug companies are driven by profits and therefore tend to invest in developing medicines for diseases that are more prevalent in Western countries, mostly addressing the so called lifestyle diseases as these richer and bigger markets helped generate better profits. Diseases that are rampant in developing countries are neglected and it is for this reason that we have not seen any new drugs for diseases like tuberculosis, leishmaniasis, shigellosis and meningitis for the last three or four decades. Between 1975-1997 there were 1,223 new chemical entities commercialized, out of which 379 (30.9 %) were considered as therapeutic innovations and only 13 were specific for tropical diseases and sadly only 4 were produced as a direct result of R & D conducted by pharmaceutical

⁷ DiMasi, J.A., Hansen, R.W. and Grabowski, H.G. (2003). “The price of innovation: new estimates of drug development costs,” *J Health Econ*, 22:151-185.

industries.⁸ Even when new drugs are developed (e.g. artemisinin for malaria), they are too expensive to be affordable for a vast majority of people that need them.

Developing countries on the other hand lack technical, financial and human resources to carry out research and develop new drugs, especially given that they must follow ‘Good manufacturing practices’. This is a process by which new drugs have to pass through various stages to ensure that it is effective, safe and of high quality before the drug is marketed. All these requirements lead to high production costs, thereby making patented drugs expensive and out of reach for the poorer section of the world.

Up until 2005, India had followed its own patent laws established in 1970, which granted patents to processes only and not for products. Therefore by using different processes such as reverse engineering, India was able to produce generic versions of patented medicines and this led to the growth of a huge generic industry, which supplies 70% of the world’s generic medicines. In addition, for registration of these generics and to prove that the drug was bio-equivalent (of the same standard in terms of efficacy and quality) to the original patented drug, it did not have to pass through the same stringent process of testing and providing supportive data. It could use the evidence of the data submitted by the original company or proof of the original drugs registration by a stringent regulatory authority in another country. It also had the freedom to combine multiple patented drugs into a single tablet/capsule (there are no patents on fixed dose combinations) thereby making it convenient for the patients in terms of compliance. Since these drastically reduced the costs of production, generic medicines were much cheaper, leading to a major reduction in drug prices. The effects of these price differences were significantly seen with anti-retroviral medicines, which are used for treating HIV/AIDS patients. With the pandemic reversing the development achievements in many African nations and threatening to do the same in Asia, a reduction in prices of anti-HIV/AIDS drugs from an unaffordable US \$ 10,000 (for treating one patient for a year) to an affordable US \$ 140 was a boon and a blessing for many developing countries combating this disease.

⁸ Pecoul, B, Chirac, B, Trouller, P et al. “Access to essential drugs in poor countries: a lost battle?” JAMA. Available at: <http://www.accessmed-msf.org/prod/publication.asp>

While the countries of the south, non-governmental organizations (NGO's), civil society and international humanitarian organizations welcomed this, the major drug companies were fuming, seeing their potential profits dwindle. They continued to exercise their influence with the support of their governments and pushed the WTO for more stringent measures to follow TRIPS protocol and on several occasions brought governments to the WTO for arbitration, which often ended in embarrassment for these companies.⁹ At the same time, developing countries continued to fight for more recognition of public health concerns and better access to cheap, effective and high quality generic drugs. This conflict came to the forefront in November 2001 at Doha, Qatar, which was regarded by many as a victory for developing countries.

The Doha Declaration of 2001 ensured access to cheap high quality generic drugs for diseases such as HIV, malaria and tuberculosis. It allowed countries such as India, Brazil and Thailand to use certain flexibilities within TRIPS, especially compulsory licenses, to continue to manufacture these essential drugs in the generic form.¹⁰ Article 31 (f) of TRIPS however, stated that compulsory licenses for the manufacture of medicines were to be issued “predominantly for the supply of the domestic market of the member”.¹¹ Non-Producing Countries (NPC), like Bhutan, with no domestic pharmaceutical industry or market, cannot make use of compulsory licenses, and importing cheap generic drugs from India is the only lifeline. The only relevant comment for such countries from the declaration, is the instruction given to the “Council for TRIPS to find an expeditious solution to this problem” by 2002. Subsequently after nearly 2 years of debate in 2003, the General Council by way of its 30th August decision¹² agreed to waive article 31 (f) of the TRIPS agreement for

⁹ Brazil, Abbot, & AIDS drugs patents. Available at: http://www.natap.org/2005/HIV/070805_01.htm

¹⁰ World Trade Organization (2001). Declaration on TRIPS agreement and public health. Ministerial declaration. Ministerial Conference, fourth session, 9-14 November 2001, DOHA. WT/MIN (01)/DEC/2, Available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

¹¹ World Trade Organization. Agreement on Trade related aspects of intellectual property rights. Part II, Standards concerning the availability, scope and use of Intellectual property rights, Article 31 (f). Available at: http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm.

¹² WT/L/540 and Corr.1. Decision of the General Council of 30 August 2003. Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and

LDC's and this was further supplemented with a statement by the General council chairman in 2003. Although several concessions were made and many of the points clarified, it made implementation of the flexibilities cumbersome and impractical.¹³ Countries intending to import or export medicines had to pursue several labyrinthine procedures and fulfill all the criteria as set out by the council making it unlikely for any member to use it effectively. Even if Bhutan attempts to meet the requirements mentioned in the decision, it is unlikely that the Indian companies willing to export drugs will take the initiative or the effort to fulfill their part of the criteria because of the myriad of labyrinthine procedures and the relatively small demand.¹⁴

India's decision to become TRIPS compliant with the passing of the Indian patent act by parliament in March 2005 will further aggravate the situation. Amidst a walkout by the opposition party, the controversial law was passed, and what was disheartening for most developing countries was that the law went beyond what was required by TRIPS.¹⁵ Under the new law, besides new chemicals and products, patents can also be given for formulations, new drug delivery systems and combinations, making it possible for companies to acquire patents on new uses of old drugs and on new combination of old drugs. This will severely restrict access to pharmaceuticals, even for those drugs that were made prior to 1995, which are exempt from patent laws. The new laws also make the exporting of compulsory licensed drugs illegal if the importing country does not have a license too. For Bhutan, which does not have to comply with TRIPS until 2016, and where there are no patents for any drugs, it seems absurd to issue a compulsory license for a non-existent patent. With limited financial resources and heavily dependent on donors, Bhutan will not be able to afford the more expensive patented drugs. This can have serious impact on the sustainability of the present provision of free medicines.

public health. Available at: http://www.wto.org/English/tratop_e/trips_e/implement_para6_e.htm

¹³ Correa, C.M. (2004). Implementation of the WTO General Council decision on paragraph 6 of the DOHA declaration on TRIPS agreement and public health. Department of Essential drugs and medicine policy, Geneva: World Health Organization.

¹⁴ For example the number of HIV infected people is only 72 and there are a few hundred with tuberculosis and malaria. (Annual health bulletin 2003. Ministry of health, Royal government of Bhutan)

¹⁵ Sharma, D.C. (2005). "Indian patents may hamper access to anti retroviral globally," *The Lancet*, 5: 136

Effect of TRIPS on pricing, affordability and access

Given its geographical location and rapid globalization, Bhutan reluctantly began its accession to the WTO in 2004, aware of the many pitfalls and the heavy disadvantages that it faced.¹⁶ However, very little discussion took place with regards to TRIPS and public health, and especially with affordability and accessibility of drugs. The application of national laws can still assist poor countries in accessing affordable drugs, however with limited trained professionals in all sectors we are yet to address such issues and to amend and refine our trade laws, in particular those related to TRIPS. Even after establishing relevant laws, it will be essential to have a system in place and a common understanding between all sectors in safeguarding our rights to use the flexibilities because companies can still find ways to block the export of drugs, as was seen in Philippines, where after issuing compulsory license for 51 drugs, only 1 managed to be distributed and that too after 10 years of effort.¹⁷

Bhutan also depends upon bilateral agencies and the UN for much of our revenue. For example, in 2000, 27.5% of our expenditure for public health came from external sources.¹⁸ Even though we spend a high percentage of our budget on health, it will be difficult to sustain the delivery of free medicines and continue our policy of free health care. Insurance companies are unlikely to take over the financing of health care because the numbers of clients are likely to be small and because of the absence of private hospitals and medical facilities in Bhutan. Moreover, more and more patients, those who can afford to pay the premiums will seek care in third countries making such ventures for insurance companies non-viable. Therefore, unless alternatives are explored and tested, Bhutan will not be able to afford the patented drugs with the present budget.

¹⁶ Wangyel, Tashi (2004). "Rhetoric and reality: An assessment of the possible impact of WTO on Bhutan," in *The Spider and the Piglet*, Thimphu: The Center of Bhutan studies.

¹⁷ Correa, C.M. (2004). *Implementation of the WTO General Council decision on paragraph 6 of the DOHA declaration on TRIPS agreement and public health*. Department of Essential drugs and medicine policy, Geneva: World Health Organization.

¹⁸ World Health Organization. Health resources: Bhutan. Available at <http://w3.who.sea.org/cntryhealth/bhutan/bhuresource.htm>.

Although health services will be accessible, the provision of free drugs may not be possible unless some mechanism of charging fees is developed. This will then lead to essential drugs becoming inaccessible to a majority of the population. Because poor people tend to pay out of pocket for medicines, there is a danger of having a 2-tier system of access, one having access to effective expensive drugs and the other to older, less effective, patent expired generics.¹⁹

Options for utilizing the TRIPS flexibilities

We are not required to be TRIPS compliant till 2016; however, since we do not have a domestic pharmaceutical industry, we are dependent on other countries, predominantly India, which has not only become TRIPS compliant but has also implemented its national laws incorporating these changes. It is for this reason that we need to address TRIPS and other issues in relation to public health so that we continue to safeguard the health of our people and ensure access to affordable and effective medicines. As a LDC/NPC, Bhutan is eligible to utilize the Para 6 Decision as an importer and to purchase generic medicines from any manufacturer. The only requirement as per the General Council August decision is for us to make a notification to the WTO in this regard. However for the exporter there are several procedures; seek voluntary license from the patent holder on commercially reasonable terms for a reasonable period, seek and obtain a compulsory license from its government, manufacture and export only the specified amount, pay royalties to the patent holder based on the commercial value in the importing country, investigate the patent holders product in the importing country and differentiate it significantly and prominently, seek registration and prove bio-equivalence to the regulatory authority in the importing country, and notify to the WTO along with postings of the entire detail on its website. This same procedure has to be replicated for every individual drug and for every country to which the exporter intends to export! Given these procedures, the consequent delay in production, and the cost implication, no generic manufacturer would be inclined to take the initiative, especially when you consider the small demand of the Bhutanese market.

¹⁹ Mudur, G. (2005). "Changes to India's patent law may deny cheap drugs to millions," British Medical journal, 330: 692.

For Bhutan, the options available from the TRIPS flexibilities are to import no-patent drugs (older) without restriction or to negotiate with exporting countries for issuing of compulsory license for export. There are no restrictions on importing medicines from a no-patent country, but where there are patents, such as in India, we can import either only non-predominant amounts or an unlimited amount depending upon whether a ordinary compulsory license (Article 31 (f)) or a compulsory license to effect Article 31 (k) (related to patent abuse) is issued in the exporting country. Both of these are unlikely because of the limited commercial benefits for the drug manufacturer, an incapacity to reach economies of scale, and its adverse impact on foreign direct investment.

Another option to consider is to seek and negotiate with the exporting country for an Article 30 Limited exception export, whereby it permits a pharmaceutical company to manufacture products for export to a no-patent country or in response to a compulsory license from a NPC. This is considered by many, including international organizations like the World Health Organization, to be the most efficient and expeditious way to access cheaper generic medicines. However, there is very limited experience in using this clause and it therefore may be considered risky by the manufacturer. It will also require strong legislative authority and the support of the government. Developed countries and the patent holder can still challenge this limited exception rule and bring the case before the WTO. But given the commercial risk, many exporters will not have enthusiasm for this route.

Therefore, even though the Doha Declaration and the Decision of the Council promises to ease access to essential medicines for developing countries like Bhutan, in practical terms it will be more difficult to do so. The inability to utilize all the flexibilities afforded by these decisions, absence of strong national laws and legislations, and the fear of repercussion from powerful Western governments and lobbies pose serious threats to LDC's efforts to safeguard public health. Moreover, there is a constant danger of powerful countries adding TRIPS plus provisions into any bilateral or regional trade negotiations, which effectively deny these very flexibilities.

Recommendations

The first and foremost action that we need to take in respect to TRIPS and public health is to develop national laws that incorporate TRIPS so as to safeguard the country's ability to import and deliver high quality drugs to its people. Regulations and legislations should address such issues as: granting of compulsory license to import drugs for government non-commercial use without prior notification; import and re-export within the region; registration of generic drugs and proof of bio-equivalence; limiting patent holders' rights of appeal; setting royalty rates; defining international exhaustion regimes; and above all to legally enable the EDP and the Ministry of Trade to resort to all the flexibilities in the TRIPS agreement and related texts. At the same time, laws to prevent the re-export of licensed generics should also be made and enforced in order to gain the confidence of patent holders. Consultation should be held between the Ministry of Health, the Ministry of Trade, the Foreign Ministry, the Royal Court of Justice, and the relevant international organizations that provide technical assistance. The waiver offered by the 2003 council meeting must be incorporated as a solution through urgently needed national laws.

Secondly, negotiations with the Indian government through regional organizations, such as SAFTA (South Asian Free Trade Agreement), should be initiated soon in order to address ways to increase access to generic drugs. A regional approach would benefit both the manufacturer in terms of reaching economies of scale and the member countries as exemplified by the African Intellectual Property Organization. The decision of the General Council in paragraph 6 also encourages such co-operation and specifically mentions that "Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question." Another mechanism that could be employed is to have a centralized pooled system of purchasing essential drugs. Pooled procurement, like the Eastern Caribbean Drug Service²⁰ helps member countries to purchase drugs from a single manufacturer and

²⁰ Rouselle, M.F. and Burnett, F. "Cost containment through pharmaceutical procurement: A Caribbean case study," *International Journal of Health Planning and Management*, 11 (2): 135-57.

because the bulk ordered is large, helps to negotiate prices and bring them down to affordable rates.

LDC's do not have to comply with TRIPS until 2016, and so Bhutan should take full advantage of the flexibilities accorded and in the meantime develop a pool of professionals from the different departments to address all the issues of TRIPS. For the Ministry of Health and especially the procurement division of the EDP, it is important that key personnel are trained to address these issues nationally and internationally so that uncertainties about patent status do not create a barrier. They should also ensure that appropriate policies on selection, purchase, appropriate taxes and prescribing practices are drawn up so that these factors do not feature in the rise of drug prices.²¹

Bhutan should continue to push for simpler and faster procedures to benefit from compulsory licenses, differential pricing and the waiver of article 31 (f). With other partners Bhutan should urge the WTO to explore new ways to benefit poorer countries, such as equity pricing,²² automatic licensing and fixed royalties for patented drugs.²³ It should negotiate with India on parallel import mechanisms and also on immediate export with a notification from Bhutan, without the cumbersome procedure of getting a compulsory license in India.²⁴

²¹ Henry, D and Lexchin, J (2002). "The pharmaceutical industry as a medicines provider," *The Lancet*, 360: 1590-95.

²² Chaudhuri, S., Goldberg, P.K., and Jia, P. (2003). "The effect of extending intellectual property rights protection to developing countries: A case study of the Indian pharmaceutical market," National Bureau of Economic Research, working paper 10159, Cambridge.

²³ Chatterjee, P. (2005). "India's new patent may still hurt generic drug supplies," *The Lancet*, 365: 1378

²⁴ Ahmed, K. (2005). "India's new patent bill threatens generic industry," *The Lancet*, 5: 265.

Summary

Bhutan has an effective EDP with more than 90% of its people having access to high quality medicines, mainly generics imported from India. With India's new patent laws, the sustainability of the EDP and free health care policy is threatened. Without a domestic pharmaceutical industry, a compulsory license is unlikely to benefit Bhutan and we should rely instead on the waiver issued by the council in 2003. It is important that Bhutan enact its own national laws to safeguard affordability and access to quality drugs and explore all the flexibilities accorded in the Doha Declaration.

It should also build a strong technical professional team to address these issues nationally and internationally. It is important to forge ties with its neighbours within the region to set up mechanisms to protect the fundamental right of its citizens to quality health care. It must ensure that its citizens have access to quality and effective drugs at a cost which the country can afford. In this highly globalised and unequal world, this will only be possible through its own political will.