วารสารวิชาการสาธารณสุข
ปีที่ 29 ฉบับพิเศษ มกราคม - กุมภาพันธ์ 2563

Journal of Health Science
Vol. 29 Special Issue, January - February 2020

International Trade Agreements and Impact on the Medicine System: Causal Relations?

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Abstract This article comprehensively reviews and analyses knowledge and information relating to international trade agreements and their implications during the past 17 years, both within and external to Thailand. To reveal the implications and impact systematically, the conceptual framework for analysis was drafted and the implications were mapped along the medicine value chain. The mapping shows cross-link of the implications and took concerns of health sectors. Focusing on medicines, despite of positive impact, international trade agreements have had significant negative impacts on the Thai medicine system. There is worldwide recognition that expensive prices and higher expenditure of medicines result from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); this research identified further implications including: the opening up of market access to government procurement and limitations on policy space for medicine management systems as well as public health. This paper also demonstrates the experiences of Thailand, India and Malaysia regarding TRIPS flexibilities. It was shown that all three countries exercised "other use without authorization of the right holder", which is a TRIPS flexibility, to strike the balance between individual right and obligation in access to affordable essential medicines, although difficulties and consequences were found in the process of exercising this right. Evidence shows that Thailand, as a developing country, may support the voluntary license but must keep all TRIPS flexibilities, including the compulsory license, as tool to overcome barriers to access and ensure the human right to health. Further system research as well as investigation of cross-country impact of FTAs in and among ASEAN members are recommended.

***Keywords*: international trade agreement; implication; impact; medicine; expenditure; compulsory license; government use of license; voluntary license**

Introduction

Economic growth is the backbone of a country's development and income generation is a source of government budget to support all aspects of development including health. One popular strategy many countries favour in driving economics and trade is through international trade agreement. As an international law, parties are bound to FTA commitments, which have measures and punishments. The agreements traditionally aim to support export industry and business by setting concrete trade rules, access to other markets and removal of trade barriers through tariff and non-tariff measures. It was found, however, that the new generation of agreements is beyond trade in goods, and is comprehensive and ambitious. It broaden trade issues to include the protection of investors; setting higher standards for sanitary and phytosanitary measures; setting higher standards of labour; promoting protection of the environment; regulating the legislative process of government policy regarding transparency and participation; increasing access to government procurement and removing the offset of state owned enterprises, according to fair competition and access to other market; extending the rights and market exclusivity of intellectual property, and so on.[1-3] FTAs containing these issues are probably not new for developed or high-income countries, but they are the new generation of FTAs for developing or middle-income countries including Thailand.

Recently, Thailand elected a new government which recommended a policy of pursuing pending and new trade negotiations.[4] This article aims to reveal the following: (1) the implications for and impact on health of the new generation international trade agreements; and (2) how some countries including Thailand exercised the right of TRIPS flexibilities to mitigate the long-term impact of TRIPS in the area of access to medicines as an important issue of a building block of a well-functioning health system.

This article reviewed the following: literature, both published and grey, on trade agreements and impact on medicine; press releases and news of key government organizations and relevant stakeholders and civil society organizations such as Third World Network, Medicins Sans Frontieres; newspapers in Thailand and Malaysia; publicly published international trade agreements; and legal instruments, both international and national.

As mentioned in the study's objectives, this article includes two key topics:

1) The implication and impact of international trade agreements on medicines, including and beyond the TRIPS Agreement (or TRIPS Plus), along the medicine value chain which is a key product and function of a health system. TRIPS allows monopolistic power and it was realized that this had an effect on the price of medicines.[5] In addition, the magnitude of the impact on market exclusivity in Thailand and the overview of the impact of TRIPS mentioned.

2) Experience from three countries on the use of TRIPS flexibilities. TRIPS provide tools or "TRIPS flexibilities" for countries to protect public health and diminish inaccessibility to medicines.

3) The attempt of Thailand, India and Malaysia to make use of such flexibilities (patent use by third parties) to improve access to medicines in accordance with their national laws.

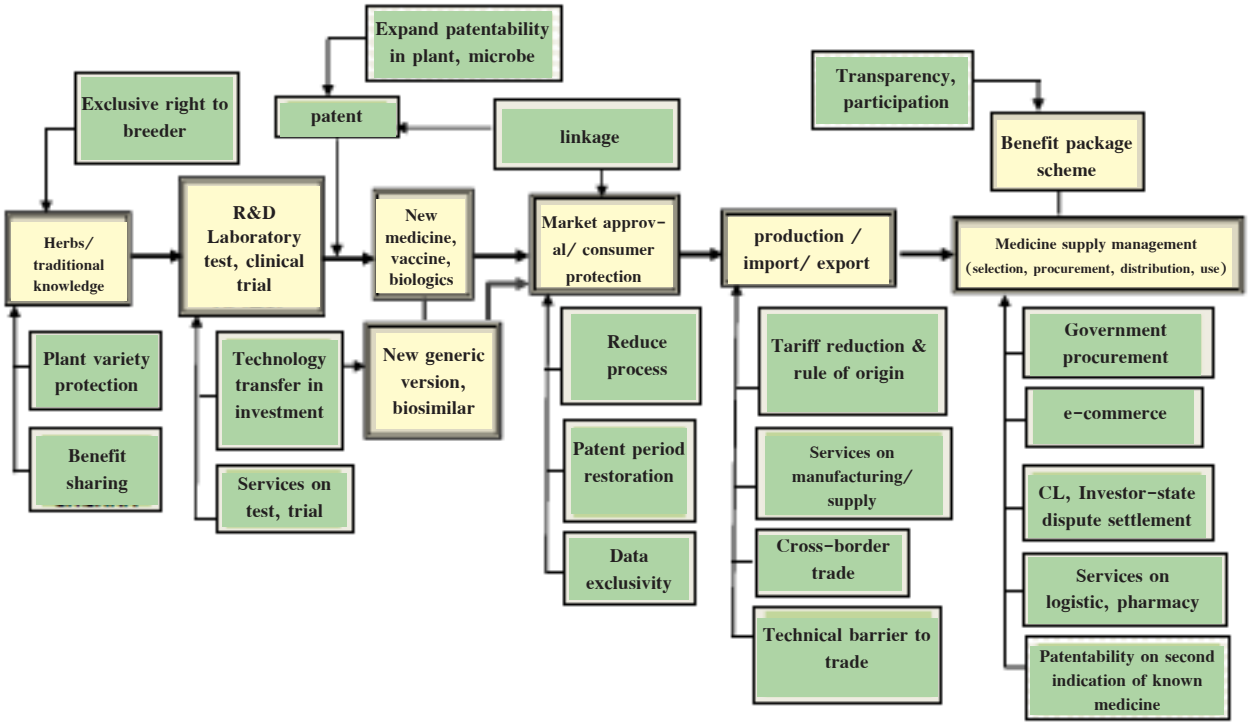
1. Implication and impact of international trade agreements on medicines

This topic illustrates the conceptual framework of and explains on the implication and impact of the new generation of trade agreements along the medicine value chain. The framework was developed from comprehensive and systematic analysis on the content of updated plurilateral agreements; i.e. the International Union for the Protection of New Varieties of Plants (UPOV) 1991 Convention, Government Procurement Agreement (GPA) and FTAs (CPTPP including some international investment agreements) that Thailand has signed or shows interest in signing. The first author drafted and matched the implications found along the medicine value chain.[6] Co-authors reviewed first, followed by experts with various pharmaceutical expertise. The implications were identified from the text of the agreement where either the terms "pharmaceutical", "medicine", "biologic", "vaccine", "health", "Doha Declaration", "TRIPS" were stated; they were interpreted in relation to the implications found in the literature as well as in Thai health policies such as Universal Health Coverage,[7] Medicine System Development and Strategy B.E.2560-2564 and Access to medicines strategy[8] and international reports such as Promoting innovation and access to health technologies,[9] and Access to Medicines from the Health System Perspectives.[10]

Implications were found in all steps along the medicine value chain (Figure 1). Starting with the fundamentals of Research and Development (R&D) for new medicine the following implications were found:

1) Resources (e.g. herbs) are affected by the UPOV 1991, the right of breeder in new plant varieties are protected with a system similar to patent.

Figure 1 Implication of international trade agreements on the value chain of medicine



However, traditional knowledge and genetic resources is subjected to benefit sharing.

2) In R&D, the technology transfer is not able to require as a condition for foreign investment. Services on R&D services are required to be supplied by foreigners without discrimination.

3) The patent system is broadened in the patentability of microbes and plants. The patent filing is linked to the process of marketing approval of generics. An inefficient patent linkage system could delay price competition in generics and delay access to cheaper medicines as a consequence.

4) The trade agreements aim to do the following: limit the policy space and to gain the involvement of stakeholders in policy formulation; shorten and regulate pre-marketing control; extend market exclusivity through patent term restoration and data exclusivity.

5) Once the medicine gets marketing approval, imported medicine as both raw material and finished product enjoys the positive impact of the international trade agreement, i.e. tariff reduction. Unfortunately, it needs to comply with the rule of origin. On trade in services, manufacturing and distribution is open for foreign business and fair competition. A country is required to decrease technical barriers to trade and also facilitate cross-border services.

6) In the medicine supply management cycle (selection, procurement, distribution and use), the trade agreements aim to access government procurement sector with removing the privilege support for Thai business, regulate the data management of e-commerce, limit the use of compulsory license on patent medicines.

Exercising rights is prone to investor-state dispute settlement. Logistics services and pharmacies (drugstores) are open for providers from other parties of the agreement. The patentability and exclusive right on the new use (or indication) of known medicines is available and protected, respectively.

Due to strong patent protection and lower capacity in upstream R&D through innovated medicines in commercial use than developed countries, Thailand relies on imported medicines. This is shown in the major proportion of consumption value, especially of biological products. The impact of international trade agreements on market exclusivity has therefore been assessed. It was also quantified, especially the known issues that result in the extension of market exclusivity, such as patent term extension, patent restoration from the granting delay and the delay of marketing approval, and data exclusivity. On the basis of market exclusivity leading to monopoly power and no price competition by generics, finally it leads to the increase in medicine expenditure, health expenditure and inaccessibility to medicines once the budget for medicines is limited. Three studies quantified the magnitude of this market exclusivity extension for Thailand depending on the one- to ten-year period of extension inclusive of short, medium and long-term impact. In addition, the negative effects of data exclusivity (DE) were quantified. All are stated elsewhere and beyond the remit of this article.[11-13]

2. Use of TRIPS flexibilities: experiences from three countries

However, since the TRIPS provide TRIPS flexibilities, countries must also comply their national law with the flexibilities. The second part of this article reviews the use of TRIPS flexibilities in three countries in which legal systems were differently designed and

exercise the rights according to TRIPS; their legal frameworks and the essence of using such tool is noteworthy. In Thailand, we look at the impact evaluation of issuing the compulsory license by government or government use of license (GUL); in India, the compulsory license (CL) by third party; and in Malaysia, the system design on data exclusivity and compulsory license in parallel with voluntary license.

A. Thailand: comprehensive monitoring and evaluation of compulsory license by government

Thailand issued the GUL on seven medicines, including antivirals for HIV/AIDS, anticancer medicines and anti-platelet aggregation between November 2006 and January 2008[14,15]. Table 1 shows the period of announcement of each medicine. This issuance drew attention from pharmaceutical companies who are the patent owners and their governments' trade representatives and embassies and raised policy questions of whether or not this GUL would have a negative effect on foreign investment and export. Hence, policy and health system research were conducted on various aspects on the impact of GUL policy. Immediate countermeasures from the United States of America government, in line with other intellectual property right protection issues, meant that Thailand was categorized in a Priority Watch List (according to the US 2007 Special 301 Report). As a result, exported commodities of Thailand in the Generalized System of Preferences (GSP) programme (one of the unilateral trade preference programme) had been withdrawn and could not enjoy the benefit of tariff-free trade and quotas from the GSP programme. On trade and economics,[16] the research reveals trends in short-term effect on firstly, the total export value of the products of Thailand by major import countries (Figure 2); and the export value of the commodities that were withdrawn from the GSP programme (polyethylene terephthalate in primary form (plastic), gold jewelry (jewelry) and flat screen colour television sets (colour TV)) shown in Table 2. In comparison with one year before and after issuing GUL, the export value of these selected commodities to the US declined. However, the export value of the same products to the rest of the world increased except colour TV. Secondly, concerning foreign direct investment (FDI) by major investor countries (Figure 3), during the period of the first quarter of 2005 to the third quarter of 2008, the trend in total export value of Thailand markedly increased. The study found a fluctuating trend of annual FDI value between 2005 and

Table 1 Medicine list and date of issuance the government use of licenses in Thailand

Group	Generic name	Issuing date
Anti-retroviral	Efavirenz (EFV)	29 November 2006
	Lopinavir/Ritronavir (LTV/RTV)	24 January 2007
Anti-platelet aggregation	Clopidogrel	25 January 2007
Anti-cancer	Docetaxel	4 January 2008
	Letrozole	4 January 2008
	Erlotinib	4 January 2008
	Imatinib (on condition)	4 January 2008

Source: Summarized from reference No. 14 and 15

Figure 2 Trend in export value of selected commodities

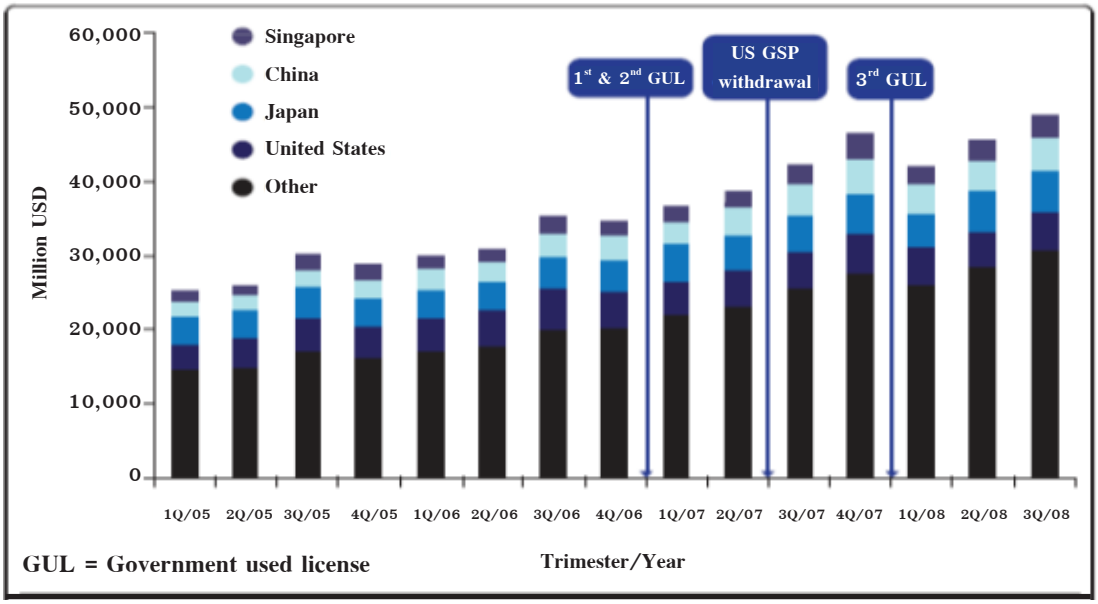


Table 2 Increased costs for US importers and changes in export value for products affected by withdrawal of GSP status (in million USD)

Product	Increased costs for US importer	Change in value of export between one year before and after US GSP withdrawal	
		US	Rest of the world
HS 3907.60.00 (Plastic)	0.4	-128	130
HS 7113.19.50 (Jewellery)	26	-220	723*
HS 8528.72.64 (Colour TV)	4.4	-40	-332**
Total	30.8	-388	+521

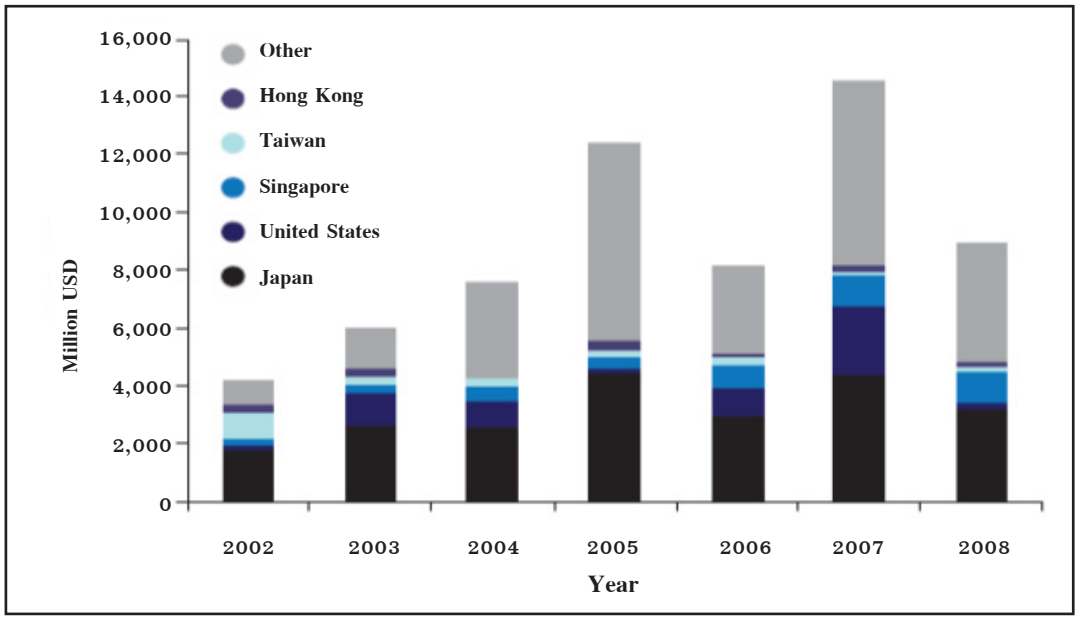
Remarks: * HS 7113.19
** HS 8528

Source: Table 4 of reference no.16

2008. The downward figures in 2006 and 2008 compared with the prior year were due to the political instability in Thailand and the world economic recession, respectively.

For overall health considerations, increase in access to essential and life-saving medicines is the ultimate goal. Saving the government budget is the subsidiary goal. The aforementioned study also estimated the number of patients that could access GUL medicines and their subsequent productivity that contributes to gross national productivity (GDP), deducted by public health expenditure.[16] Regardless of Erlotinib for which data was not completely available, the study found the net benefit of

Figure 3 Foreign direct investment of selected countries in Thailand



Source: Board of Investment of Thailand

the GUL medicines were greater than the alternative medicines. The incremental benefit of such medicines ranges from 2.3 to 67.0%. In addition, the National Health Security Office (NHSO) and Government Pharmaceutical Organization (GPO), which are the main implementors of this GUL policy, systematically collected the actual numbers of patients as well as the estimated budget saving (to get comparison between the price of generic version and the patented medicine) as shown in Table 3 and 4. The data shows that the cumulative saving in five years for all GUL medicines was USD 566.5 million. Later, the saved government budget from GUL was spent on access to non-GUL essential medicines for other diseases and patients.

Concerning policy, another study analysed and summarized the key to Thailand's success. With the synergy between three sides of a triangle - knowledge and evidence generation, mobilization of civil society and public sup-

Table 3 Numbers of patient accessed to selected GUL medicines

Year	Clopidogrel	Letrozole	Docetaxel
2009	5,556	0	321
2010	131,389	1,558	527
2011	76,586*	2,629	879
2012	88,000	1,330	1,439
2013	105,600	1,382	1,447
2014	126,720	2,282	2,893

Note: *indication and use was restricted since then

Source: Bureau of Drug and Medical Supply Management, National Health Security Office

Table 4 Comparing to patented medicines, saved budget (Million USD)

Year	Antiretroviral	Anti-platelet aggregation and anti-cancer
2010	27.3	3.4
2011	56.8	57.0
2012	74.6	37.7
2013	77.3	46.5
2014	88.4	73.3
5-year total saving	338.8	227.7

Source: Bureau of Drug and Medical Supply Management, National Health Security Office

port, and the leadership of politician and policy makers - the GUL eventually succeeded in policy formulation and implementation. The triangle refers to "the triangle that move the mountain" – a well-known conceptualisation of a philosophical and strategic approach to policy advocacy by Dr Prawase Wasi[17]. The first attempt by Thailand to use the GUL was in 1999 for Didanosine (DDI), a medicine for HIV/AIDS. However, at that time policy makers decided on alternative option.[17]

B. India: use of compulsory license by third party

The first use of a compulsory license on Sorafenib tosylate, indicated for patients with late stage hepato-cellular carcinoma (HCC) and renal cellular carcinoma (RCC), sold in India. This innovative medicine had patented in India, held by Bayer Corporation (Bayer), and was launched into the Indian market in 2008. The cost of treatment per patient per month was USD 4,559 (INR 280,000) and Bayer provided the patient assistance programme (PAP) with conditions. In accordance with the Patent Act and regime on the use of CL, a private generic-version manufacturer, Natco Pharma Ltd (Natco), submitted the request for the voluntary license (VL) from the patent owner, Bayer on 6 December 2010. However, the application was refused on 27 December 2010, so the CL process was started by Natco's submission on 29 July 2011 on three grounds of the Patent Act Section 84(1). The Controller General of Patents (Controller) of India filed this prima facie case from the evidence and proposed conditions submitted by Natco.[18-20]

It should be noted that the Section 84(1) of the Patent Act allows any person interested to make an application after 3 years after the date of patent grant and on 3 grounds (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India. Section 85(5)(iv) also insists that prior to CL application that applicant should make efforts to obtain a license from the patentee on reasonable terms and condition (6 months is provided as a reasonable time period)[18].

After careful consideration, the Controller granted CL to Natco on 9 March 2012 with 13 terms and conditions and including: setting the price of Sorafenib generic version to no more than USD 176 (INR 8,800) per patient per month; reporting the details of

sales to the Controller and licensor on quarterly basis; having the right to manufacture the medicine covered by the patent only at its own manufacturing facility with no outsourcing; paying royalties at the rate of 6% of net sales; ensuring the granting license is solely for making, using, offering to sell and selling the medicine for treatment of HCC and RCC in patients within the Territory of India; supplying medicine for 600 needy and deserving patients per year free of cost; have no right to import medicines covered by the patent; ensuring licensed medicine is visibly distinct from the patented one including the trade name and packaging.[21]

Submissions and argument of the applicant and opponent for CL, and the decision of the Controller can be found elsewhere.[21] The case was not yet finished, with the patent holder appealing the granting; however the Intellectual Property Appellate Board (IPAB), Chennai rejected it in March 2013.[22] Later, Bayer challenged the Controller's decision and IPAB's order through the Bombay High Court where his Writ Petition was dismissed in July 2014.[23]

This first CL of India is important because it set a precedent for future CL in accordance with the three grounds of CL granting. It has a view on the balance between right and obligation includes (a) the reasonable requirement of the public with respect to the patented invention has not been satisfied; (b) the patented invention is not available to the public at a reasonably affordable price; (c) the patented invention is not available in the territory of India. It could also encourage Indian generic manufacturers who have increasingly felt that the legal risk and uncertainty of the patent system prevents the production of generic versions of newer medicines.[19]

C. Malaysia: use of GUL and VL at one time

Introduced in late 2013, countries and the World Health Organization recognised new medicines in the group of direct-acting antivirals (DAA) which is a highly effective treatment (95% cure rate) with less adverse reaction and less treatment duration (8-12 weeks) for chronic Hepatitis C (HCV) than the current treatment medicines which is the combination of Pegylated Interferon injection and oral Ribavirin for 24-48 weeks, with 50% cure rate[24]. However, the first oral form of medicine of the group Sofosbuvir, the backbone of the treatment and needs in combination with another DAA, is excessively high in price at USD 84,000 (RM 0.3 million or THB 2.5 million) per patient per cost of treatment. The prices triggers the problem of access to medicines worldwide because of unaffordability for patients and governments, even in its originated country[25, 26]. Therefore, the global target of eliminating HCV as a major public health threat by 2030 set in the Global Health Sector Strategy on Viral Hepatitis 2016-2021 and adopted in World Health Assembly 2016, would be out of reach.[25,27]

The patent holder, Gilead Science (Gilead) had responded to the worldwide concern on price and availability with strategies on tiered pricing and voluntary generic licensing. Later, it was announced in September 2014 that the company gave voluntary licenses for 91 developing countries and license agreements to 7 generic manufactures based in India in 2014. This campaign of the patent holder allowed the generic manufacturer to supply generic versions which would be expected to sell for significant lower prices in certain countries in the list.[28] This binding, the other way round, limited those generic manufacturers to be unable to supply the generic version to non-listed countries, including China, Brazil, Egypt, Belarus, Thailand, Malaysia, Indonesia and Russia. This announcement

was interpreted as a preemptive move to gain momentum, after a series of patent oppositions in some countries, and prevent effective independent market competition.[29]

Countries that aim to eliminate the disease but were not in Gilead's VL list, such as Thailand and Malaysia, can provide the highly effective DAA, especially Sofosbuvir, at a cheaper medicine price by negotiation with the patent holder. Alternatively, countries can make use of TRIPS flexibilities such as other use without authorization of the patent holder or CL.

With the price of RM 0.3 million per person per treatment course and an estimated 500,000 infected patients, Malaysia, in 2017, issued the CL by government or GUL. Certainly, the preparing phase would be started at least several months beforehand. The Malaysian cabinet approved GUL on 14 September, although Gilead expanded the VL list to include Malaysia, Thailand, Ukraine and Belarus from 24 August 2017[30,31]. GUL would support an expected 400,000 patients in public hospitals and maintain the competition with VL[32]. The GUL Sofosbuvir would be imported from an Egyptian manufacturer in combination form and the VL from India. At the time of the announcement, GUL medicine had been in clinical trials for marketing approval and provided free of charge to HCV patients.[31,33] Malaysia also took this opportunity to fight hepatitis C and issued GUL to improve collaboration among stakeholders and to have South-South collaboration between generic manufacturers of Malaysia and Egypt for medicine combination.[34] It is believed that the GUL supported Gilead's policy on expanding the VL to include Malaysia and three other countries.

Regarding data exclusivity (DE) for the CL, Malaysia issued the Directive on DE under the Control of Drug and Cosmetic Regulation 1984 and it came into force on 1 March 2011. In general, only two types of new medicines could be submitted for DE: new chemical entities and new indication of registered medicines. Within the scope and according to several conditions, the DE could be granted. The Directive indicated two circumstances in which DE cannot be applied for: issuing the CL and a government's necessary action to protect public health and others.[35]

Discussion

This review explores the implication and impact of the new generation of international trade agreements along the medicine value chain, which is complicated and complex. It has advanced the ways in which to define the scope of the impact and cross-cutting issues; for example, the impact of government procurement is not only related to the budget and expense of government but also to the impact on local pharmaceutical manufacturers. Currently, the government procurement law provides privilege to local manufacturers. If the privilege is removed, taking into account different sizes of businesses, it was anticipated that local manufactures could not compete with foreign ones. Finally, without any promotion, the local business would be lost and withdrawn from the market, and Thailand would rely on importation. As a result, evidence on the impact of FTAs and quantifying their magnitude can help to develop negotiated strategies and set compensation for any negatively affected sectors.

With respect to the three country cases, the review gives a sense of the difficulties that countries face when exercising their rights, although they are supported by TRIPS Agreement and countries have full legitimacy. From a health perspective, patients have equity in their right to health, regardless of whether they are the

poorest or better-off. In other words, they have the fundamental right to access essential medicines without any financial barriers. So, with the use of the TRIPS flexibility, CL is one measure to overcome issues of access to essential medicines. Monitoring and evaluation of the impact, as shown by the experience of Thailand, could notionally provide evidence of short-term impact on economics (importation and investment), the ultimate goal of GUL (access for patients), and government expenditure. However, information about the long-term impact is required.

The lesson learned from India concerns the CL by a third party. The private local pharmaceutical producer requested for the provided right to comply with country's patent law. It was mandated that the patented medicines must properly contribute to the publics, e.g. access to affordable medicines in the territory that the patent covered. In addition, both the patentee and the third party have rights to propose and oppose on opposite sides with supported evidence. The fairness and balance of the right of the individual and the obligation to public health, considered by the 'middleman', was markedly observed. The system provides the opportunity to express different views, including authorized organization within the patent system and court. However, the most important consequence was that the process for CL took a long time of several years; three years after the patent was granted, plus the request for VL, plus the process of CL, plus appeal. In this regard, the applicant for CL and the patent office must be firm on the goal and knowledge on patent law, health and pharmaceuticals. Other countries, such as Thailand which has never used the CL by a third party, should explore the legal system on a similar matter.

In the third case, the Malaysian government issued the GUL while the pharmaceutical company provided VL during the same period of considering the GUL. Even though VL was offered the government had not abolished the GUL for a few reasons, particularly as it provided an environment of price competition and relied on more than one source of medicines (Egypt, rather than India alone) which resulted in better security in medicine supply. In addition, nationwide patients in public health facilities can get GUL medicine, while VL medicine is only available in private facilities. The effects on price competition should however be monitored.

Finally, although all three countries used the CL and complied with international and national law, the U.S. unilateral preference system considered that its intellectual property (patent) was not protected efficiently. Countermeasures, therefore, were exercised and Thailand and India were categorized into the Priority Watch List of the Special 301 report while Malaysia had been under consideration, as stated in the 2019 Report.[36]

Recommendations

Focusing on Thailand, the voluntary license can be considered as a useful tool, but all TRIPS flexibilities including compulsory license must be continued as the public has the right to health, and this is a tool to overcome barriers to access. Regarding CL by a third party, Thailand should explore the method and process for using it. Both VL and CL might strengthen the transfer of technology covered by the patent to local R&D and build the capacity of Thai pharmaceutical manufacturing. More system research is needed as well as investigation of cross-country

impact regarding FTAs of and among ASEAN members. This is due to the trend in regional and bilateral FTA and the concept of the global supply value chain; many countries have lots of international trade agreements, resulting in cross-country impact.

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บทคัดย่อ: ความตกลงการค้าระหว่างประเทศ และผลกระทบต่อระบบยา: เหตุและปัจจัย?

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วารสารวิชาการสาธารณสุข 2563;29(ฉบับพิเศษ):S153-66.

บทความนี้ทบทวนความรู้อย่างรอบด้านและวิเคราะห์ความตกลงการค้าระหว่างประเทศ และผลกระทบหรือประเด็นที่เกี่ยวข้อง ด้วยข้อมูลทั้งในไทยและต่างประเทศย้อนหลัง 17 ปีนับจากปี 2562 เพื่อให้เห็นผลกระทบอย่างเป็นระบบของความตกลงการค้าระหว่างประเทศตลอดห่วงโซ่คุณค่ายา ซึ่งการระบุประเด็นผลกระทบดังกล่าวนำมาซึ่งความห่วงกังวลอย่างมากต่อผลที่จะเกิดขึ้นต่อประเทศไทย แม้ว่าจะมีผลกระทบด้านบวกอยู่บ้าง แต่ผลกระทบด้านลบต่อระบบยามีมากกว่า โดยเฉพาะประเด็นจากความตกลงการค้ายุคใหม่ นอกเหนือจากประเด็นผลกระทบต่อราคายาที่แพง และค่าใช้จ่ายด้ายยาที่สูงขึ้นจากความตกลงทริปส์ซึ่งเป็นที่ทราบกันดีทั่วโลกแล้ว ยังมีผลกระทบจากประเด็นอื่นอีก เช่น การเปิดตลาดด้านการจัดซื้อจัดจ้างภาครัฐ การจำกัดการกำหนดนโยบายด้านการบริหารจัดการระบบยาและนโยบายด้านการสาธารณสุข เป็นต้น บทความนี้ยังได้นำเสนอประสบการณ์ของประเทศไทย อินเดีย และมาเลเซียในการใช้ข้อยืดหยุ่นของความตกลงทริปส์ พบว่าทุกประเทศใช้มาตรการการใช้สิทธิเหนือสิทธิบัตรเพื่อให้เกิดสมดุลระหว่างสิทธิส่วนบุคคลและพันธสัญญาที่มีต่อสาธารณะในการเข้าถึงยาจำเป็นในราคาที่จ่ายได้ แม้จะพบความยากในการใช้และเกิดผลกระทบต่อเนื่องตามมา จากความรู้ต่าง ๆ เหล่านั้นได้แนะนำว่า ไทยอาจสนับสนุนการให้สิทธิโดยสมัครใจ แต่จะต้องคงไว้ซึ่งข้อยืดหยุ่นทั้งหมดของความตกลงทริปส์ซึ่งเป็นสิทธิของประเทศและเป็นเครื่องมือที่จะช่วยแก้ไขปัญหาการเข้าถึงยา โดยที่การใช้จะต้องไม่ยุ่งยาก ไทยควรเพิ่มการศึกษาวิจัยเชิงระบบในด้านผลกระทบข้ามประเทศโดยเฉพาะจากความตกลงการค้าเสรีของสมาชิกและระหว่างสมาชิกอาเซียน

คำสำคัญ: **ความตกลงการค้าระหว่างประเทศ; สิ่งที่เกี่ยวพัน; ผลกระทบ; ยา; ค่าใช้จ่าย; การบังคับใช้สิทธิ; การใช้สิทธิเหนือสิทธิบัตรโดยรัฐ; การให้สิทธิโดยสมัครใจ**