

The Trans-Pacific Partnership Agreement (TPPA): Impact on health in Malaysia

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ABSTRACT: TPPA stands for Trans Pacific Partnership Agreement (TPPA) and is also known as the Trans-Pacific Strategic Economic Partnership Agreement. It is a multilateral free trade agreement currently being negotiated by 12 countries, led by the United State (US). Malaysia is one of the parties negotiating in the TPPA. It aims to further liberalize the economies of the Asia-Pacific region, covering a broad spectrum of areas and has 29 chapter's altogether and some areas affect our public health, environment and courts system. The TPPA have their own advantages and disadvantages and this paper is to discuss the advantages and challenges of TPPA in general that Malaysia will be faced if Malaysia signed the TPPA and the likely impact of TPPA on health in Malaysia. The analysis result by UNDP showed if Malaysia does not join the TPPA, Malaysia would be at a disadvantage in terms of seeking bigger and better market access for Malaysian products and services. Analysis on the TPPA document showed if Malaysia signs the TPPA, it will have an impact on the cost of medicines and health matters. In conclusion, the government has to be very careful in dealing with TPP agreement to ensure the advantages in favor of Malaysia. Every action needs to be refined and addressed with care otherwise Malaysia has to bear all the cost in health sectors.

KEYWORDS: health impact, challenges, intellectual property, Free Trade Agreement, cost

1 INTRODUCTION

The Trans-Pacific Partnership Agreement (TPPA) builds on the Free Trade Agreement (FTA) signed by the Pacific 4 (P4) countries, New Zealand, Singapore, Chile and Brunei Darussalam. The P4 FTA was signed in 2005 and came fully into force in 2009 [1]. The P4 was then expanded and the TPPA negotiations began with the entry of the United States, Australia, Peru, and Vietnam in March 2010. The scope has been expanded to include new issues with the goal to develop a comprehensive and high standard agreement [1].

The Trans-Pacific Partnership Agreement (TPPA) has been heralded as a twenty-first century agreement with an ambitious agenda and the potential to set a new baseline for future trade and investment agreements [2]. Twelve countries currently negotiating include Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and the United States. The purpose of the TPPA is to enhance each of the countries' economic development and that this, in turn, is expected to lead to improved social and health development [3]. Malaysia was involved in the third round negotiations in October 2010 [4]. Under health, there are 2 areas of public health regulation – tobacco & alcohol and access to medicines have also been part of the discussion.

But, how far the TPPA will improve social and health development if we are bound by rules and regulations? Currently, the TPPA is still under discussion. However if Malaysia agreed to sign TPPA then Malaysia may be does not have the freedom to decide otherwise bound by a greater power. Do Malaysians willing to colonize after more than 50 years of independence?

Thus, this paper is to discuss the advantages and challenges of TPPA in general that Malaysia will be faced if Malaysia signed the TPPA. The likely impact of TPPA on health in Malaysia will be discussed specifically and comprehensively in this paper takes into account the opinion of other countries that are also involved in the TPPA.

2 RATIONALE FOR MALAYSIA JOINING TPPA

Formal negotiations have been underway since 2008, since which time new negotiating countries have come on board. Once signed, the TPPA will be a legally binding agreement that regulates trade – and by extension practices – between these nations. Although amendment and new members will be possible, the TPPA is intended to be a ‘landmark, 21st-century trade agreement’, establishing new norms for global trade [4]

Until December 2013, 19 rounds of negotiations have been held in the interest countries. The latest was in August which was held in Brunei. The objective of the negotiations is covers traditional FTA elements as well as new elements for Malaysia such as competition, labor, environment, government procurement and intellectual property rights which will be able to adapt and incorporate current issues, concerns and interests. There were 21 working groups have been established in the following areas: Market Access; Technical Barriers to Trade; Sanitary and Phytosanitary Measures; Rules of Origin; Customs Cooperation; Investment; Services; Non-Conforming Measures; Financial Services; Telecommunications; E-Commerce; Business Mobility; Government Procurement; Competition; Intellectual Property; Labor; Environment; Capacity building; Trade Remedies; and Legal and Institutional to undertake negotiation [5,19].

The Government views the TPP as an important initiative as Malaysia seeks to expand market access opportunities, enhance our competitive advantage, builds investor confidence in the country which draws foreign investments and builds capacity through FTAs.

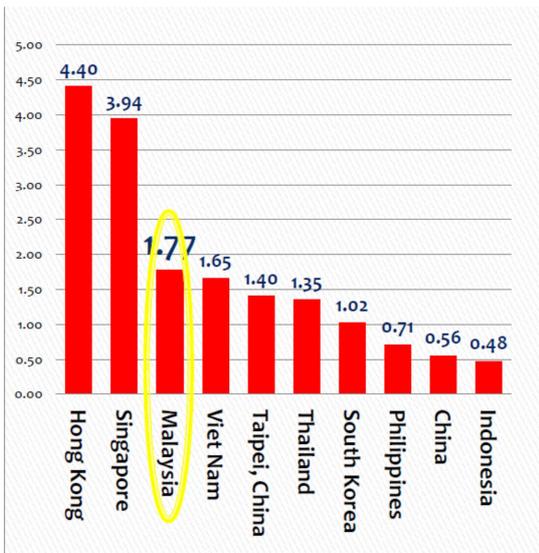


Figure 1: GDP trade ratio (Trade openness)

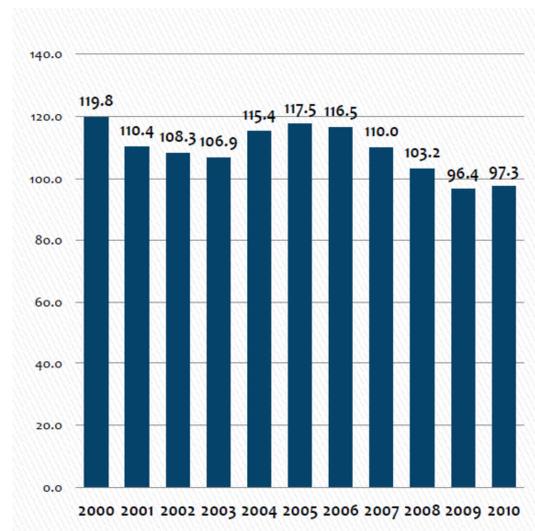


Figure 2: Malaysia: % exports to GDP

As an open economy, trade plays an important role to Malaysia. Slide presentation on the MITI Open Day on TPP Briefing, 1 August 2013 figure 1 shows the openness trade of Malaysia is only 1.77 behind Singapore 3.94. Figure 2 show the percentage of Malaysia export to gross domestic product (GDP) was range between 90 - 120% from year 2000 to 2010 [20].

Before deciding to join the TPPA negotiations, the Malaysian Cabinet undertook a series of consultations and engagements with relevant stakeholders. After having considered feedback from relevant stakeholders, on March 2010 the Malaysian Cabinet decided that Malaysia should join the TPPA negotiations. With that Cabinet mandate, Malaysia participated as a full negotiating member at the 3rd round of negotiations held in Brunei Darussalam from 5 to 8 October 2010. The Government had also commissioned the UNDP to conduct a comprehensive study on the costs and benefits of negotiating the TPPA [5].

The Malaysian Cabinet has mandated Ministry of International Trade and Industry (MITI) to co-ordinate Malaysia's participation in the TPPA negotiations. MITI is the Chief Negotiator but other ministries and agencies lead the working groups for areas under their responsibility. Others Ministries and Agencies involved in the negotiations are the Ministry of Finance, Ministry of Domestic Trade, Consumerism and Cooperatives, Ministry of Human Resource and the Ministry of Natural Resource and Environment [5]. Consultations with various stakeholders have revealed an increasing need by our own companies for more open markets and trade facilitative measures. Malaysian products have met world standards and are able to compete at the global level. Malaysian companies are also increasingly becoming global investors and they require a level of transparency and predictability that can only be guaranteed effectively through binding agreements like FTAs [5].

The TPPA will also allow Malaysia to continue to be an integral part of the deepening economic integration taking place within the Asia Pacific region, but also enable Malaysia to engage in a more concrete way with important trading partners such as the US, Canada, Mexico and Peru, with which we currently do not have any structured framework, such as trade agreements. As a member of the TPPA, Malaysia will also be able to participate as an important link in the whole regional supply chain [5]. In the long run, the TPPA will bring benefits of lower cost of goods and more efficient production by taking advantage of the competition and economies of scale. The successful conclusion of the TPPA will form an unprecedented market of 793 million people, with a combined GDP of USD27.5 trillion. This far surpasses the limited domestic market of 29.5 million people and a GDP of USD 300 billion in Malaysia [1]. With the TPPA, Malaysia aim to open up new market opportunities and horizons for Malaysians to go on the offensive and take advantage of the international market place [5].

In the recently implemented FTA with Australia, Malaysia now enjoys duty free access into the Australian market from the day the FTA entered into force. This is a huge benefit for Malaysian companies that are already exporting but also provides opportunity for Malaysian companies that have yet to do so. The TPP will provide such an opportunity to a seamless market with preferential access, far beyond our population and also provide investment opportunities globally and also regionally. While acknowledging these benefits, the Government will ensure that the cost to the Government will not outweigh the benefits. The Government will continue to strongly protect Malaysia's interest in this important negotiation. Government will not sacrifice the right of the Government to continue to chart our own course in pursuit of economic growth, socio-economic restructuring and developed nation status [5].

3 OBJECTIVES OF TPPA

The objectives of TPPA can be categorized into three main areas [5]:

- I. To continue the trade and investment liberalization efforts being undertaken through the WTO and the FTA initiatives of each of the TPP member countries in the region
- II. To develop transparent and predictable rules and disciplines with adequate recourse in the event of any disputes
- III. To develop a more transparent and inclusive regulatory environment which allows all relevant parties to engage in a meaningful and constructive manner on matters of significant economic impact. And these goals are no doubt in line with Malaysia's economic transformation and domestic reform programs.

4 ADVANTAGES OF TPPA FOR MALAYSIA

Consultation with various stakeholders before joining the TPPA negotiations demonstrated that there are increasing demand among Malaysian companies to a larger market and commercial facilities. Malaysian companies that become global investors are increasing and they need a level of predictability that the effectiveness is guaranteed by the trade agreements (FTA) [5]. Concurrently, there is also interest from foreign companies in non-TPPA countries that are exploring Malaysia as a base for their operations to enjoy the benefits of the TPPA [1].

The Government has taken a conscious decision to address small and medium enterprise company (SME) concerns in all areas under negotiations. These concerns, such as increased competition, are addressed through longer transition periods for liberalization. It is also addressed in the form of carve-outs for government procurement and through higher thresholds. The TPPA also aims to develop uniform rules to ensure predictability. The Government is well aware that there are concerns regarding the sustainability of SMEs in light of increased competition from large international corporations. As such, these concerns are being addressed by the government [1].

The combination of greater market access for Malaysian products and services under the TPPA and the continued inflow of foreign investments will create a powerful catalyst in driving Malaysia's economic transformation agenda [1]. Through the TPPA, Malaysia will become part of a greater economic integration within the Asia Pacific region. It will also significantly

enhance Malaysia's engagement with important trading partners such as the United States, Canada, Mexico and Peru. As a member of the TPPA, Malaysia will also be able to increase its participation in regional and supply and value chains and facilitate access for to Malaysian products and services into a bigger market [1].

Copyright is part of an effort to recognize talent in the country. Thus, Malay and Bumiputera entrepreneurs who are active in the creative industry and relating thereto, should be given due recognition with a longer copyright. If a longer time period is provided under the TPPA, Malay and Bumiputera entrepreneurs will get the protection of intellectual property not only in Malaysia but also in other TPP countries also. Recognition in the form of longer copyright will ensure Malay intellectuals will remain active in Malaysia than having to migrate overseas simply to develop their talents [11].

One of the main benefits of the TPPA to consumers is trade liberalization. Tariff elimination, a key feature of FTAs, allows the consumers to enjoy a wider range of imported goods and services, with better quality and at competitive prices. In addition, manufacturers are able to source cheaper inputs as a result of liberalization [5]. Gradual competition brought about by liberalization has made domestic producers of goods and services suppliers to be more competitive. A good example is the local furniture industry. Gradual liberalization has resulted in better quality products for the domestic consumers and made the industry competitive in the international market. In the services industry, the liberalization of the education sector has allowed Malaysians to be educated locally in reputable institutions at a much lower cost [5].

The TPPA also deals with technical regulations on products and health and sanitary matters. These chapters build on the WTO provisions and will facilitate regulators to ensure that consumers are protected through standards and health and food safety measures. In an increasingly competitive global environment, our absence from the TPPA will also make Malaysia less attractive as an investment destination, compared with other TPPA members. Investors' perception of Malaysia will also be affected. As investors avoid Malaysia, this could result in less opportunities for job creation. Similarly, Malaysian companies that are investing in the TPP countries will not enjoy the privileges and investment protection as provided under the TPPA [5].

The TPPA is expected to become a platform for the Free Trade Agreement for the Asia Pacific (FTAAP) involving the 21 APEC member economies. By not being in the TPPA, we will not have a first mover advantage to write the rules and ensure our interests and sensitivities are addressed. Abandoning the TPPA negotiations now would mean allowing other countries to set the terms of the agreement without having to consider the interests and concerns of Malaysia. Acceding to the TPPA later would result in Malaysia having to accept the rules, disciplines and terms and conditions decided by others [5].

5 CHALLENGES OF TPPA FOR MALAYSIA

In the interest of TPPA, Malaysia is aware that while the TPPA would offer many benefits to Malaysia and its people, it also has a few challenges which the Government has to deal with and further negotiate for the best outcome. The challenges are:

5.1 GOVERNMENT PROCUREMENT (GP)

GP issues relate to the Build-Operate-Transfer (BOT) and threshold for construction services. On BOT, Malaysia has carved it out from the scope of commitments. As for threshold for construction services, Malaysia's current offer has been set at a very high threshold. Areas of interests to the Bumiputera business community and SMEs have been excluded from our initial offers and Malaysia will maintain this position. Malaysia will continue to maintain preferences for selected groups, but at the same time allowing the business sector in Malaysia to participate in the sizable government procurement market of other parties [5].

5.2 INTELLECTUAL PROPERTY RIGHTS (IPR)

Intellectual property is another area of challenge that received a lot of attention. IPR issues revolve around access to medicine and healthcare, increase in pharmaceutical prices and longer copyright protection term. One of the main concerns about the field of intellectual property revolves around the issue of access to medicines at a lower cost and the issue of the protection that would delay the production of generic drugs. Malaysia has strongly raised objections towards proposals that could delay the entry of generic drugs into the market and result in high cost in the prices of medicines [5].

5.3 STATE-OWNED ENTERPRISES (SOE)

On SOE, the issue is the impact arising from the proposed disciplines on the role of SOEs in the Malaysian economy with regard to provision of public goods and services, development of strategic industries and implementation of socio

development programmes. In the SOE Chapter, while acknowledging that a level-playing field is necessary to allow both local and foreign companies to grow, Malaysia is advancing the argument that countries have different economic systems in place with SOEs and Government Link Companies (GLCs) playing important roles in economies such as Malaysia [5].

In the case of Malaysia, SOEs or GLCs are an important tool for the Government to achieve social and development goals, and also an important catalyst to develop sectors viewed as strategic where there is no commercial presence. To do this, some support is required especially where the commercial incentive is lacking. Consequently, Malaysia is seeking flexibilities in the agreement that will allow the continued existence of such entities to participate in the economy and provide public and social goods and services [5].

5.4 LABOR AND ENVIRONMENT

For labor, Malaysia is seeking to strike a balance between workers' rights and maintaining harmonious employer-employee relations within the context of the Malaysian scenario [19].

In the area of Environment, while supporting a chapter that provides for environmental preservation, we do not want to allow environment clauses to be used as a disguised barrier to trade. Some of the key issues for Malaysia are enforcement where forestry, biodiversity, water and land are under the State Jurisdictions; elimination of fisheries and fossil fuel subsidies, adopting stronger provisions in conservation, binding all the commitments in Multilateral Environmental Agreements (MEAs) under this chapter, and subjecting the environment chapter to Dispute Settlement Mechanism [5].

In both Labor and Environment, Malaysia together with other parties is seeking to have a dispute resolution mechanism that is more consultative in nature and also not sanctioned based [5].

5.5 INVESTOR – STATE DISPUTE SETTLEMENT (ISDS) AND SOVEREIGNTY

On the issue of ISDS, foreign investors are drawn to Malaysia not only by economic incentives, but also a transparent and predictable investment regime which allows recourse in the event of disputes. Likewise, we now have many private Malaysian companies who have become active overseas investors, driven by reasons such as securing market access, gaining access to raw materials, gaining strategic assets, brand and technology as well as decentralizing of operations to diversify risks and improve returns, as Malaysia is relatively a small economy. Thus, ISDS is not only for foreign, but also Malaysian investors which are increasingly looking outwards. Furthermore, ISDS is not new to Malaysia as we have signed and ratified 64 Investment Guarantee Agreements (IGAs) since 1963 which also have provisions on ISDS [5].

To date, only two cases have been taken against Malaysia under the ISDS, one of which has been decided in favour of the Government and the other is annulled. ISDS provisions have been used by Malaysian companies on two occasions to protect their investments abroad. In one case, the decision was in favour of the Malaysian investor and in the other, there was a settlement between the disputing parties. There are adequate provisions in the TPP that gives countries the policy space to adopt measures to fulfil specific purposes, including for environment, health and other regulatory objectives [5].

Investor State Dispute Settlement (ISDS) mechanism is meant to give assurance to investors that in the event of a dispute, investors have recourse to international arbitration in addition to domestic courts. ISDS in no way infringes the policy freedom of a Government; it merely outlines the process by which a dispute over the underlining substantive principles in the Agreement will be arbitrated [5].

5.6 SMALL AND MEDIUM ENTERPRISES

The TPP has taken a conscious decision to address all SME issues in all areas under negotiations. These concerns such as increased competition are addressed through longer transition periods for liberalization. It is also addressed in the form of carve-outs of GP procurement activities and through thresholds. The TPP aims also to develop uniform rules which will have a significant positive impact on SMEs where different standards or rules and regulations used for trade can have a debilitating effect on their overcall cost of doing business [5].

In addition, the TPP has developed a Chapter that touches on SME-specific issues such as lack of information and through the Chapter hopes to look into ways how the TPP can facilitate the development of SMEs and promote SMEs into the international market [5].

5.7 CONFIDENTIALITY OF NEGOTIATIONS

A number of issues have been raised pertaining to the confidentiality of these negotiations. On this subject, apart from the need to comply with the confidentiality requirement as provided by Malaysia's domestic law, Malaysia too owe a duty of care to preserve and protect its positions as well as the positions of the other countries from being exposed during the course of the negotiations [5].

During negotiations, no commitments are firmly taken and these commitments remain fluid. If the position/stance of the countries is revealed, it may have an adverse impact particularly when a compromise needs to be taken. Negotiations require countries to consider the positions or proposals from other negotiating partners. Not all of such positions can be accommodated without some form of flexibility or changes. A compromise has to be achieved to enable parties to obtain a win-win situation. Negotiation process must allow room for the negotiators to work through a solution acceptable to all. In addition, some of these positions relates to sensitive issues which cannot be disclosed [5].

There is a need to respect each other's laws on confidentiality and the understanding reached between the negotiating partners. It is for this reason that Malaysia signed the 'confidentiality agreement' together with all TPP members. While there is a need to maintain a certain degree of confidentiality of negotiating proposals and positions that are evolving as the negotiations progress, this has not prevented governments from consulting stakeholders on the proposals. Furthermore, for transparency purposes dedicated sessions are held at each negotiating round to enable negotiators to brief and have a dialogue with stakeholders [5].

5.8 ENGAGING STAKEHOLDERS

The Government will continue its engagement with the public. Relevant Ministries have in the past conducted numerous consultations with various groups and individuals. These groups and individuals represent both the commercial interests of the country as well as civil society organisations. Stakeholders consulted by MITI include business groups such as Federation of Malaysian Manufacturers (FMM) and various Chambers of Commerce and Industry, specific industry associations and also NGOs like the Malaysian AIDS Council, *Majlis Tindakan Ekonomi Melayu* (MTEM), Third World Network, Malaysian Treatment Access and Advocacy Group, Consumers Association of Penang, PT Foundation, MyPlus, Suara Rakyat Malaysia, Jaringan Rakyat Tertindas, Pesticide Action Network Asia and the Pacific, Malaysia Trade Union Congress (MTUC) and National Cancer Society [5].

Besides consultations and dialogue, the Government also enlists technical experts from the Malaysian private sector. To date, we have enlisted an expert to assist with technical issues related to textile, clothes and footwear negotiations. Others Ministries and Agencies involved in the negotiations like the Ministry of Finance, Ministry of Domestic Trade, Consumerism and Cooperatives, Ministry of Human Resource and the Ministry of Natural Resource and Environment, have also undertaken consultations with their own stakeholders on a continuous basis [5].

6 DISCUSSION

TPPA has its own advantages and disadvantages. Yes we understood that there are a few proposals from the involved countries to ensure that the agreement can fulfill the every country needs. But how we could ensure that the entire proposed document will be considered and put in the final agreement before we sign?

Our former Prime Minister, Tun Dr Mahathir Mohamed has warned government regarding the TPPA; "After we sign the TPP we will be bound hand and foot. No more capital control. We will be colonised again" [10]. He added that the government must ensure that Malaysia will not be on the losing end if it chooses to sign the Trans-Pacific Partnership Agreement (TPPA), said Tun Dr Mahathir Mohamad after presenting his keynote address at the IFLA Asia Pacific Congress 2014 [22]. The opinion from the experience people should be considered and analyzed before we decide any result.

6.1 EFFECT ON ECONOMY

There is a study by United Nation Development Programme (UNDP) in August 2013 on the impact of TPPA on welfare, GDP, employment and trade in Malaysia. The study was a quantitative analysis using a Computable General Equilibrium (CGE) model was applied to assess the impact, in terms of welfare, GDP, employment and trade, of an agreement for mutual tariff elimination among Malaysia and the seven other participating countries, exploring the impact of tariff liberalization. Malaysia's policy objectives aim at achieving developing country status by the year 2020. This study is to identify how the outcome could be shaped if Malaysia participates in the TPPA [21].

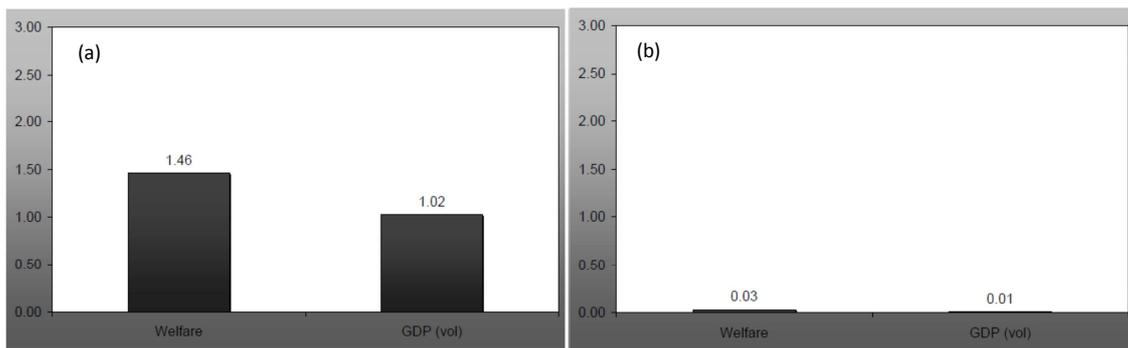


Figure 3: Effect on welfare and GDP (a) if Malaysia joins the TPPA (b) if Malaysia does not joins the TPPA

Figure 3 (a) shows that the implementation of the TPPA would generate a welfare gain of 1.46 percentage points and 1.02 percentage points in GDP in 2020 for Malaysia economy. The impact if Malaysia does not joint the TPPA (figure 3, (b)), suggest that Malaysia is likely to achive a small positive impact on its welfare and GDP in 2020. These benefits are directly achived from higher economic growth in TPPA members countries which will result in slight increase in Malaysian exports to these market [21].

Figure 4 (a) shows the TPPA will generate salary increase for both skill and unskilled labor (1.20 and 1.11 percentage points) in 2020. It also shows employment in agriculture sector will be reduced by 0.65 percentage points while it will increases by 0.07 percentage points in non-agriculture sectors in 2020. Because of the GDP is small if Malaysia does not join the TPPA, the positive impact on GDP is too small to improve the level of labor remuneration. In contrary, real wages for both skilled and unskilled workers decreased compared to their levels in 2020 in the baseline scenario (Figure 2 (b)). This decline is the result of slightly higher absorption of new investments by capital-intensive activities instead of labor-intensive activities [21].

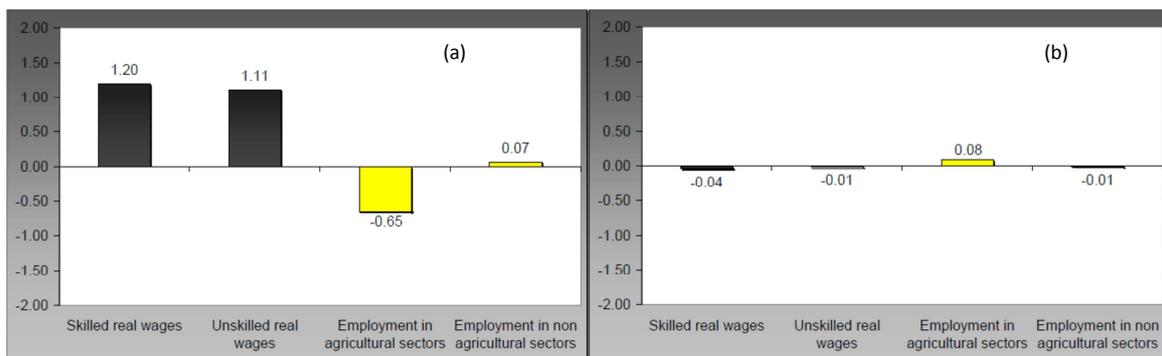


Figure 4: Effect on labor market (a) if Malaysia joins the TPPA (b) if Malaysia does not joins the TPPA

Finally, the implementation of the TPPA is expected to generate an increase in total exports by 0.82 percentage points in 2020 and increase in total imports by 1.06 percentage points (Figure 5 (a)). Figure 5 (b) shows the trade balance is negatively affected given that imports increased more that exports. The increase of imports is mostly originated from the TPPA member’s countries which show their international competitiveness improved as a result of lower domestic prices, more efficient competition and lower production costs [21].

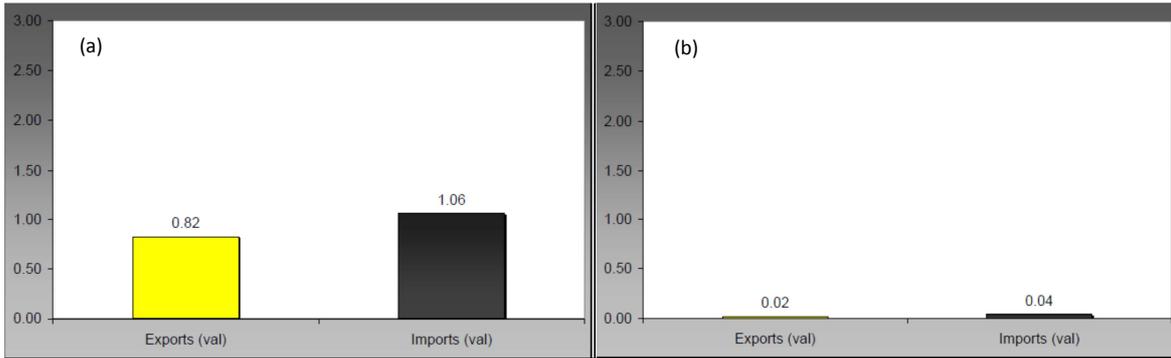


Figure 5: Effect on trade (a) if Malaysia joins the TPPA (b) if Malaysia does not joins the TPPA

The TPPA will result in a huge duty free market for Malaysian goods and services. Market access for our goods and services to 800 million people is not an opportunity that we can afford to miss, especially given that we are an open economy, highly-dependent on international trade. The TPPA is an initiative to establish an FTA among 12 countries with a market of 800 million people with a combined GDP of USD 27.5 trillion. From this study, if Malaysia does not join the TPPA, Malaysia would be at a disadvantage in terms of seeking bigger and better market access for Malaysian products and services. The impact of that disadvantage will be even more significant should countries such as China, South Korea, Taiwan, Thailand and other competitors decide to join the TPPA later. A decision not to participate in the TPPA will result in Malaysian exporters being less competitive in the TPP market because Malaysia will be excluded from enjoying the preferential tariffs compared with countries like Vietnam and Singapore that are our competitors [21].

Although the study by UNDP says that Malaysia will be less competitive if Malaysia choose not to sign the TPPA, but Malaysia also have to study from the different side of the TPPA. Either Malaysian competitive enough with other TPPA countries or not because in the TPPA content there are a few suggestion that Malaysia have to follows which are elimination of import duties on goods coming in from America, giving people the freedom of other countries to work and compelling business in this country with no strings attached, production of capital out of the country freely, indigenous ownership to foreign companies wishing to operate in the country is no longer a requirement Malaysia could be sued by a foreign company or a foreign government if the change of law or regulation that is seen harming their business and government contracts must be open to foreign companies without, we treat the interests of the indigenous.

If countries agree to sign this agreement, it means that Malaysia will lose hundreds of millions of dollars a year, local entrepreneurs difficult to compete and may be among the people who lost their jobs will result in unemployment and the destruction of the social system of the country. Countries participating in the TPPA, mostly already have FTAs with the U.S., excluding Japan, New Zealand, Malaysia and Brunei. Japan and New Zealand is a developed country that has one of the largest rail networks in the world trade, while Brunei is a country that is very rich in resources, even a small trading. This makes Malaysia, as a country most threatened by status as a developing country and the new agreement with America's TPPA. For a country that already has bilateral agreements existing FTA with the U.S., TPPA may involve only minor changes to the status of an existing agreement. But for a country with little economic scale, TPPA will leave a greater impact.

6.2 EFFECT ON ISDS AND SOVEREIGNTY

This issue is arguably the most important issue, because almost all the chapters related to the discussion. This chapter will restrict space policy making by the government through clause 'Investor -To -State Dispute Settlement (ISDS)' and 'State -To -State Dispute Settlement' (SSDs). ISDS is under the provisions of the investment chapter, which basically allows any company to drag the government to court to claim damages and compensation [9].

TPPA would strengthen the "corporate justice" across all countries on the grounds of "fairness and equality". What is equality and equality is meant here? In short, multinational companies can be comfortable with the understanding that no changes to domestic laws that will affect them badly, as soon as they started operations in partner countries TPPA them. In fact, this is the ticket to giant multinational companies to move the legal system of a country, through an international judicial tribunal composed of three judges; two international judges and one local judge. For example, if Malaysia suddenly found that there is little content in tobacco are harmful and make the decision to ban such content, thereby affecting the profitability of multinational tobacco companies, the company has the right to sue the government based on the potential

losses incurred during the period of their permit operating in Malaysia, with interest. That is what happened in the case of Philip Morris, when the company was suing the Australian government over the creation of a new law on cigarette packaging.

In fact, not extreme if we expect that lawmakers and the Parliament will be allowed to not work; they cannot enact laws that affect the profits of multinational companies and business continuity. We still remember how Mexico sued the U.S. \$ 16 million for not allowing the removal of hazardous wastes into the environment by the American company. Another well-known case is that developed countries like the U.S. and Japan are working to implement the ISDS by TPPA and also anything that is seen as lacking under the agreement of the World Trade Organization (WTO). While we can only assume that this clause shall not be ratified because of the potential negative effects, there is concern that there are essentially [9].

6.3 EFFECT ON SME AND AGRICULTURE

TPPA is expected to open up government procurement market for Malaysian companies in all 11 of the other TPPA countries. This will create more business opportunities for Malaysian companies. It is true that the government procurement market in Malaysia will also be open for other TPP member countries. However, the Government will ensure that the level of openness of government procurement market is based on the interest and feedback from stakeholders in the country, including establishing an appropriate level of protection for industrial SMEs in the country. Limit determined in the field of government procurement (for example, the offer will be open to the members of the TPP) will be decided in consultation sessions with government-linked companies (GLCs) locally. Field of interest to the business community Bumiputera SMEs has been omitted in Malaysia offer [4].

TPPA aims to liberalize trade and reduce tariffs, which could lead to drastic job losses in many sectors. The direct impact is direct pressure on wages and thus widens the income gap already big now. Mexico is a good example; a result of the signing of the General Agreement on Trade in North America (NAFTA) with Canada and the United States, three million of the ten million Mexicans lost their jobs. Tariff reduction will have a direct impact especially on agricultural products. How noble motives TPPA promote efficiency and healthy competition, the intention being unfair when we look at the fact that over 90 per cent of Malaysian companies involved in the agriculture sector are small and medium enterprises (SMEs). They will face competition disproportionately from agriculture giant companies from countries like the U.S., Canada and Japan, where the government does not reduce the already huge subsidies to their farmers.

The study by UNCTAD shows that subsidies have lowered the cost of production of rice by 45 percent American, 32 percent of soybeans and cotton by 52 percent. Rough calculations show that the yield of rice they can meet the Malaysian market as low RM1.40/kg. What will happen to BERNAS, and the fate of the smaller local producers?

6.4 EFFECT ON IPR AND HEALTH

Although there are advantages of copyright, intellectual property (IPR) and patent medicine which are to take care of the individual hard work but the disadvantages are greater especially in cost. The latest proposal on issues affecting the field of IPR patent will have an impact on the cost of medicines and health matters. Malaysia's stance in this regard is clear - this Agreement cannot pose a negative impact on Malaysian health. Malaysia must continue to enjoy the protection of quality health and can afford to buy medicines, including generic drugs [5]. TPPA negotiations should take into account the importance of this. Malaysia recognizes companies that produce drugs has invested heavily in research and development, and there is no easy way in the innovation process and the production of new medicines. Malaysia also recognizes the incentives for such innovation should be rewarded as an incentive to the manufacturers of drugs to remain in the industry to continue to produce essential medicines to address new diseases. Malaysia believes a balance can be reached between protecting the rights of producers of drugs and the rights that assure the ability of people to obtain affordable medicines. Malaysia will strive to achieve a balance in the TPPA.

A few countries such as New Zealand, Australia and Canada and World Health Organization have discussed in detailed and come out with their own policy and report especially in the impact of TPPA in health. Unfortunately Malaysia was not serious in this discussion. There are NGOs that are talking about the impact on health but no one has come out with a policy and proposed to the Malaysian government.

We know that about 80% of the medicines that Malaysians consume are generic medicines, which are generally much cheaper and thus more affordable than 'original', patented medicines. For example, in Malaysia, patented medicines can be 1,044% more expensive than their generic equivalents. Malaysia already provides adequate protection for pharmaceutical companies' research and products, which it seeks to balance against the need for affordable access to medicine and medical

treatment. With the TPPA, access to affordable, life-saving medicines for millions of people is under threat as it provides higher protections for the patents and clinical data of big pharmaceutical companies, making it harder for generic companies to produce affordable medicines, thus delaying and restricting the access to generic medicines.

UNITAID, World Health Organisation (WHO) reported on the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement. These so-called “TRIPS-plus” provisions delay generic market entry and competition. Public interest and public health groups, as well as a number of United Nations agencies, have voiced concern over such “TRIPS-plus” provisions [17]. A dramatic illustration of the direct impact of TRIPS-plus rules captured global attention when, in 2007 and 2008, shipments of generic medicines from India to other developing countries were detained at European ports on allegations of intellectual property infringement. One of the shipments included an HIV medicine, *abacavir sulfate*, the purchase of which had been funded by UNITAID and which was destined for a project implemented by the Clinton Foundation in Nigeria [17].

The ongoing TPPA negotiations have attracted significant controversy and debate. Aside from the proposed scope and potential impact, the secrecy under which the TPPA negotiations have been conducted has attracted criticism. Negotiating texts that have been leaked to the public domain have caused disquiet regarding the scope and content of the provisions under negotiation [17]. In addition to TRIPS-plus intellectual property provisions being negotiated as part of the TPPA, there are also serious concerns that proposed provisions related to financing and/or reimbursement of medicines, as well as to investment, will have adverse implications for access to medicines and the protection of public health in general [17].

In 2004, the monthly cost of treating HIV patients were reduced from RM1,200 per patient to only RM200-220, after generic medicines replaced patented ones. As a result, 4,000 patients could be treated compared to only 1,500 previously. With the TPPA, cheaper generic medicines could be under threat. There are proposals from several countries participating in the TPPA negotiations to extend the copyright term of 70 years after the death of the copyright holder. If we just look to the side, of course we will view that copyright protection should not be extended over a long period of up to 70 years after the death of the original copyright holder. This is because the Malaysian import of intellectual property is said to be in excess of the rate of intellectual property generated within the country or exported out. However, it is government policy to promote the development of knowledge-based and innovation as the creative industries, software, writing books and other related activities [11].

Several articles of the intellectual property chapter proposed by the USA relate to patents. Overall, the USA's TPPA proposal appears to weigh heavily in favor of patent applicants by requiring lower levels of disclosure, lower standards of patentability, no pre-grant opposition proceedings, and multiple opportunities to amend patent applications. The overall impact of these measures is likely to be the granting of a greater number of patents on medicines and medical technologies, including a greater number of weak or “poor-quality” patents. The proposed intellectual property chapter also includes requirements regarding data exclusivity and patent linkage (formally referred to as “Submission of information or evidence concerning the safety or efficacy of a new pharmaceutical product”). A placeholder remains for data exclusivity for biologicals.

Alongside the provisions on patents and data exclusivity, the proposed intellectual property chapter of the TPPA also includes TRIPS-plus provisions related to the protection of trademarks. Trademark protection is typically provided for distinctive signs—including symbols, letters or names—which enable consumers to identify easily specific producers of goods and services with an established reputation. The provisions in the USA's TPPA proposal suggest a shift away from this consumer-oriented justification for trademarks towards the protection of the producer's investment in advertising and promotion. Such a shift can have implications for access to medicines and protection of public health [17].

The proposed intellectual property chapter sets out the provisions proposed for copyright and related rights in the TPPA. As with other intellectual property protection in the USA's TPPA proposals, copyright protection is also significantly expanded. The overall effect of the proposed copyright provisions would be an extension of international obligations relating to the length and scope of copyright protection. While the implications of these provisions for access to medicines and public health are unclear, it would be prudent to explore whether such expanded copyright protection could be interpreted in ways that hamper or prevent the production and sale of generic medicines.

One of the leaked TPPA texts is the annex on “Transparency and procedural fairness for healthcare technologies”. The text proposed by the USA in the annex would require TPPA signatories to comply with obligations relating to pharmaceutical pricing and reimbursement schemes. The probable effect of these proposals would be to limit countries' policy space to adopt and enforce therapeutic formularies, reimbursement policies and other price-moderating mechanisms within public health systems. While many developing countries have yet to establish pharmaceutical reimbursement schemes, adoption of the provisions proposed in this annex would have the effect of prescribing the type of system that governments would be

permitted to establish, instead of allowing them to choose or design the system that is most suited to the specific national context and priorities. The proposal would also have the effect of imposing obligations in an area of domestic regulation that is well beyond the protection of intellectual property rights; it would affect health policy-making itself [15].

As an alternative to signing the TPPA and adopting TRIPS-plus provisions that can threaten treatment access for many in developing countries, the negotiating parties may wish to consider the types of measures that would strengthen and further expand the gains made in the effort to increase treatment access. Governments may wish to adopt coherent approaches in which trade and intellectual property policies are formulated in a manner that preserves the ability to provide long-term, affordable and sustainable access to medicines. As an interested stakeholder, UNITAID supports the adoption of a “positive agenda”, wherein governments actively identify and implement policies that can help achieve the goals of trade and economic growth alongside the objectives of ensuring access to needed medicines and the protection of public health. Such a positive agenda might include some of the approaches outlined below [17].

Malaysia knows that increased costs of medicine can cause financial burden for patients which can impact their health. In a 2008 survey on patient behavior, more than 75% of respondents said a price increase in co-payments would cause financial difficulty. However, despite the added financial burden most would continue prescribed medicine use. This indicates that the financial impacts of cost increases may impact other areas of life, such as food or housing, than prescription use alone [6].

Generally women, elderly, cultural and linguistic minorities, and low-income populations report the most difficulty with financial barriers to prescription use. Both geographically remote and low-income populations have the lowest use of prescription medications [6]. People with chronic disease are also more vulnerable to price fluctuations. In a study of the financial burden of managing a chronic illness, 45% of Sydney households were unable to pay at least one medical or living expense in the past year. People who were economically disadvantaged spent more to manage their illness than those who were not experiencing economic hardship [3].

Malaysia is working with TPP members for an outcome that would strike a balance between the continued need to allow access to affordable drugs and healthcare and sufficient incentives for drug companies to innovate. Malaysian negotiators will continue to negotiate an outcome that will ensure Malaysians will continue to have access to affordable medicine and healthcare.

6.4.1 TOBACCO

Besides the copyright and intellectual property, provisions in the TPPA for tobacco may impact the ability of Government to enforce existing policies and implement new policies that support public health. In Malaysia, a comprehensive tobacco control programme has existed since 1993 [13,14]. This programme includes the Control of Tobacco Product Regulations and its enforcement, the tobacco duty, the national anti-tobacco campaign, school-based programmes, and the quit-smoking clinics. The tobacco control regulations are similar to those in developed countries and include the restriction of smoking in public places, advertisement regulations, display of health warnings on cigarette packs, provision of the tar and nicotine content, and regulation of the sale of tobacco products [13,14].

If Malaysia signs up to the TPPA, we'll be putting our smokefree goal at risk. This is because a leaked TPPA text shows that the agreement will give more rights to big overseas companies, including the right to sue the government for making decisions which significantly hurt their investment. This process is called Investor-State Dispute Settlement and it takes place in secretive offshore arbitration tribunals, bypassing local courts. Anti-smoking measures taken by our government could be challenged by the tobacco companies if we sign the TPPA [12].

If you think this sounds far-fetched, it's not — the Australian government is currently being sued by Philip Morris for its new plain packaging policy under an old international agreement between Australia and Hong Kong. Even though Australia's highest court has ruled in favour of plain packaging, the government still faces international arbitration away from the eyes of the public, and could end up paying hundreds of millions of dollars to big tobacco for trying to protect the health of its citizens. Like Australia, our smokefree law could be challenged under an existing agreement, but it would be difficult and involve back door manouvering [16]. The TPP would let big tobacco stride through the front door. It isn't just plain packaging laws that will face problems if the TPPA negotiations are completed. Other policies that could fall foul of the rules include: banning the use of terms like 'mild', 'smooth', 'fine'; controlling the use of flavors that disguise the foul taste of tobacco; reducing the nicotine content of tobacco products; and capping the number of tobacco retail outlets [7].

Many different chapters of the TPPA would impact on the smokefree policies, for example: intellectual property laws could be strengthened in favour of big tobacco companies, making it easier for them to claim that tobacco control policies infringe their trademarks; big tobacco's factories, distribution chains and intellectual property rights would be 'protected

investments' who could also sue; advertisers, duty free stores, retailers, and other parts of the tobacco supply chain would also have special rights, even if they were operating by Internet from offshore; and new "transparency" and "regulatory coherence" rules would give tobacco companies much more influence over government decisions on tobacco control [16]. This would go against another agreement signed by Malaysia — the Framework Convention on Tobacco Control (FCTC) — requiring the government to take steps to prevent tobacco company interfering in policy-making [8].

In the Tobacco issue, the cost to the healthcare system from health effects of tobacco, alcohol, and obesity — three target areas of the preventative health strategy — is estimated to be roughly \$6 billion per year, and lost productivity as a result is estimated at almost \$13 billion in Australia. Provisions in the TPPA may have an impact on Australia's tobacco plain packaging laws and our capacity to introduce other progressive tobacco control policies in the future [3].

In 2013, the Malaysian Government tabled a proposal to "carve out" (i.e. exclude) tobacco from the TPPA. This would mean tobacco control measures (such as tobacco plain packaging) would not be covered by any of the provisions in the TPPA. However, reports suggest that the Australian government is not supporting this proposal [3].

6.4.2 ALCOHOL

Alcohol abuse is also a problem in Malaysia. Part of the solution is setting rules around the sale of alcohol — for example, a minimum price per unit of alcohol, lower limits on the alcohol content of RTDs (ready to drink), and banning advertising and sponsorship by alcohol companies [16]. The government will also face pressure to allow imports of products that meet the alcohol product standards in other TPP countries, even when they are inconsistent with our own.

Provisions for alcohol from the TPPA may impact the Government's ability to implement effective alcohol control policies such as restrictions on liquor licenses, bans or limits on alcohol advertising, and alcohol health warning labels. Alcohol contributes towards 4% of the world's disability adjusted life years, or years lost due to alcohol-related injury or death. This is approximately the same proportion as tobacco (4.1%). Alcohol is associated with significant health effects to the brain, heart, liver and other organs, as well as social and psychological impacts [6].

The TPPA is likely to impose significant restrictions on certain forms of government action. These restrictions are significant not only to TPPA parties, but also to other trading nations. A number of legitimate concerns arise from the potential impact of the TPPA on certain aspects of public health regulation, including tobacco control regulation and ensuring equitable access to medicines. Public health concerns are elevated by the inclusion of ISDS in the treaty, even though an ISDS mechanism may bring benefits to TPPA parties. A general health exception applicable to the treaty as a whole — complemented with clarification of the extent of investment obligations — would be preferable to a product-specific exclusion of tobacco. However, TPPA parties must take care to avoid overly prescriptive regime with respect to regulatory coherence or transparency given the risk of tobacco industry interference in tobacco control regulation and the potential of placing government agencies in a position of conflict. The TPPA's intellectual property provisions must also be crafted taking account of the need to enable access to medicines, including in respect of pharmaceutical patent protection [16].

As the TPPA negotiations reach their final stages, the broader community can only speculate on how the text has progressed since the leaking of particular provisions, proposals and chapters. Unfortunately, critiques of the final text after the conclusion of the treaty are unlikely to have much practical effect, and academic and public debate while the negotiations are ongoing has gone largely into a vacuum, with little indication of the extent to which concerns are being taken into account by negotiators. This is a common flaw of the treaty negotiation processes in many countries, and a particular flaw of the TPPA negotiations. In the case of public health, among other issues, the goal of promoting sensible and effective policy should continue to be balanced in the development of PTAs with the goal of promoting international trade and investment, and open discussion of this balance may help achieve the optimal solution. Malaysia has to include more experts in health to look into the issue before really involved into the TPPA.

Médecins Sans Frontières urges all governments' negotiation the TPPA specifically to [18]:

- a. Remove TRIPS-plus requests - TPP negotiators should not agree to final text that includes TRIPS-plus provisions, which can severely limit access to medicines in developing countries. Instead, TPP negotiators must insist on language that protects public health safeguards and enables developing countries to effectively balance commercial interests and public health.
- b. Increase transparency - Trade negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, including providing access to the negotiating texts.
- c. Fulfill previous commitments to access to medicines - TPP negotiators should ensure that the final text is aligned with global health priorities and specifically mentions and honors relevant public health commitments, including the 2001 WTO Doha Declaration on TRIPS and Public Health and the 2008 WHO Global Strategy and Plan of Action on Public

Health, Innovation, and Intellectual Property. In addition, the U.S. should adhere to its own May 10, 2007 New Trade Policy, which includes a commitment to refrain from imposing some of the most damaging TRIPS-plus provisions on developing countries.

Sustainable economic development brings potential improvements to health and wellbeing. There may be potential for the TPPA to contribute to economic development, higher standards of living and better health. However, there is a risk that the economic gains which the TPPA may represent, as well as the health of the Malaysian community, will be threatened if certain proposed provisions are adopted for the TPPA. This brief has presented evidence about some of the economic, health and social costs associated with medicines, alcohol and tobacco which could eventuate from the TPPA. These include increased direct costs in terms of providing health care and increased use of hospitals, higher costs of obtaining pharmaceuticals, indirect costs associated with lost productivity across society, continuing or exacerbating inequalities in society and worsening the health of Malaysia's already vulnerable communities.

Because of that a few organizations and NGO's urge Malaysia to delay the TPPA negotiations until all the text and relevant documents exposed to the scrutiny of the public and NGOs and profit and loss analysis conducted to find out the interest of the people, entrepreneurs and state. In addition, a negotiation relating to investments such as adverse local service status has to be removed from the TPPA. But if the government wants to continue negotiations in connection with the investment, the organizations urged the government to such matters as settlement of the dispute between the investment and the excluded as done by Australia.

The overriding priority of any international agreement must be the long-term best interests of a country's citizens. NGOs have serious concerns that the partnership agreement will cause patients to suffer and will load governments with additional, unreasonable costs for medical technologies (both new and existing). NGOs urge government to ensure that the MITI rejects any proposals within the TPPA negotiations that would require changes existing law, policy settings or practices that threaten Malaysia ability respond to new health care and public health challenges in the future. Further, NGOs hope that the Government can share the text of the TPPA prior to signing in order to discuss and debate to the best.

Improving regulatory coherence, maximizing efficiency and economic growth are valid and worthwhile goals of TPPA negotiations. A signed agreement would almost certainly be benefit Malaysia's economic measures. However, it is important that legitimate health goals can coexist with economic aims. In the presentation by MITI on 18 June 2014, minister has informed that TPP ministers have been meeting regularly to resolve the key issues. The latest update is they will meet next in early December 2014 for the discussion. However, the finalized text of TPPA will be debated in parliament. We hope that the minister will hold what he said in the presentation that we need to open up, but on our terms and on balance advantages more than challenges, must benefit the people.

7 CONCLUSION

In dealing with TPP agreement, the government has to be very careful and taken necessary steps to ensure the advantages in favor of Malaysia especially in health. Every action needs to refine and address with care. The advantages and disadvantages should be considered before a final decision is taken to sign the TPP agreement especially in health matter. High cost of medicine and treatment to the patient definitely will burden the people. Government has to ensure that the TPP agreement will not burden Malaysia people especially with higher cost in health sectors. So, support of all parties is required by the government to ensure that decisions will be made later is the best decision for all Malaysians.

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