WHO Collaborating Centre
for Regulatory Control of Pharmaceuticals

Member of Pharmaceutical
Inspection Cooperation Scheme

MS ISO 9001:2008 Certified

MS ISO 17025:2005 Certified

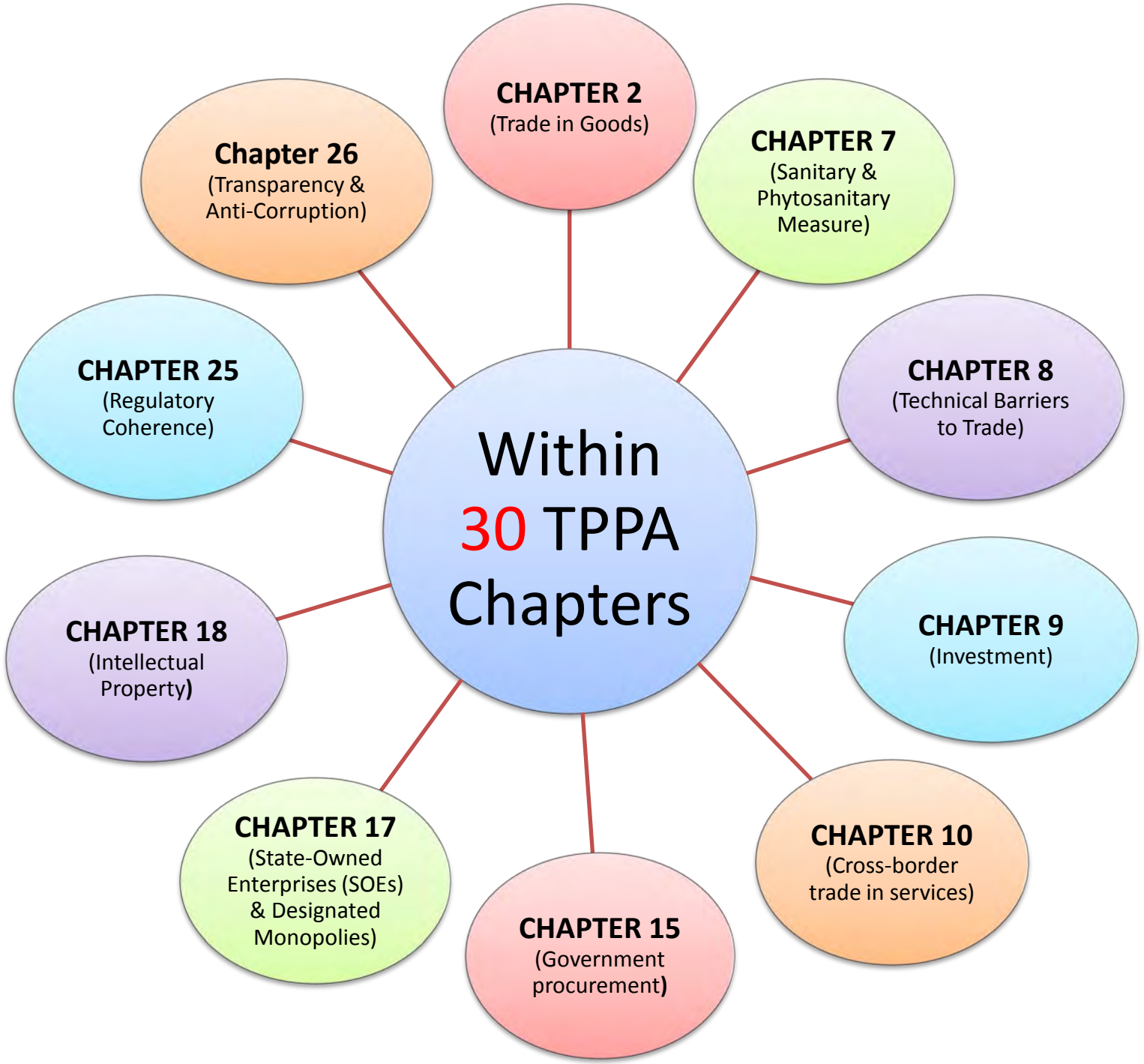
Non-OECD Member
full adherence to the Mutual
Acceptance Data (MAD) System

NATIONAL PHARMACEUTICAL REGULATORY AGENCY
(NPRA)

Experience on TPP, from joining the negotiation through agreement finalization and system reform

TRANS PACIFIC PARTNERSHIP AGREEMENT (TPP): MINISTRY OF HEALTH MALAYSIA'S EXPERIENCE

ITH TECHNICAL CONFERENCE 2016
BANGKOK, THAILAND
8TH OF AUGUST 2016



10 TPPA CHAPTERS WITH POSSIBLE IMPACT ON HEALTH SECTOR

Issues Related to TPPA and Possible Implications on Health in Malaysia – MOH Perspectives:

4 **Main Areas :**

1. **PHARMACEUTICALS**
2. **FOOD (INCLUDING ALCOHOL)**
3. **MEDICAL DEVICES**
4. **TOBACCO**

Trade and Access To Medicines

MOH is sensitive to the challenges faced by Malaysia on the issue of free trade of pharmaceutical products and access to medicines

MOH, through the National Pharmaceutical Regulatory Agency (NPRA)

- harmonization initiatives which aims to minimize technical barrier to trade
  - ✓ Pharmaceuticals (PPWG)
  - ✓ Traditional Medicines and Health Supplement (TMHSPWG)
  - ✓ ASEAN Cosmetic Committee (ACC)

- bilateral and multilateral engagement (including TPPA).

Participating in the TPP

TPP is a national endeavour

- √ 16 Ministries and government agencies
- √ IP Chapter lead -Ministry of Domestic Trade, Co-operatives and Consumerism

MOH has been part of the TPP negotiating team .

to ensure the agreement does not negatively impact

✓ timely access to affordable medicines and

✓ growth of the local generic pharmaceutical industry

TPP PROCESS

	Stakeholders	Process
NEGOTIATION PROCESS	Negotiators	MITI is the Chief Negotiator but other ministries and agencies lead the working groups for areas under their responsibility.
	TPP Ministers	TPP ministers have been meeting regularly to provide political guidance
	TPP Leaders	TPP Leaders Meeting
DOMESTIC PROCESS	Engagement	Government has been continuously engaging with stakeholders and different interest groups to update and get feedback.
	Cabinet	Cabinet is constantly updated on the TPP process and provides the mandate to our negotiators
	Parliament	The finalized text debated in parliament. Decision for signing
	Ministries	Ratification

Trans-Pacific Partnership Agreement (TPPA)

Chapter 18. Intellectual Property

IP AND PHARMACEUTICALS
KEY PROVISIONS

Subsection C :Measures relating to pharmaceutical /regulated products

i. Patent term adjustment
ii. Patent linkage
iii. Pharmaceutical data protection/ Protection of undisclosed Test or other data
- small molecules (other than biologics medicines)
- biologics

IPR and Pharmaceuticals
Key Provisions in TPPA

- Subsection C :Measures relating to pharmaceutical /regulated products
  1. Patent term adjustment
  2. Patent linkage
  3. Pharmaceutical data protection/ Protection of undisclosed Test or other data
     - small molecules (other than biologics medicines)
     - biologics

Issue 1: **Intellectual Property**

Chapter	Summary of chapter	Implication
CHAPTER 18 : **Intellectual Property** **1.** ***Article 18.48 Patent Term Adjustment for Unreasonable Curtailment***	**<u>Patent Term Adjustment</u>** In the TPPA Malaysia is obligated to make available **a patent term adjustment** to compensate the patent owner if there is a delay in the medicines marketing approval	Adjustment due to delays may lengthen patent term beyond 20 years, will then possibly delay entry of generics. However, impact is expected to be minimal as MOH is efficient at processing marketing approval for medicinal products. MOH has to ensure that a proper system is in place : • A proper time tracker or stop clock that accurately records the time taken for the review process, and shall not include anything other than the time taken for review. • A maximum number of applications that can be reviewed annually – to match the resources available to process such applications.

Efficiency in the marketing authorization approval process (NCE & Biologics)

Year	Category of Product	Total no of products	Breakdown of processing time (working days)				
			<100	**101-150**	**151-200**	**201-245**	**>245**
	Biologics	22	9	4	2	7	0
	NCE	50	12	10	19	9	0
2012	**Total**	**72**	21	14	21	16	0
	Biologics	26	2	12	7	4	**1**
	NCE	41	6	10	11	14	0
2013	**Total**	**67**	8	22	18	18	**1**
	Biologics	12	4	1	1	6	0
	NCE	58	7	6	9	36	0
2014	**Total**	**70**	11	7	10	42	0
	Biologics	13	1	2	6	1	**2**
	NCE	24	3	6	2	13	0
2015	**Total**	**37**	4	8	8	14	**2**

- The statistics of NPCB indicates that the approval process is efficient, as applications for NCE and biologics can be processed within the specified time

- A TPP country can also determine what length of period is considered an **unreasonable delay**

*with the exception of
1 case in 2013 Vectibix 100mg Concentrate for Solution for Infusion(257 working days)
2 cases in 2015 Tisseel, (Fibrin Sealant) Frozen Solution(270 working days)
Fluarix Tetra Influenza Vaccine (261 working days)

Issue 1: **Intellectual Property**

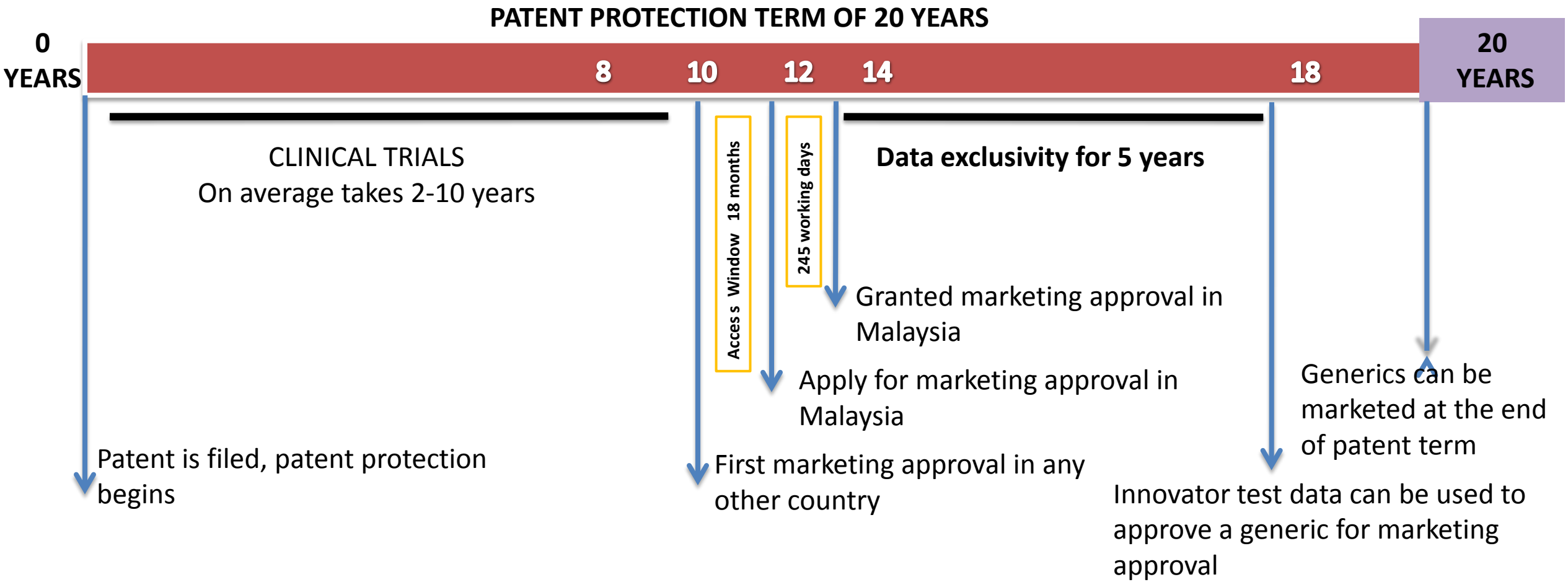
Chapter	Summary of chapter	Implication
CHAPTER 18 : **Intellectual Property** **2. *Article 18.51 Measures Relating to The Marketing of Certain Pharmaceutical Products***	**<u>Patent Linkage</u>** In the TPPA, Malaysia is obligated to **provide a notification system** to a patent holder that the generic or biosimilar company is seeking to market an approved pharmaceutical product during the term of a patent.	There is no impact on the public's timely access to latest generics as the commitment only entails a "soft" linkage To fulfil this obligation, MOH needs to increase efficiency and continue to provide capacity building as well as enhancing its online registration system (QUEST)

Issue 2: **Intellectual Property**

Chapter	Summary of chapter	Implication
CHAPTER 18 : **Intellectual Property** **3 . (i)** ***Article 18.50 Protection of Undisclosed Test or Other Data***	**<u>Protection of test data / Data Exclusivity (DE)for (i) small molecules</u>** In the TPPA, Malaysia **will continue to provide test data protection for pharmaceuticals for five years.** **The DE period starts from the approval date in Malaysia.**	Minimal impact as DE provisions under TPPA similar to current regulatory practices. The TPP will not affect Malaysia's **'access window'** (application for marketing approval must be submitted within 18 months from the date first approved in any other country), which **is a condition before any data protection is granted** This **'access window' is fundamental**, and will ensure that new pharmaceuticals/biologics would enter into Malaysia early, thus enable Malaysians to have **access** to these life saving products.

Timeline for Patent Protection and DE

- Granting pharmaceutical test data protection within the patent term of the product **will not delay access of generics and biosimilars to the public** as the period of protection for the patent and test data is **concurrent**.
- Imposing the **'access window'** condition will avoid **overhang of a patent term.**



Issue 1: **Intellectual Property**

Chapter	Summary of chapter	Implication
CHAPTER 18 : **Intellectual Property** **3. (ii) *Article 18.52 Biologics***	**<u>Protection of test data / Data Exclusivity (DE)for (ii) biologics</u>** Agreement on biologics gives two options for TPP Parties: ➢ countries to offer 8 years market protection for Biologics; or ➢ countries to offer 5 years of data protection, and other measures such as regulatory measures and patent to deliver comparable market protection for biologics. The biologics agreement also provides a review to be undertaken 10 years after entry into force of the TPPA.	Currently Malaysia does not provide DE for biologics. Malaysia is taking the second option of a minimum standard of 5-year exclusivity and other measures. Patient's timely access to the latest biosimilars may be delayed, but this impact, however, may not be significant since the 18-month access window safeguard also applies.

Biosmilars takes more than 5 years to be developed

Biosimilar (company) -first approved	Reference Product (company) -first approved	Years gap before first biosimilars were registered
SciTropin (Sandoz) EU 2006	Genotropin (Pfizer) Feb 1997	9 years
Binocrit (Sandoz) EU 2009	Eprex (J&J) Sept 1998	11 years
Zarzio (Sandoz) EU 2009	Neupogen (Roche) Aug 2002	6 years
Nivestim (Hospira) UK 2010	Neupogen (Roche) Aug 2002	8 years
Insugen (Biocon) Jan 2014 India 2006-not biosimilar pathway	Actrapid / Insulatard / Mixtard (Novo Nordisk) Sept 1999	7 years
Remsima (Celtrion) Korea 2012	Remicade (J&J) Aug 1999	13 years

- DE protection for biologics is expected to have low potential in deterring new investments in biosimilars, as historical statistics suggest that new biosimilars were generally registered **6 to 13** years after the first marketing approval of their biologics counterparts were granted

- In contrast, the intellectual property protection to biologics could attract biologics manufacturers to expand operations in Malaysia

Section K: Final PROVISION

Transition Periods –

Malaysia needs time to implement obligations.

- ✓ needs resources to ensure efficiency
- ✓ leverage on other TPP partner's experience.

- ➢ Patent term adjustment due to unnecessary delays- 4.5 years
- ➢ Patent linkage -4.5 years
- ➢ Test data Protection for Biologics -5 years

- Transition Periods
- Within this transition period; Malaysia needs to
  - Proceed with legislative amendments
    - The Patents Act 1983
    - The Sale of Drugs Act 1952
    - The Control of Drugs and Cosmetics Regulations 1984
  - continue to provide capacity building and ensure enough personnel to process efficiently all applications for marketing approval for pharmaceuticals and biologics
  - enhance efficiency of on-line system to process application for medicines approval (QUEST)

TPPA and Public Health

- TPPA continues to recognize The Declaration on the TRIPS Agreement and Public Health (Doha Declaration and exceptions for pharmaceutical products)

- the government can issue a compulsory license to enable the local manufacture of a patented product or make use 'Rights of Governments' to import a patented product from a different source at a lower price.

- Malaysia has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The TPPA will....

Improve Market Access

- As a member of PIC/S, Malaysia's pharmaceutical industry has established high manufacturing standards
- Malaysian companies will benefit from preferential market access in new FTA markets: US, Canada, Mexico and Peru
- Patent expiration of major 'blockbuster' drugs opens up an attractive white-space for generics exports.
- Shorter data exclusivity period for biologics could attract biosimilar manufacturers to expand operations in Malaysia

The TPPA

Improves Governance and Transparency

- enhance transparency and good regulatory practices, both internally and among TPP members, through better coordination and information exchange
- The efficiency of NPRA and MyIPO in processing marketing approval and patents for medicinal products respectively will be increased as to avoid extension and adjustment of a patent term
- Although implementation of a notification system for patents under the TPP may seem to favour patent holders, this obligation promotes transparency as NPRA will also be requiring patent holders to declare all patents associated with their products upon registration.
- This win-win situation will ensure that neither innovators nor generic manufacturers are at a disadvantage.

Conclusions

- The perspective of The Ministry of Health (MOH) was integral in the IP negotiations for Pharmaceuticals, to ensure that the agreement strikes a balance between promoting innovations so that new medicines can continue to be discovered, and addressing the needs to obtain essential medicines.

- Early participation in the TPP negotiations have accorded Malaysia with certain safeguards and flexibilities. Therefore we anticipate that the TPP has minimal impact to access to medicines and the growth of the local pharmaceutical industry

- Local generic industry aware that local market is insufficient, and TPP will create opportunity to upscale manufacturing capabilities for produce generics for export

- While initiatives taken to meet TPP obligations may seem burdensome to the government, the process and outcome will improve governance, enhance capability and efficiency and keeps pace with international standards

Conclusion on Pharmaceuticals

- There are many factors that influence the prices of medicines besides IP protection, such as :
  - Uncontrolled mark ups in the private sector
  - Currency fluctuations
  - Volume based tier pricing
  - Differential pricing between countries for innovator products
  - Government procurement policies
  - Imported generics cheaper than locally produced generics
  - Trends towards using newer drug therapies instead of other treatments

THANK YOU

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