

# Compliance Issues in the Context of Public Health: Practical Perspectives - THE MALAYSIAN PERSPECTIVE



**Unny Sankar Ravi Sankar**  
Policy and International Relations  
Division, Ministry of Health Malaysia

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# Overview

- 1. Laws & Regulations Relevant to IPR - Health**
- 2. IPR Provisions Related to Pharmaceutical Products**
- 3. Ministries/ Agencies Involved**
- 4. FTAs**

# Laws & Regulations Relevant to IPR & Health

- **Act 291: Patents Act 1983**
- **Drug and Cosmetic Regulations 1989**
- **Directive under Regulation 29 of the Control of Drugs and Cosmetic Regulations 1984**

# IPR Provisions Related to Pharmaceutical Products

- **Data Exclusivity (DE)**
- **Patent Term Restoration (PTR)**
- **Patent Linkage**
- **Parallel Imports**
- **Compulsory Licensing**

# Data Exclusivity (DE)

**Drug  
Regulatory  
Authority**

**Clinical  
Test  
Data**

- **Safety**
- **Efficacy**
- **Quality**



**Generic Drug  
Manufacturer**

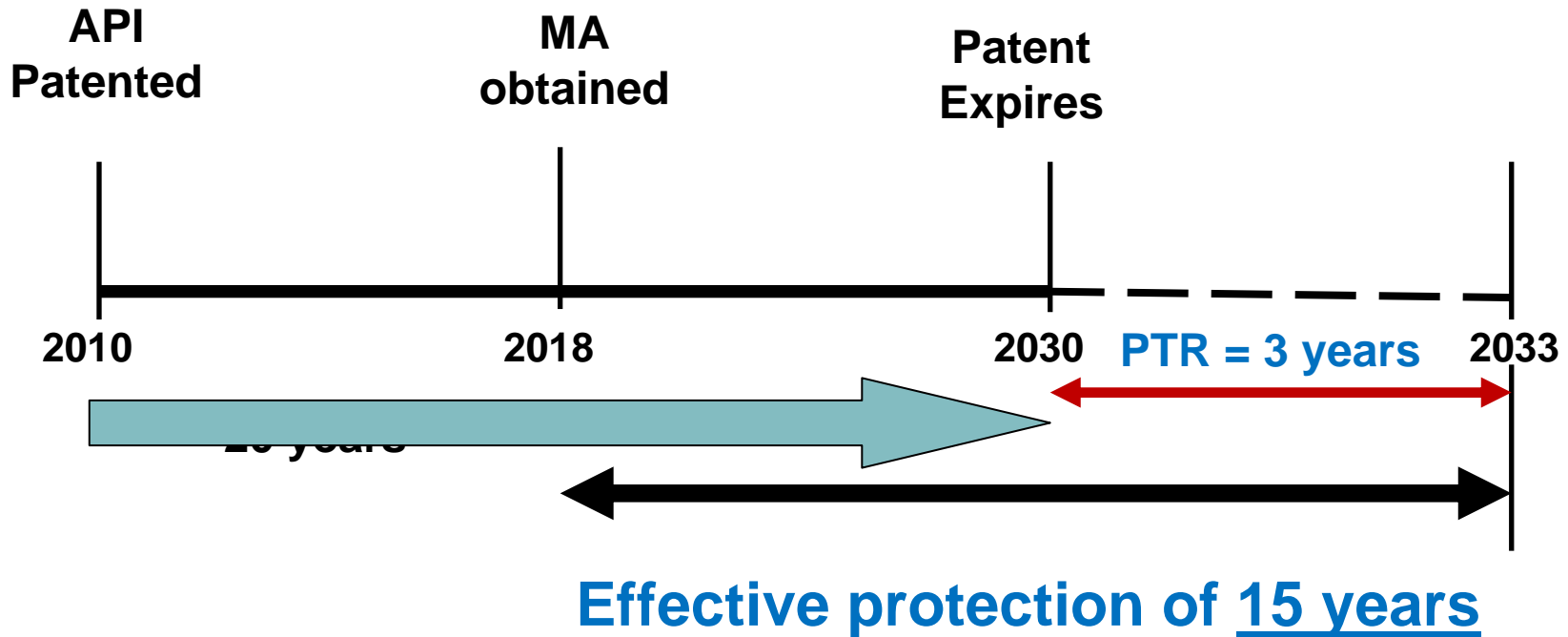
## DE (cont.)

- **Within 20 years of patent**
- **Global Exhaustion – 18 months**
- **5 years for new drug product**  **new chemical entity**
- **3 years for second indication of a registered product**

## DE (cont.)

- DRA holds the right to issue DE
- Dosage strength and forms - **not allowed**
- right to issue compulsory license **will not be affected**

# Patent Term Restoration (PTR)



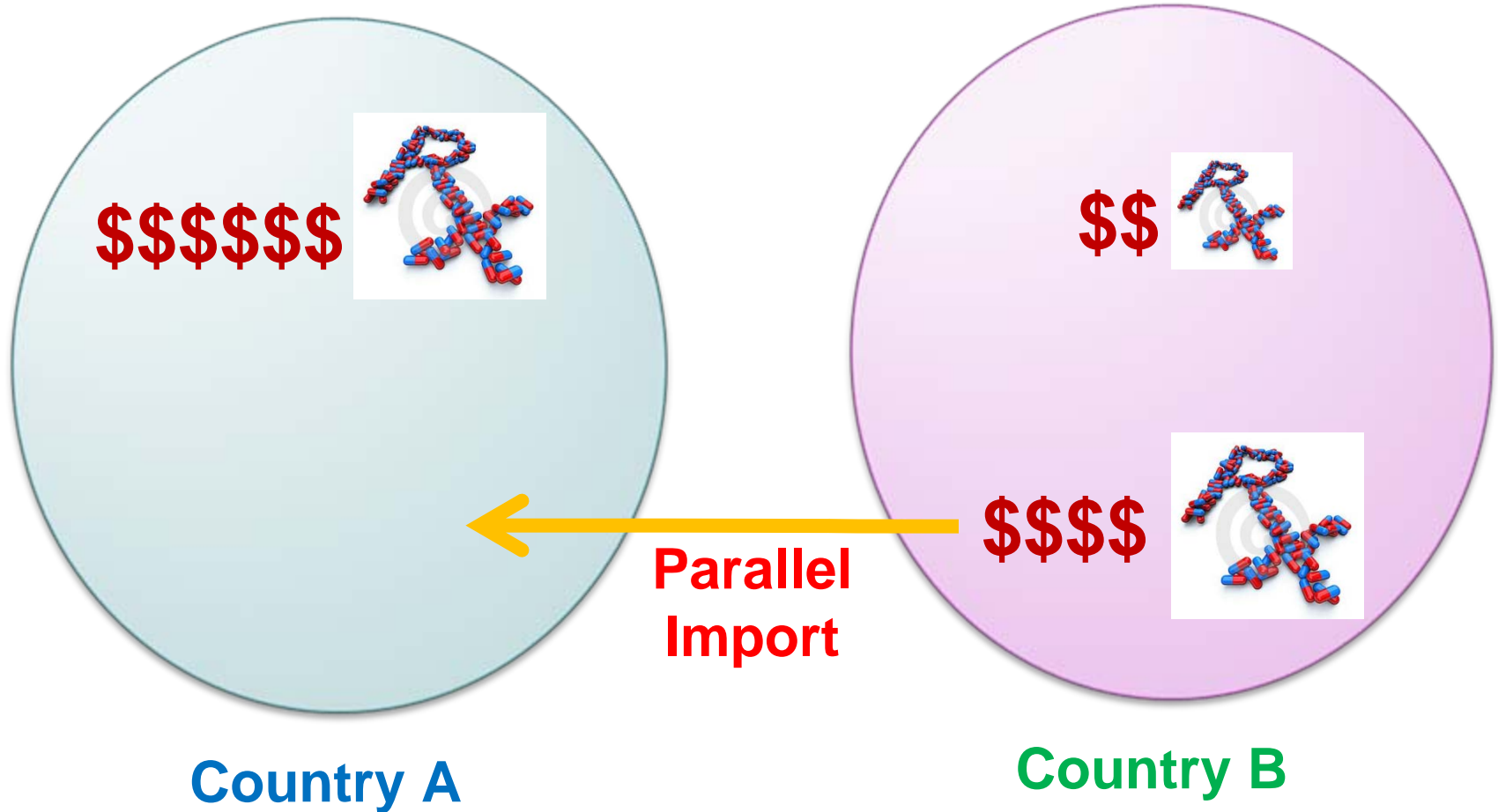
Example based on EU's PTR model



# Patent Linkage

- Refers to the **system or process** by which a country **links** drug marketing approval to the **status of the patent(s)** corresponding to the originator's product
- Malaysia do not plan to implement this system/process
- Costly - **\$\$\$ & human resource**
- Burdensome to DRA – **enforcement**

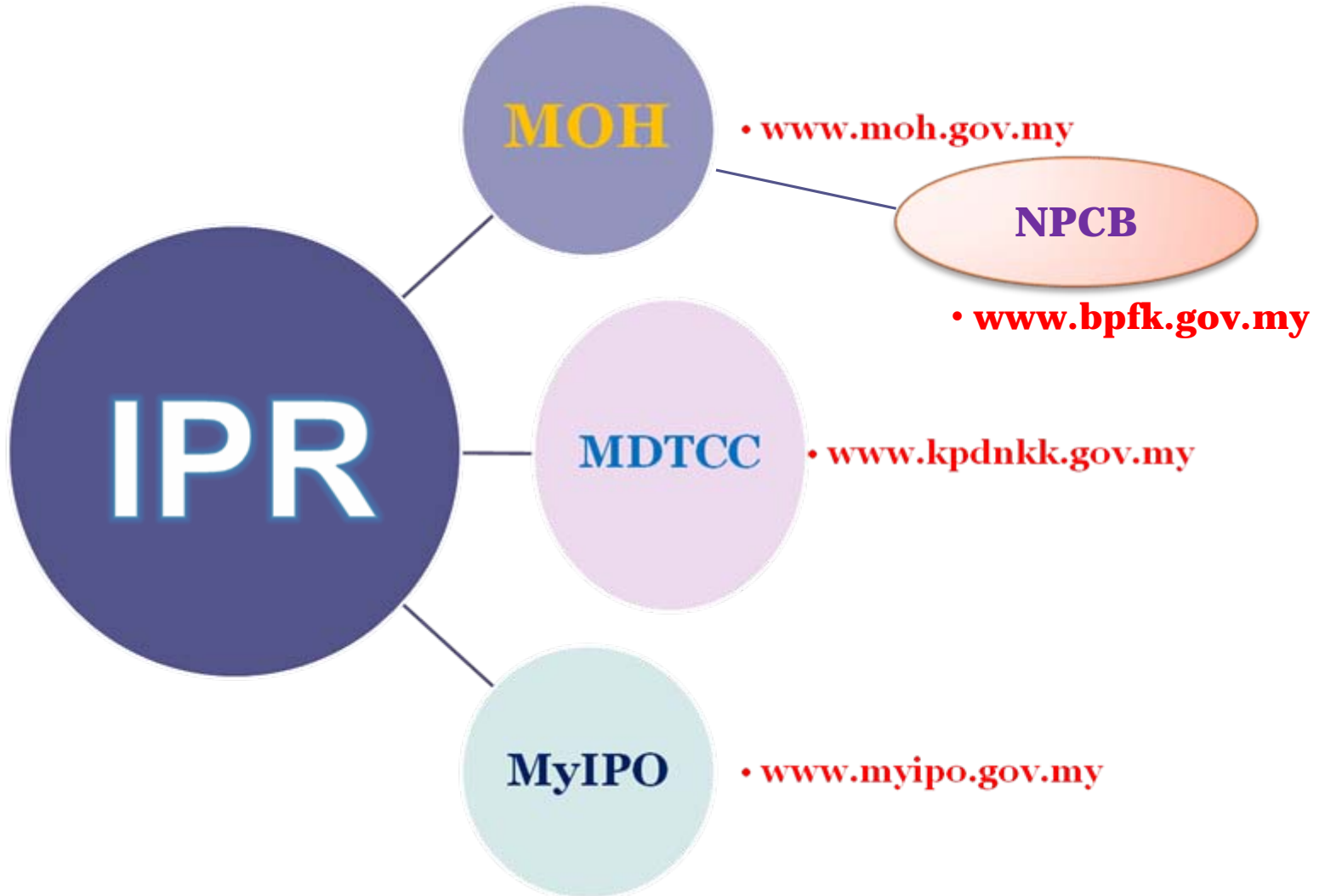
# Parallel Imports



# Compulsory Licensing

- Compulsory licensing is when a **Government allows** someone else to produce the patented product or process **without the consent** of the patent owner.
- This flexibility on patent protection **included in the WTO's agreement** on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

# Ministries/ Agencies



# Free Trade Agreements (FTAs)

- Malaysia – European Union Free Trade Agreement (MEUFTA) – **ongoing negotiation**  
- **DE & PTR**
- Trans Pacific Partnership Agreement (TPP) – **ongoing negotiation**  
- **DE, PTR & Patent Linkage**

*Terima kasih*



[unny@moh.gov.my](mailto:unny@moh.gov.my)