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

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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)

Clinical Test Data

Drug Regulatory Authority

- Safety
- Efficacy
- Quality

Generic Drug Manufacturer

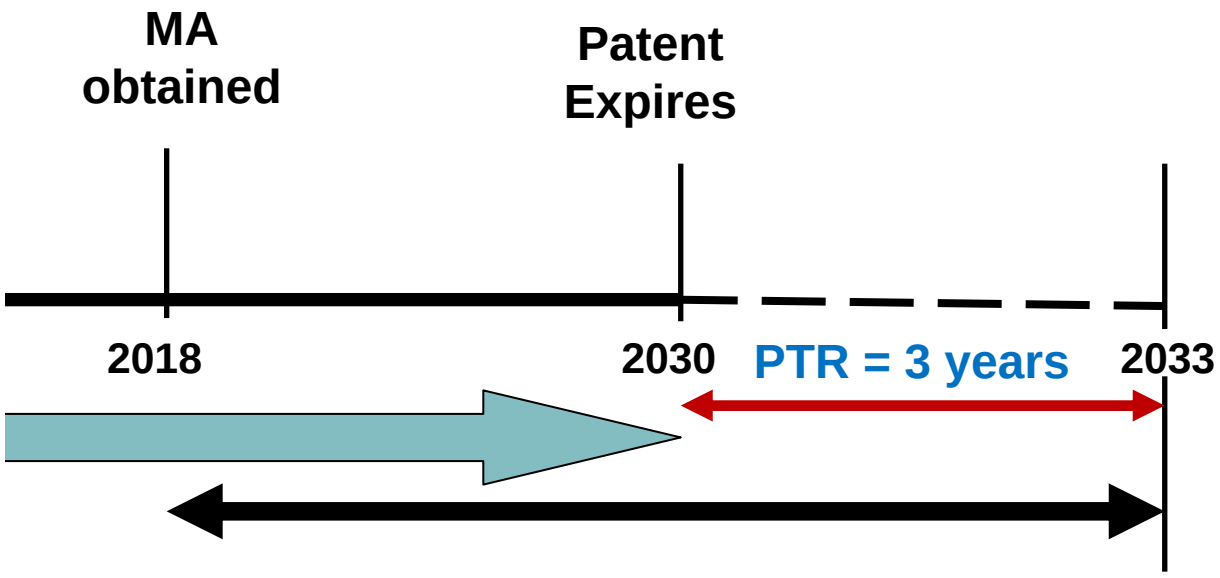
DE (cont.)

- 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**

Term Restoration (PTR)



Effective protection of 15 years

ed on EU's PTR model