The Challenge of Ensuring Access to Medical Technologies in MICs

Innovation and Access to Medical Technologies: Challenges and Opportunities for Middle-Income Countries (MICs)

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Dr. Chua Hong Teck
Director Healthcare and Low Income Households
Performance Management and Delivery Unit,
Prime Minister’s Department, Malaysia
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• Background

• Access to medical technologies in Malaysia

• What next?
Malaysia is a upper middle income country with a GNI Per Capita of US$10,060 in 2013

<table>
<thead>
<tr>
<th>Year</th>
<th>GNI Per Capita (US$)</th>
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</thead>
<tbody>
<tr>
<td>2010</td>
<td>8,373</td>
</tr>
<tr>
<td>2011</td>
<td>9,700</td>
</tr>
<tr>
<td>2012</td>
<td>9,928</td>
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<tr>
<td>2013</td>
<td>10,060</td>
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</tbody>
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Source: Department of Statistics, BNM
Malaysian healthcare spending continues to grow at a fast rate, at 4.5% of its GDP in 2012

*About 8.5% on pharmaceuticals in 2012*
There is universal access to healthcare in the Malaysia with pooling of resources and pre-payment

1. Public healthcare system (MOH, MOE and MOD)
2. It is like a national healthcare system where everyone is able to access
3. MOH collects only 2% of what it spends
4. Maximum that is spent (for 3rd class ward) is only RM500 or given total exemption
5. There is a compulsory medical insurance for all foreign workers (1.6 million)
6. There is also compulsory medical insurance for all foreign students
7. Consultation fees in private sector are regulated by MOH
8. All civil servants (& retirees) including their parents are covered by government

Source: PEMANDU
The value of the Malaysian Pharmaceutical Market is about US$1.4 billion in 2013.

- **Generics**: RM 1.157 bil (26%)
- **Originators**: RM 3.3 bil (74%)
  - Non-gov: RM 2.12 bil (60.6%)
  - Gov: RM 1.18 bil (39.4%)

Total Market Size: RM 4.457 bil

Source: IMS Health Combined Market Audit MAT Q1 2014
RM3.2 = US$1.00
About 66% of the Pharmaceutical Market consists of Generics in 2013

Total Volume Sales: 166,034,282 units

Market Size

Generics
109,828,116 units

Originators
56,206,166 units

Non-gov
56%

Gov
44%

Non-gov
40.9%

Gov
59.1%

Source: IMS Health Combined Market Audit MAT Q1 2014.
Healthcare is one of economic sectors in the Economic Transformation Programme (ETP)

Source: PEMANDU
The Healthcare NKEA has identified Pharmaceuticals as one of the Entry Point Projects (EPP)

Taking advantage of patent expiry cliff by pursuing generic opportunities.

- Upcoming patent expiration of major 'blockbuster' drugs (2010-2014) open up an attractive white-space for generics manufacturing and exports
- Transform the industry with a 3-pronged approach
  - Localisation and upgrade
  - Create an export platform
  - Collaboration between MNCs and local manufacturers
- In 2013, we have expanded the scope to include all pharmaceuticals, vaccines, biosimilars, OTC and Supplements

Source: PEMANDU
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I agree that the overarching determinant for access to medical technologies must be based on the WHO Health System Framework.

**System Building Blocks**

- Service Delivery
- Health Workforce
- Information
- Medical Products, Vaccines & Technologies
- Financing
- Leadership / Governance

**Overall Goals / Outcomes**

- Improved Health (level & equity)
- Responsiveness
- Social & Financial Risk Protection
- Improved Efficiency

The Six Building Blocks of a Health System: Aims and Desirable Attributes

Source: WHO (2007)
To support the growth of the pharmaceutical industry and faster access to medicines, a comprehensive patent study was conducted in 2011. It covers the following areas:

1. Patent period & term restoration
2. Novelty requirement vis a vis foreign patent application
3. New use, form, dosage
4. Compulsory licensing
5. Bolar provision
6. Post & Pre Grant
7. Data exclusivity & Patent linkage

Source: PEMANDU
Other Initiatives that have been done include the following:

| Generic Policy And Prices                          | • National Medicines Policy  
|                                                  | • Zero rated GST for Drugs under the National Essential Drug List |
| Localization of Products                          | • Various types of drugs by pharmacological class/dosage forms have been identified  
|                                                  | • MNCs are keen to support this |
| Off-take Agreement (OTA)                           | • To support the above policy, a 3+2 years OTA with MOH  
|                                                  | • Support the Export Agenda |

Source: PEMANDU
Other Initiatives that have been done include the following:

**Clinical Trials**
- Clinical Research Malaysia
- Clinical Trials and access to market

**Orphan Drugs**
- Definition includes difficulty in sourcing and rare diseases
- Fast track in registration including waving BE studies

**Export Initiatives**
- Support by government agencies including redefined role of Minister of Health as a KPI
- Familiarization of Foreign Regulators

Source: PEMANDU
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The next steps will include the following:

**Health**
- Bigger role for MOH
- Better Access to Medicines

**Trade**
- Working with IMS Health for better data
- TPPA and FTA

**Patents**
- Amendments to Patent Act
- Increased role of MOH in granting patents

Source: PEMANDU
Dr. Chua Hong Teck  
Director, Healthcare & Low Income Households  
chuahongteck@pemandu.gov.my

Thank You

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