

# 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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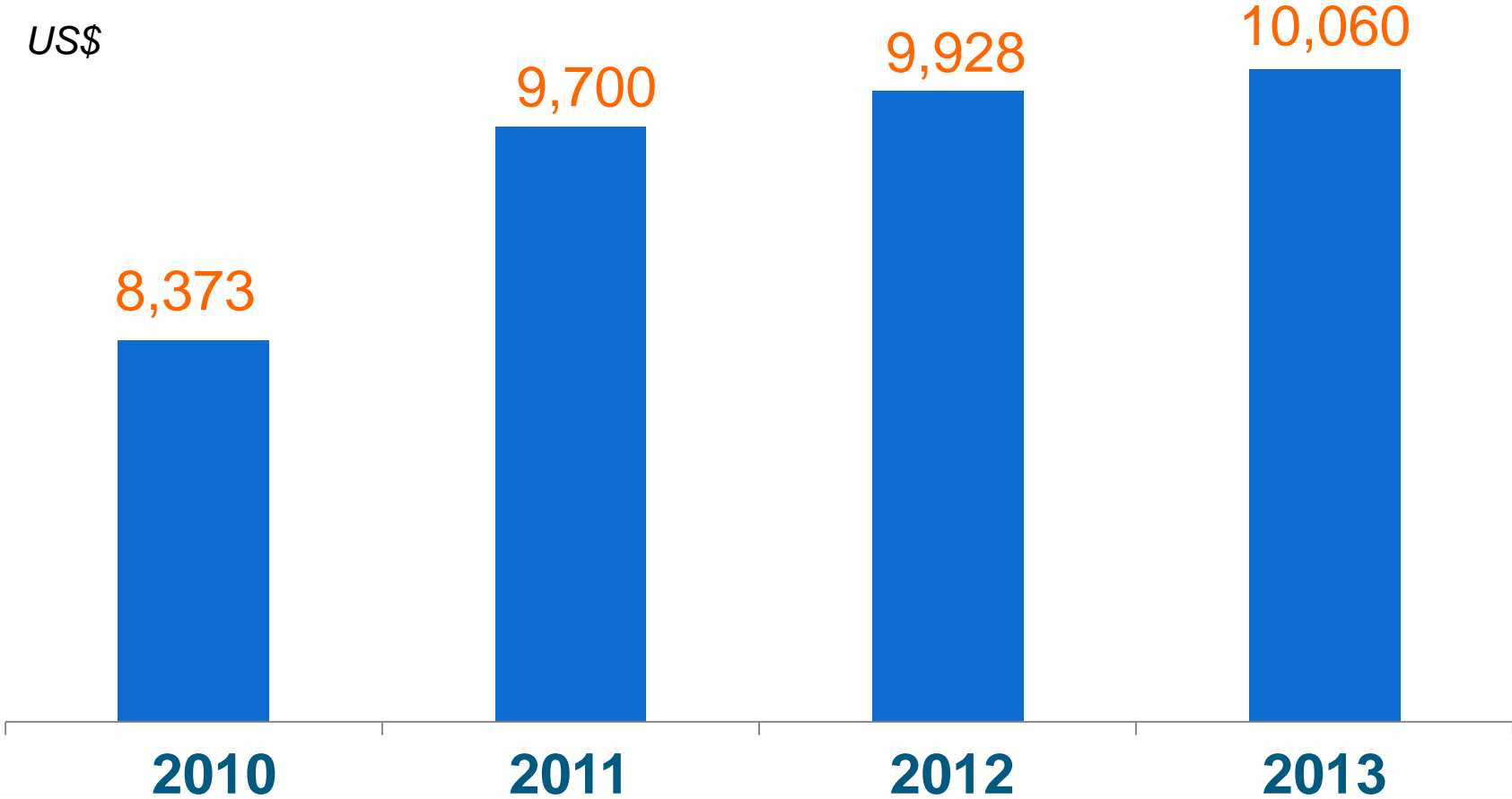
# Table of Content

- **Background**

- Access to medical technologies in Malaysia
- What next?



# Malaysia is an upper middle income country with a GNI Per Capita of US\$10,060 in 2013

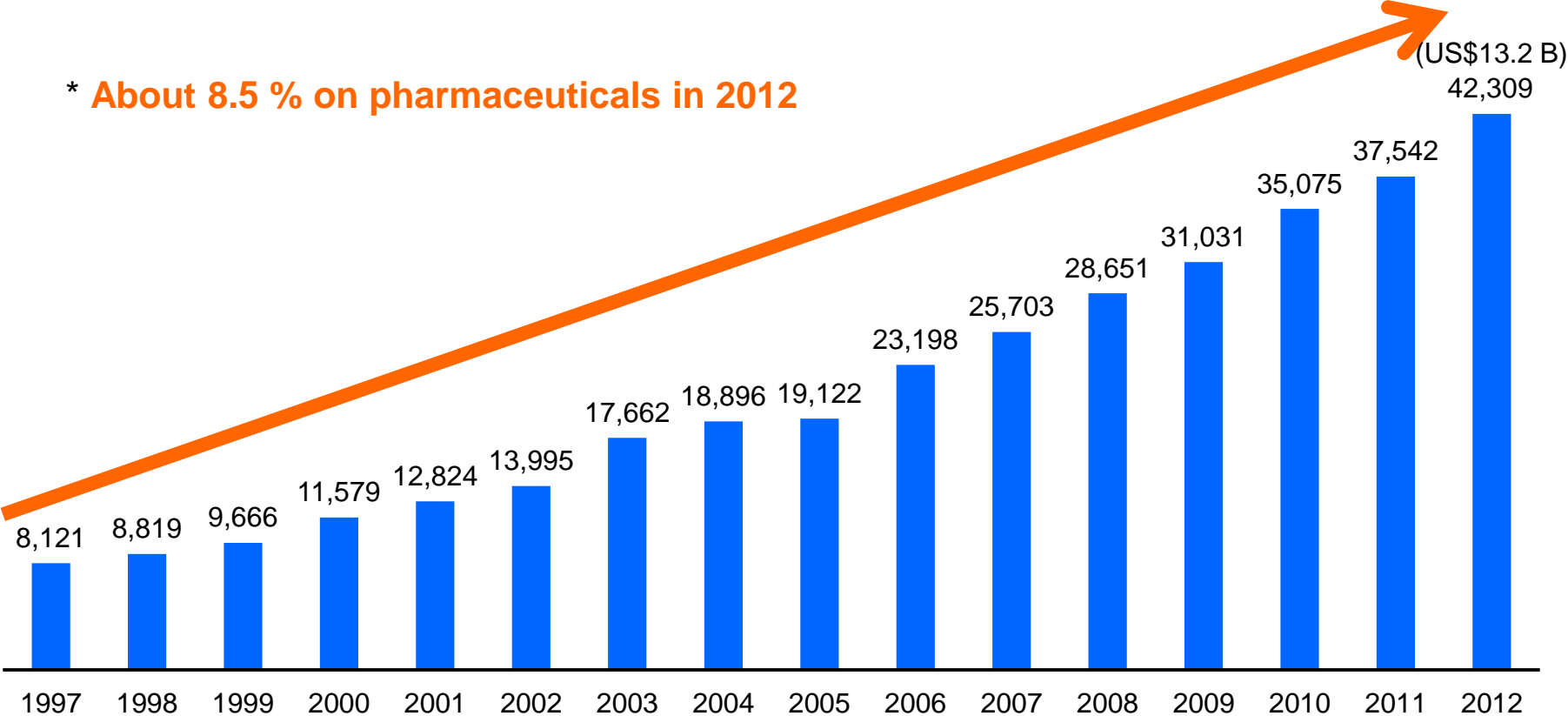


Source: Department of Statistics, BNM

# Malaysian healthcare spending continues to grow at a fast rate, at 4.5% of its GDP in 2012

Total expenditure of health  
RM billion

\* About 8.5 % on pharmaceuticals in 2012



Source: MNHA 1997-2012 database; MOH  
RM3.20 = US\$1.00

# 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 3<sup>rd</sup> 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

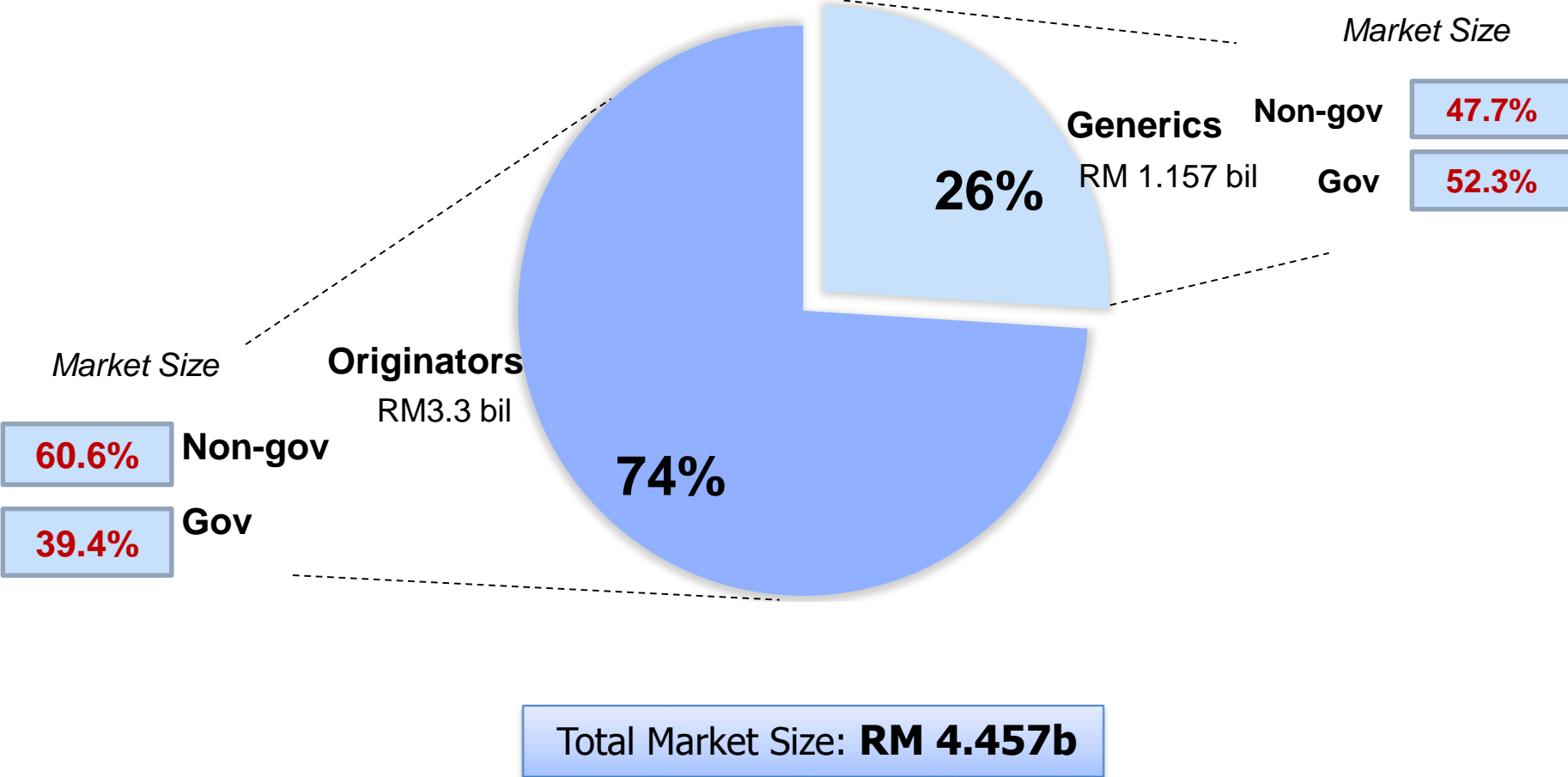
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Consultation fees in private sector are regulated by MOH

8

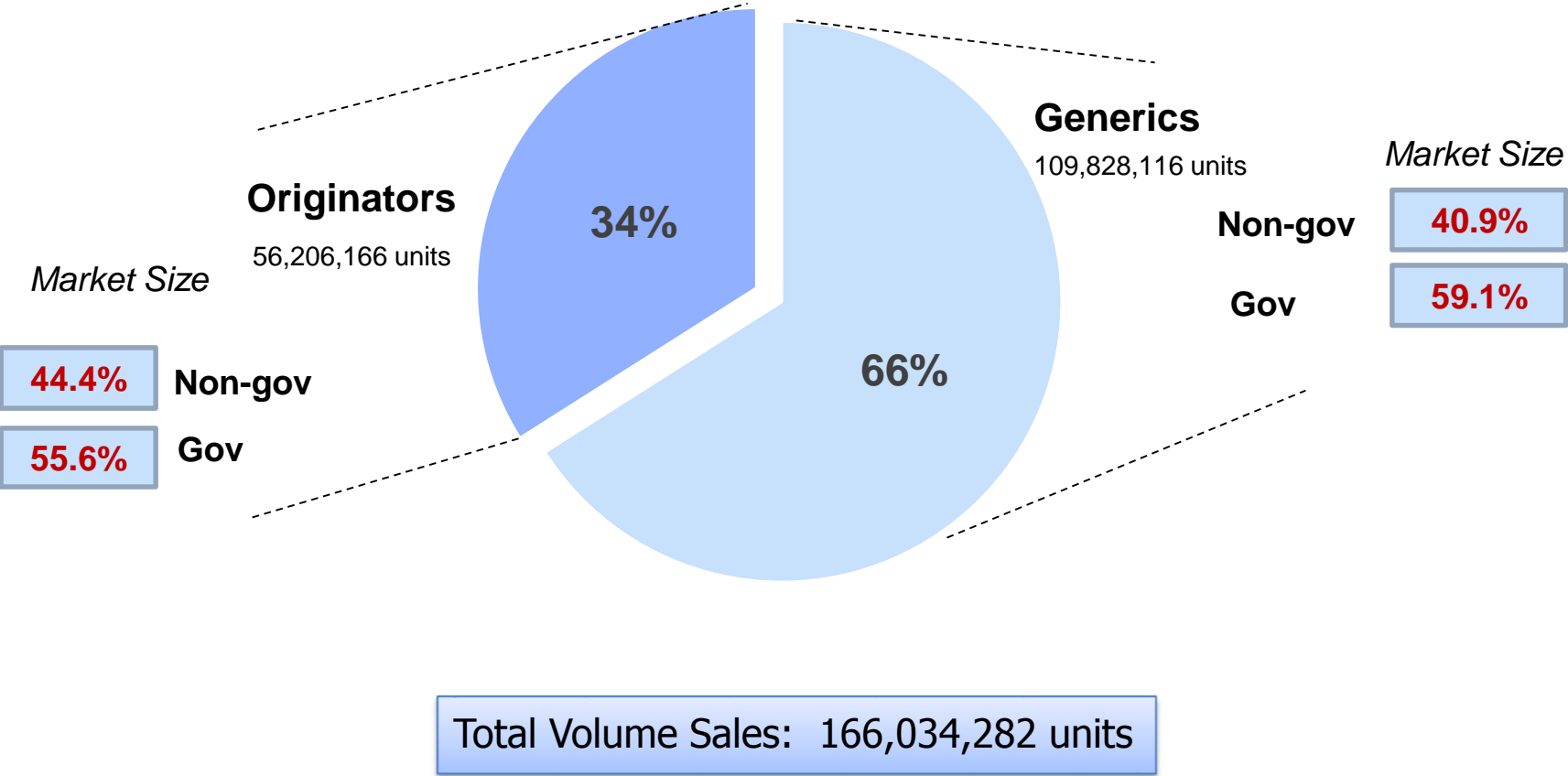
All civil servants (& retirees) including their parents are covered by government

# The value of the Malaysian Pharmaceutical Market is about US\$1.4 billion in 2013



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



Source: IMS Health Combined Market Audit MAT Q1 2014.

# Healthcare is one of economic sectors in the Economic Transformation Programme (ETP)



Greater KL / KV



Education



Business Services



Oil & Gas



Healthcare



Wholesale & Retail



Financial Services



Palm Oil



Electronics & Electrical



Agriculture



Tourism



Communication Contents & Infrastructure

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



RM <b>13,853.7</b> million	<b>12.5 k</b>
<b>GNI</b> Impact	<b>Jobs</b> Created

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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



ACCESS  
COVERAGE

QUALITY  
SAFETY

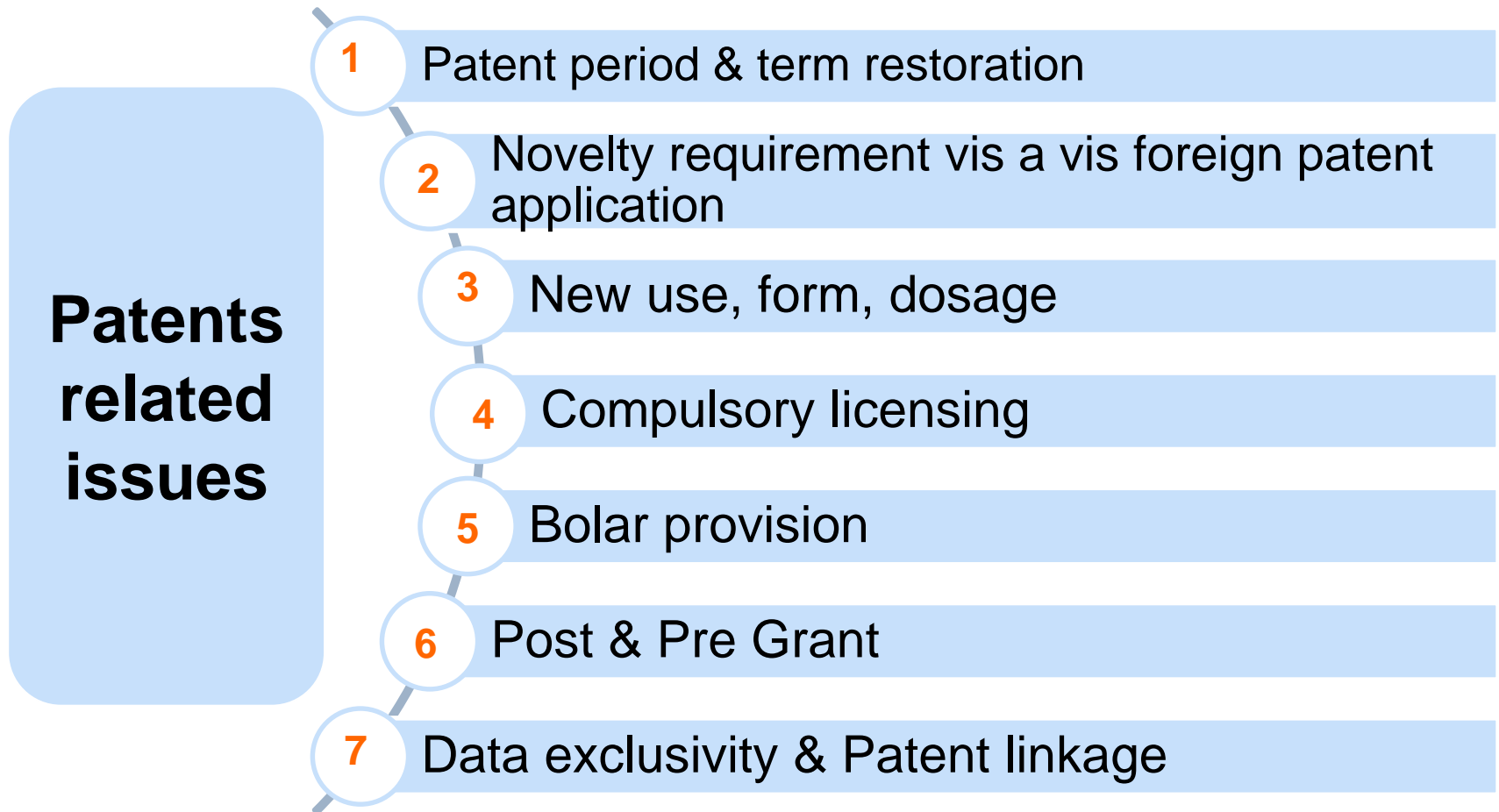
## OVERALL GOALS / OUTCOMES



*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:



# 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

# 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

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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



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**Thank You**



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