



CHALLENGES WITH ASEAN PHARMACEUTICAL REGULATION SCHEMES TO OTC PRODUCTS INDONESIA EXPERIENCE

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INTRODUCTION

ASEAN : Association of South East Asian Nations



Founded in 1967

**Comprises 10
Southeast Asian
Member States :
Thailand, Malaysia,
Indonesia, Singapore,
Philippines, Brunei,
Cambodia, Laos,
Myanmar & Vietnam**

INTRODUCTION

- **ASEAN Economic Community (AEC) will be implemented in 2015. It covers 13 Sectors, including Pharmaceutical Sector, through ASEAN Free Trade Agreement (AFTA).**
- **ASEAN Consultative Committee for Standards and Quality (ACCSQ) and Pharmaceutical Product Working Group (PPWG) are established to develop harmonization schemes of pharmaceutical regulations of the ASEAN member countries.**



SCOPE OF ASEAN REGULATION SCHEMES

- **Pharmaceutical Product Registration :**
Implementation of ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD)
- **ASEAN GMP Requirements for Facilities :**
Implementation of PIC/S (Pharmaceutical Inspection Cooperation Scheme) standards, include PIC/S GMP for Medical Products

CHALLENGES ON OTC PRODUCT REGISTRATION

ACTR / ACTD format documents,
not all member countries
have fully implemented

In Indonesia : ACTD & ACTR
documents for drug (incl. OTC) have
been implemented since October 2011

**Product
Licences
Approval**

CHALLENGES ON OTC PRODUCT REGISTRATION

ACTR / ACTD Documents

- ❖ OTC API used in formula should be completed with GMP Certificate of API Manufacturer and it's Drug Master File (DMF).
- ❖ BA/BE studies, Analytical & Process Validation, Stability studies data are required for registration

These may cause :

Higher cost
and time
consuming

More
complicated
requirements

Uncertain time
period for
approval

Limitation of
OTC API
Resources

Multisourcing
become
more
difficult

CHALLENGES ON OTC PRODUCT REGISTRATION

- **Licence Approval :**

- ❖ Product registration can only be submitted after approval of facilities (GMP certification issued)
- ❖ Pre Registration is needed before filing the Registrastion to NADFC (National Agency of Drug and Food Control) . It takes 6 – 12 months
- ❖ In practice, it may take 12 to 18 months or *longer time* for NADFC to issue market approval.
- ❖ OTC Product Licence valid for 5 years in Indonesia.

CHALLENGES ON OTC PRODUCT REGISTRATION

- **New Drugs Category / Definition :**
 - ❖ New Drug categories are defined differently in some ASEAN countries.
 - ❖ In Indonesia : a new drug is a drug with active chemical entity, new additive chemical, new dosage form / route of administration, new strength, or *new combination that has not been approved in Indonesia.*
 - ❖ New Combination of OTC Product without originator *should have a clinical trial .*

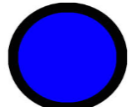
CHALLENGES ON OTC PRODUCT REGISTRATION

- **Country Specific Requirements :**

- ❖ **Packaging in Indonesia must be marked with:**



- => Green Dot : Drugs could be sold to all retails**



- => Blue Dot : Drugs could be sold only to drug store and pharmacy.**



- => Red Dot : Prescription only.**

Green Dot and Blue Dot are OTC category that will be reviewed again.

- ❖ **Other country sometimes need different requirements. As in Vietnam, primary packaging for drug products must be manufactured by company that has a GMP certificate.**

CHALLENGES ON OTC PRODUCT REGISTRATION

- **Drug Category Changes from OTC drug to Rx (Prescription) drug might happen in Indonesia.**
 - ❖ **Retailer of OTC drugs will be limited to licensed drugstores and pharmacies.**
 - ❖ **Recently, some OTC drug category has been evaluated by NADFC and may be changed to Rx (Prescription) drug category.**
- e.g: Single product contain :Dextromethorphan,
Pseudo Ephedrine, Ephedrine, Phenylpropanolamine,
Chloroquine, Levamisole**



CHALLENGES ON ASEAN GMP HARMONIZATION

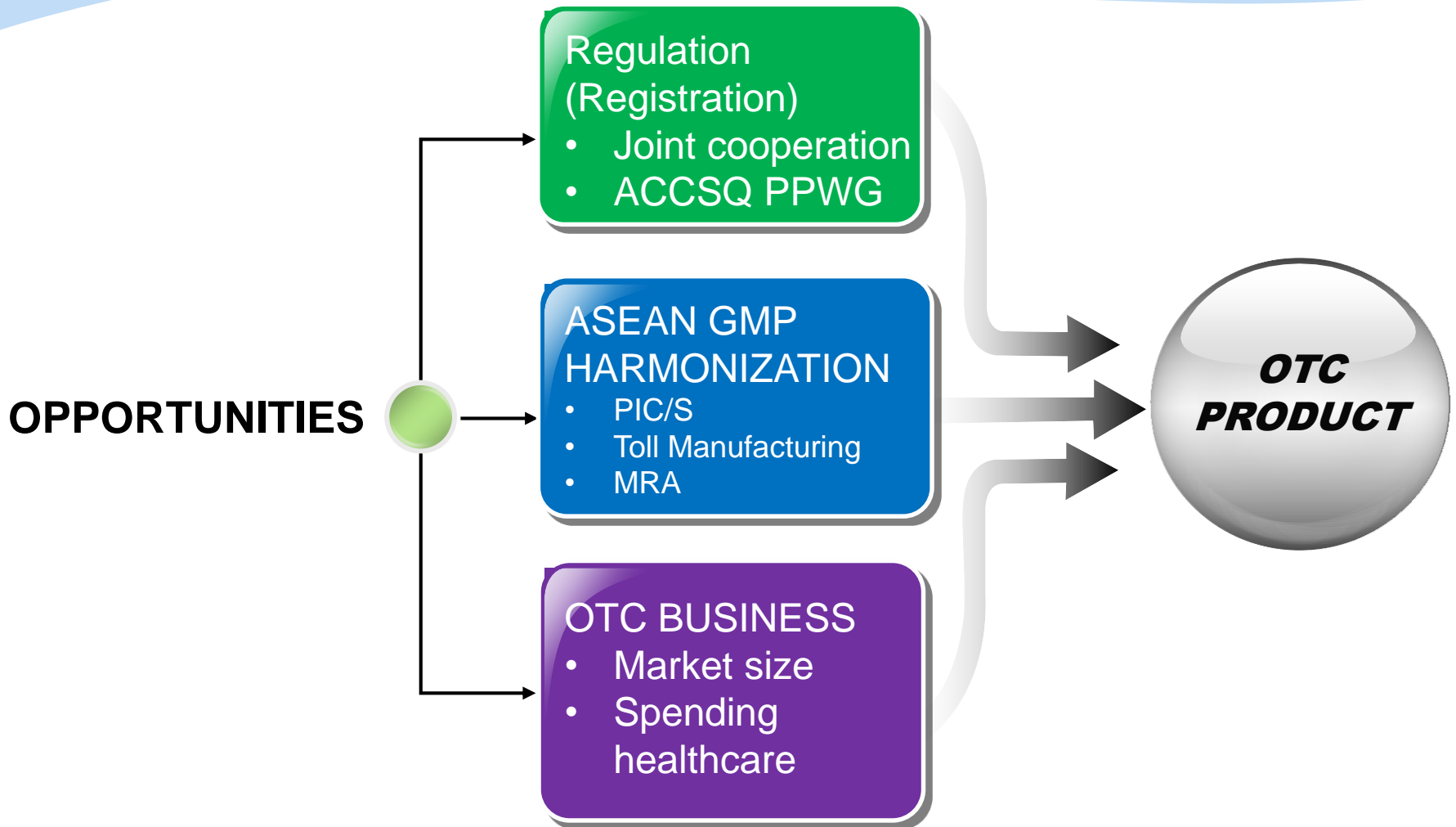
- **ASEAN GMP requirements for facilities :**
 - ❖ **Only 3 countries : Singapore, Malaysia and Indonesia already complied with the Pharmaceutical Inspection Cooperation Scheme (PIC/S) standards. Some other member countries still take effort to meet PIC/S requirements.**
 - ❖ **Many Pharmaceutical companies has invested heavily to meet GMP with PIC/S requirements :**
 - ✓ **Capacity, Systems, Human capital.**
 - ✓ **Facilities and equipments.**

CHALLENGES ON ASEAN GMP HARMONIZATION

ASEAN MRA on GMP Inspections :

- ❖ Obliges each member countries to have a **PIC/S – equivalent to GMP Inspection** framework.
- ❖ **Technical Assistances is needed** to improve inspection capability of each ASEAN member countries.

OPPORTUNITIES

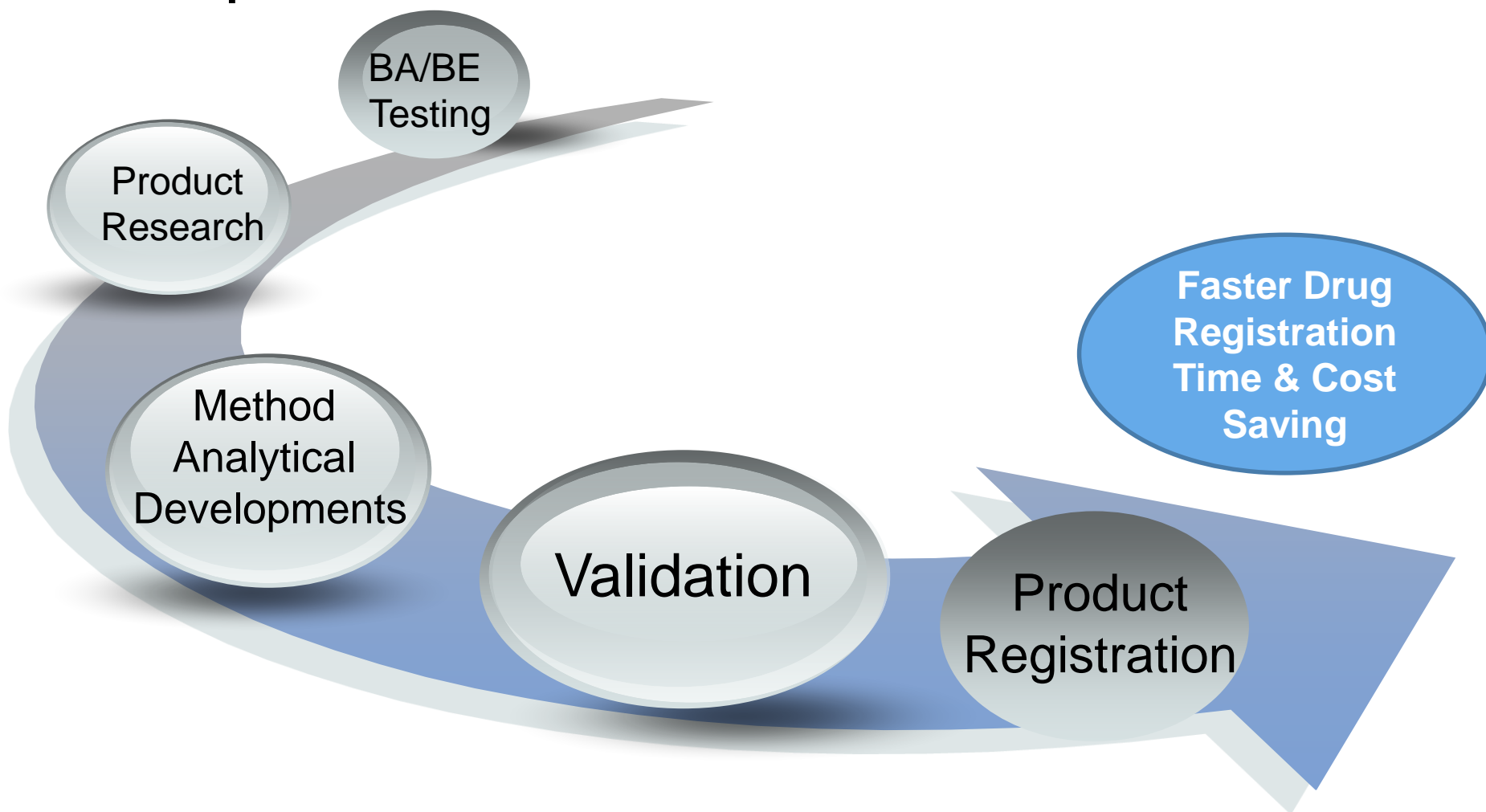


Regulation (Registration)

- Joint cooperation
- ACCSQ PPWG

OPPORTUNITIES ON OTC REGULATION

Joint cooperation in between Pharmaceutical Industries to covers :



Regulation
(Registration)

- Joint cooperation
- ACCSQ PPWG

OPPORTUNITIES ON OTC REGULATION

❖ **ACCSQ PPWG provide some Technical Guidelines to harmonize implementation of regulation :**

- ✓ **ASEAN Stability Guideline**
- ✓ **ASEAN Manufacturing Process Validation Guideline**
- ✓ **ASEAN Analytical Method Validation Guideline**
- ✓ **ASEAN Variation Guideline**

❖ **PIC/S Standard :**

- **Same Level of Competencies with other member countries.**
- **Higher export opportunities**

❖ **TOLL MANUFACTURING :**

- **Potentially receive Contract Manufacturing from other countries.**
- **Open opportunities to make a contract manufacturer industry.**

ASEAN GMP HARMONIZATION

- PIC/S
- Toll Manufacturing
- MRA

OPPORTUNITIES ASEAN GMP HARMONIZATION

❖ **Benefits of ASEAN Sectoral MRA on GMP inspection :**

- ✓ **Avoiding duplication of GMP Audits within ASEAN**
- ✓ **Saving time, resources & costs for regulator & industry.**
- ✓ **Facilitating trade in OTC products within ASEAN countries.**
- ✓ **Quicker access of OTC products by patients**

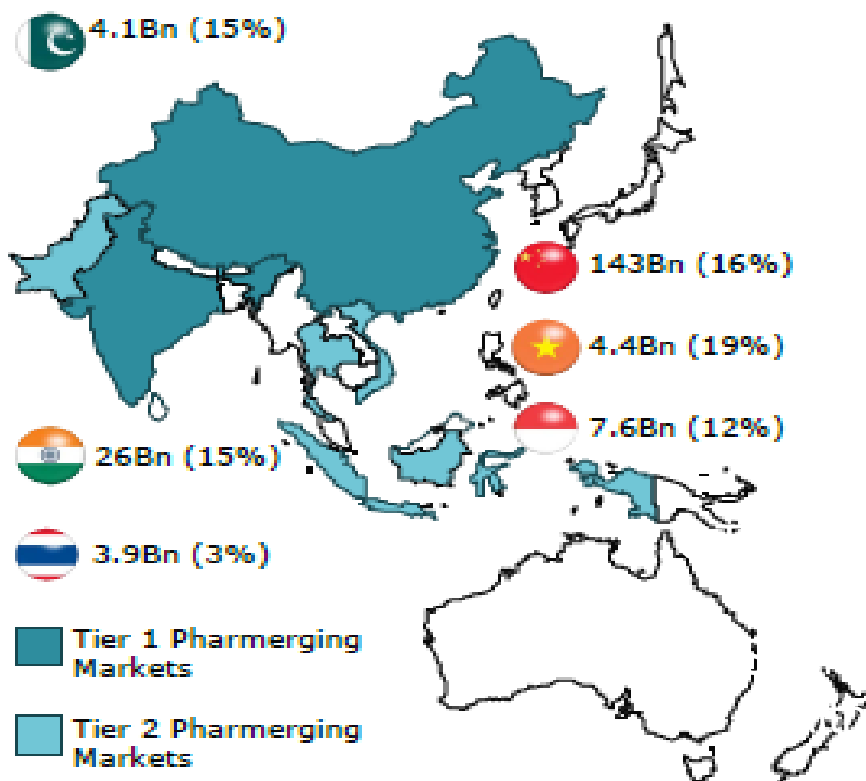
OTC BUSINESS

- Market size
- Spending healthcare

OPPORTUNITIES ON OTC BUSINESS

c.55% of this Pharmerging Market growth will be driven by Asia
Growth prospects in Tier 2 markets, while dwarfed by China, are not insignificant

Pharmerging Markets in Asia, 2016 (FCAGR %)



- Asian Pharmerging Markets will add c.US\$97Bn in annualized market value by 2016, c.75% of which is in China alone
- Tier 2 Pharmerging Markets will add an annualized c.US\$8.5Bn by 2016
- The expanded SEA region (ASEAN + South Asia ex-India) will grow by c.US\$11Bn in annualized market value by 2016
- This represents over c.US\$30Bn in cumulative value over the next 5 years!

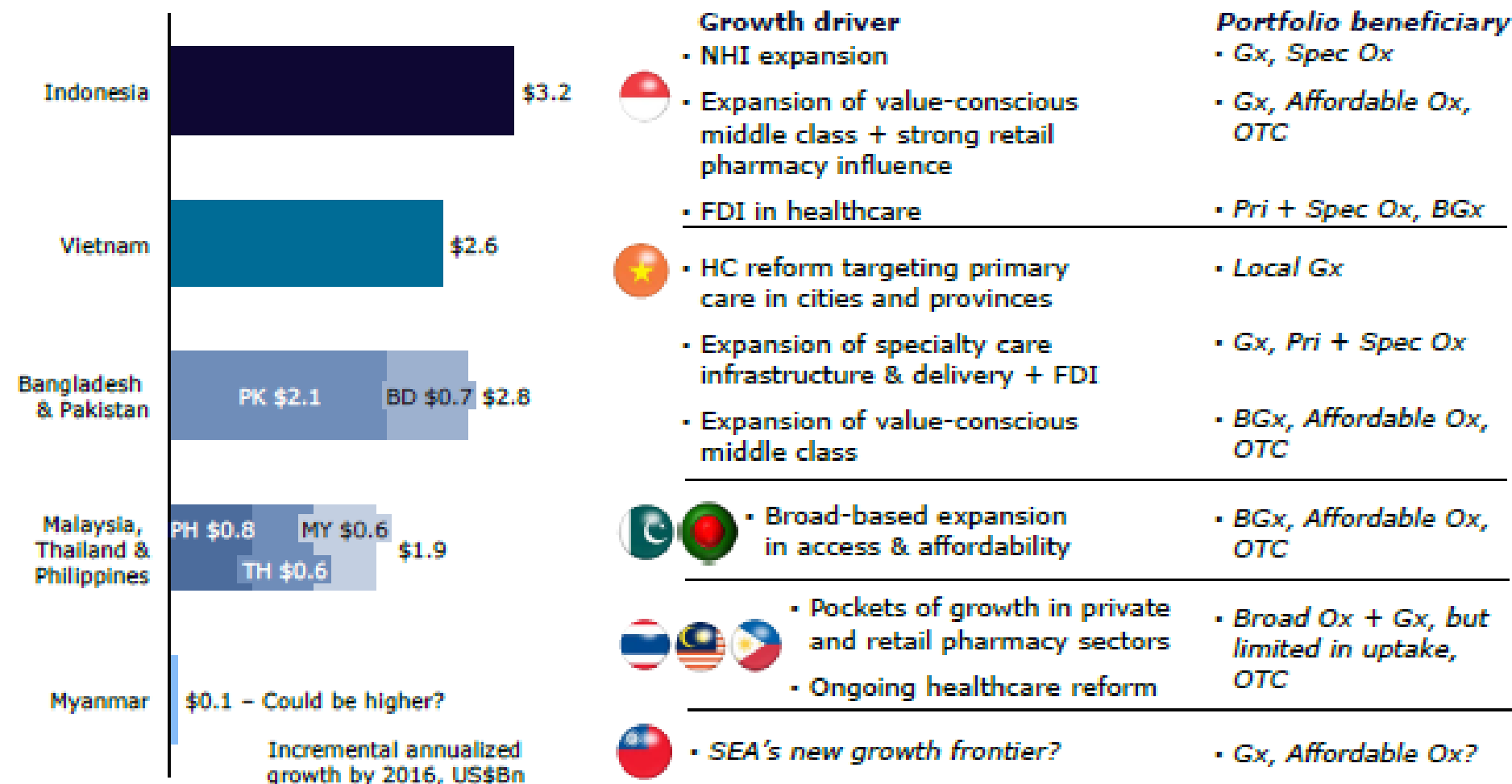
So, where will the growth opportunities in this region be?

Growth opportunities in SEA region are numerous, but diverse

Consequently, the "cost" of achieving success is high

Split of forward growth across the expanded SEA region...

...with numerous ways to tap into this growth



Source: IMS Analysis, IMS MIDAS Data

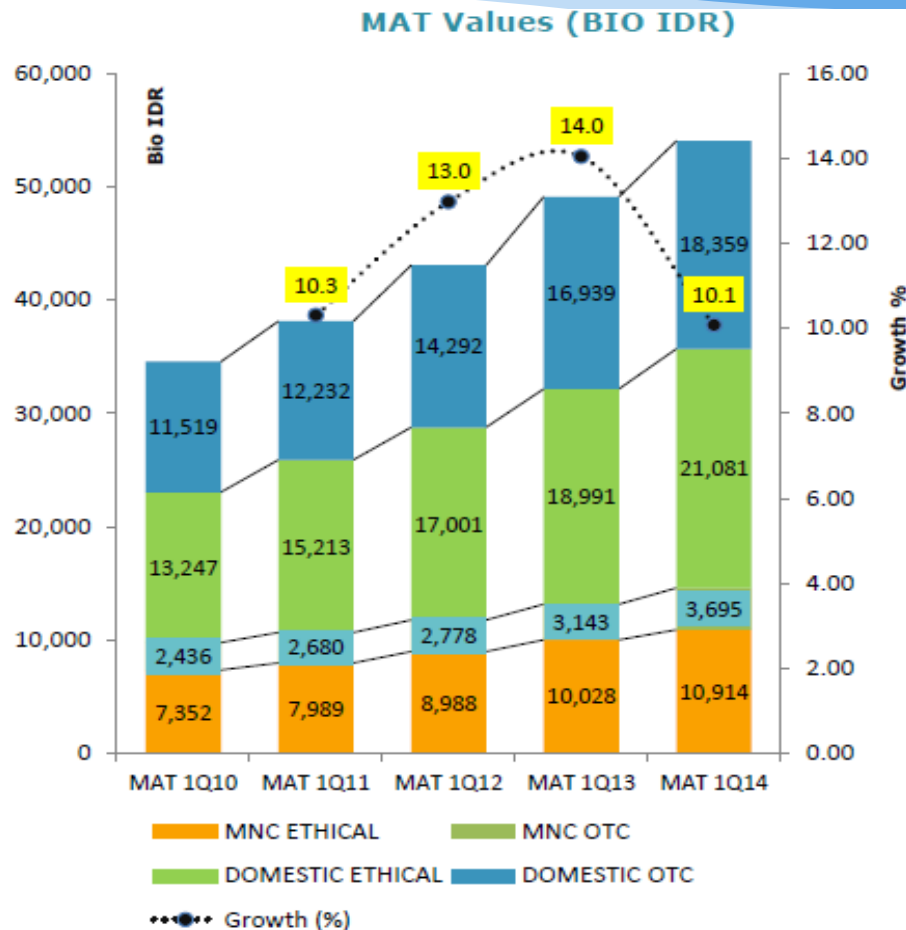
MY: 1C1M Priority TAs such as CVM, Onco, COPD/Asthma, MH; Vaccines + Preventative Care; Medical Tourism; Gx in public sector | TH: Retail pharmacy driven Affordable Ox, OTC

INDONESIA PHARMA MARKET Q1 2014

JKN
Implementation
(Unbranded Generics
VOLUME ↑)

Branded
Generics &
OTC Price ↑

Hospital
Demand ↑



JKN
Implementation
(Unbranded Generics
PRICE ↓)

Foreign
Exchange Rate
↑

New Products
Launched ↓

MAT 1Q14 VALUE GROWTH : 10.07%
MAT 1Q14 VOLUME GROWTH: 10.37%

Pressure on Price & Profitability

INDONESIA PHARMA MARKET Q2 2014 (Latest Update)

MAT Value Growth
7.9%

YTD Value Growth
3.3%

MAT Branded
vs. Unbranded
Growth

**7.1% vs.
16.2%**

YTD Branded
vs. Unbranded
Growth

**3.0% vs.
6.9%**

ITMA MAT Q2 2014
Rp 55.32 trillion

ITMA YTD Q2 2014
Rp 27.63 trillion

MAT Domestic
vs. MNC
Growth

**7.4% vs.
9.5%**

YTD Domestic
vs. MNC
Growth

**2.2% vs.
6.5%**

MAT Ethical vs. OTC Growth
8.3% vs. 7.4%

YTD Ethical vs. OTC Growth
4.0% vs. 2.3%

OTC BUSINESS

- Market size
- Spending healthcare

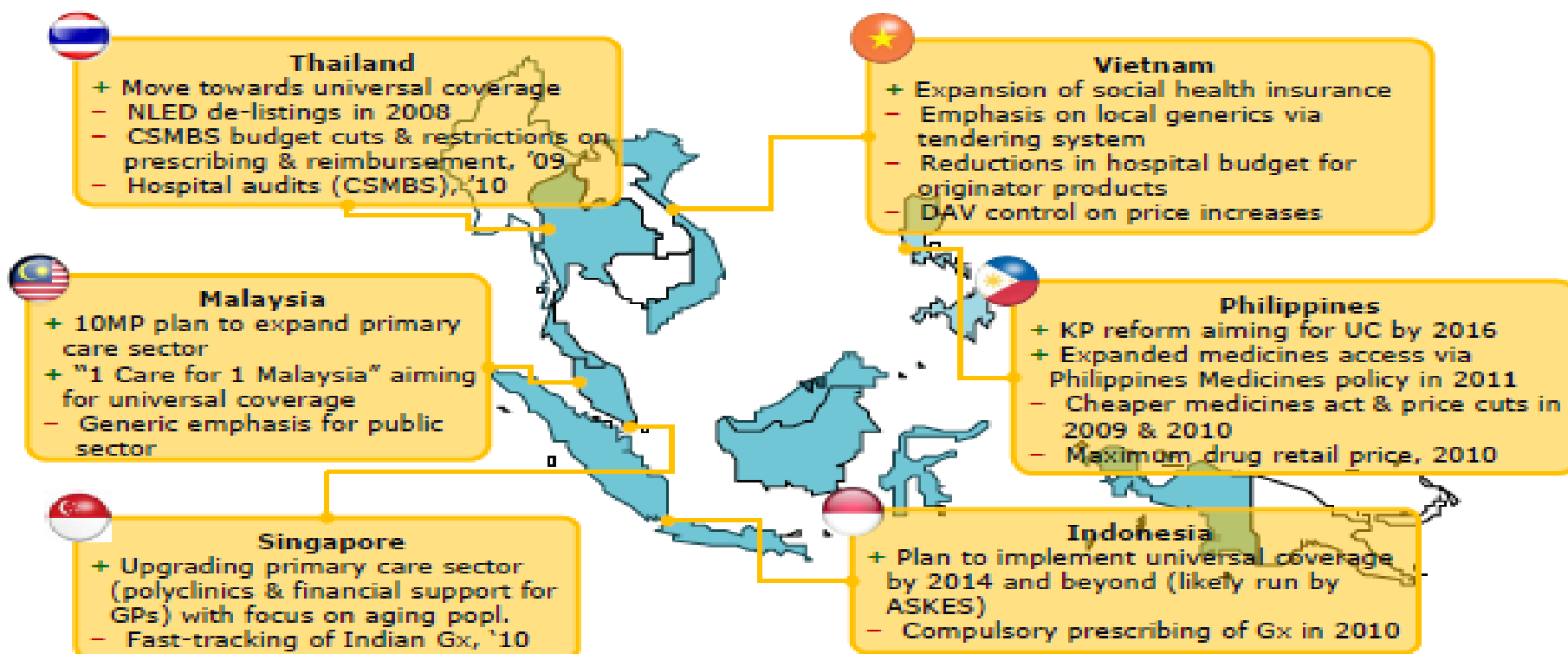
INDONESIAN SPENDING ON HEALTHCARE

National Health Insurance Government spending increased.

Dynamics and Trends in SEA

The dominant trend impacting the region today is healthcare reform and cost containment

Healthcare is firmly on the agenda in SEA – While this drives overall growth, it also entails cost containment to balance budgets



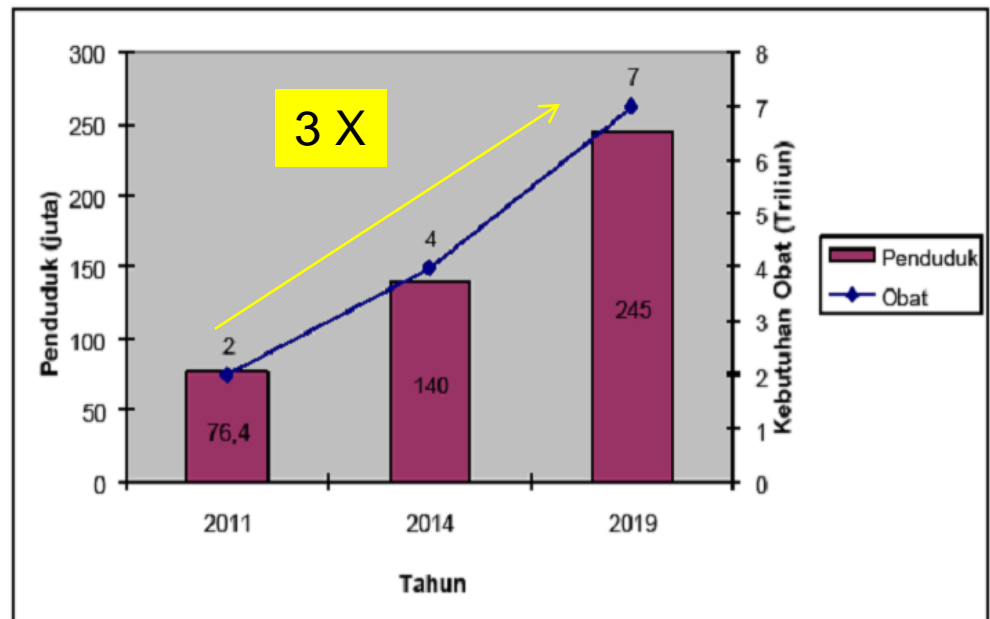
OTC BUSINESS

- Market size
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INDONESIAN SPENDING ON HEALTHCARE

Minimum prediction of drug consumption for *Universal Health Coverage*

- UHC significantly ↑ 3x volume (capacity) of drugs with standardized quality when sales ↑ 2x → CAGR total pharma market ↑ 15% to 20%
- Government Spending for drugs :
96 million x 25% x Rp 19.225 x 12 = Rp 5,54 T / Year



- Note :
- 96 million Poor people (PBI)
 - 25 % Government Spending for drug consumption from Universal Health Coverage (UHC)
 - Rp. 19.225 : contribution / people / month

CONCLUSION

- ASEAN regulation harmonization is still on progress to achieve AFTA objective, especially in elimination of technical barriers through these regulations without compromising drug quality, safety and efficacy.
- Although regulations in product registration and implementation of GMP are more complex and dynamics, there are still opportunities for OTC business to grow.



Thank You !