



BADAN POM



UHC Expansion & Innovative Medicine Position Indonesian Perspective



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OUTLINE



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3 The Pharmaceutical Industry's Development in Indonesia

4 Innovative Medicine Position

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INTRODUCTION

STRATEGIC ISSUES IN INDONESIA



- **Universal healthcare coverage (JKN)**
- **Growth of pharmaceutical industry**
- Pharmaceutical wholesale and distribution
- Pharmaceutical services
- Business operator's compliances
- Dependency of APIs and New Drug, and its development
- Public empowerment
- Spurious/false-labelled/falsified/counterfeit (SFFC) medicines
- **AEC 2015**
- Product competitiveness
- **Development of New Drug**



67th World Health Assembly Resolutions (2014)

ASEAN Harmonization

**APEC: Regulatory
Convergence**



**Increase public access to
affordable, safe, and efficacious
essential drugs and biologicals
with assured quality.**

The Mandate For Regulatory Authorities (BPOM)



Current Vision:

**Safe Food and Medicine to Improve Public Health and
Nation's Competitiveness**

Current Mission:

- 1. Protecting public health by strengthening risk-based food and drug control system**
- 2. Ensuring the resilience of business operator to provide medicine and food safety assurance, strengthening partnerships with stakeholders**
- 3. Improving institutional capacity of Badan POM**

GOALS OF BPOM 2015 - 2019



1. Ensuring safety, efficacy, and quality of food and drug to increase public health
2. Improving food and medicine competitiveness nationally and globally through quality assurance and innovation.

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Strengthening Drug and Food Control System based on risk analysis.

Strengthening partnership between NRA and related Stakeholders.

Enhancing the competencies of Human Resources in NRA for Drug and Food Control.

Strengthening capacity and capability for drug and food testing.

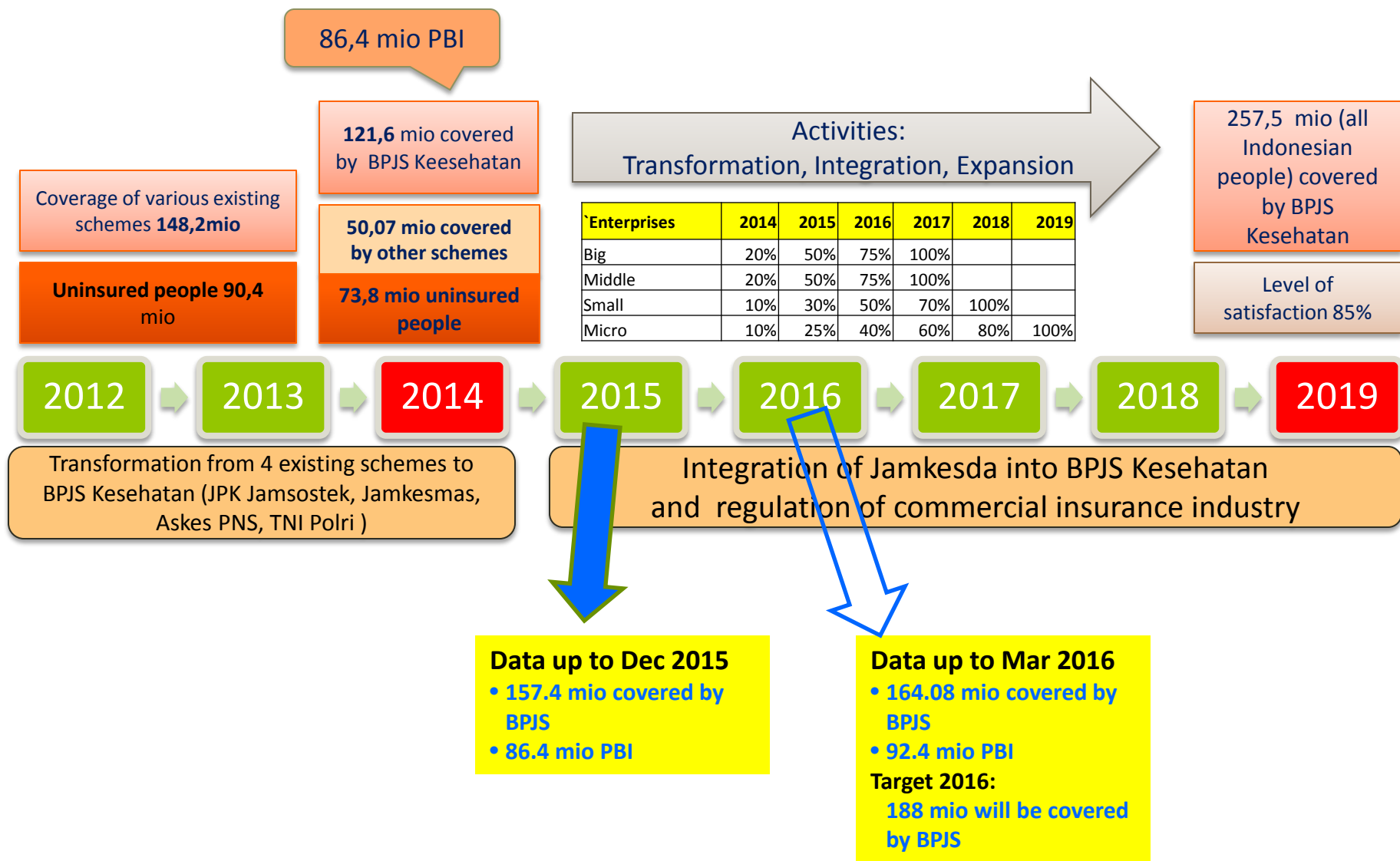
Improving self assessment on drug and food control based on risk analysis by people and stakeholders.

Increasing capacity and innovation of businesses in order to boost the competitiveness of Drug and Food.



UHC Challenges

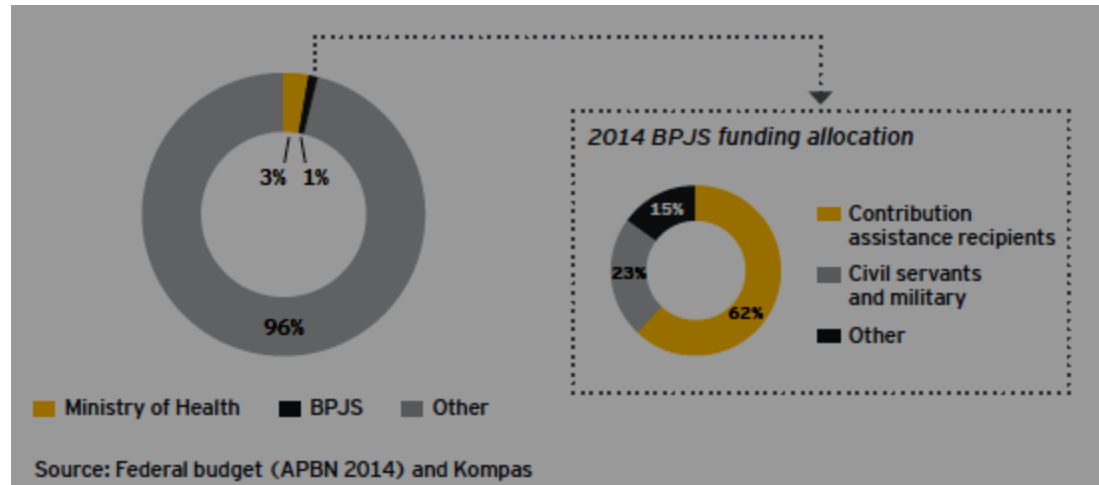
UHC in INDONESIA



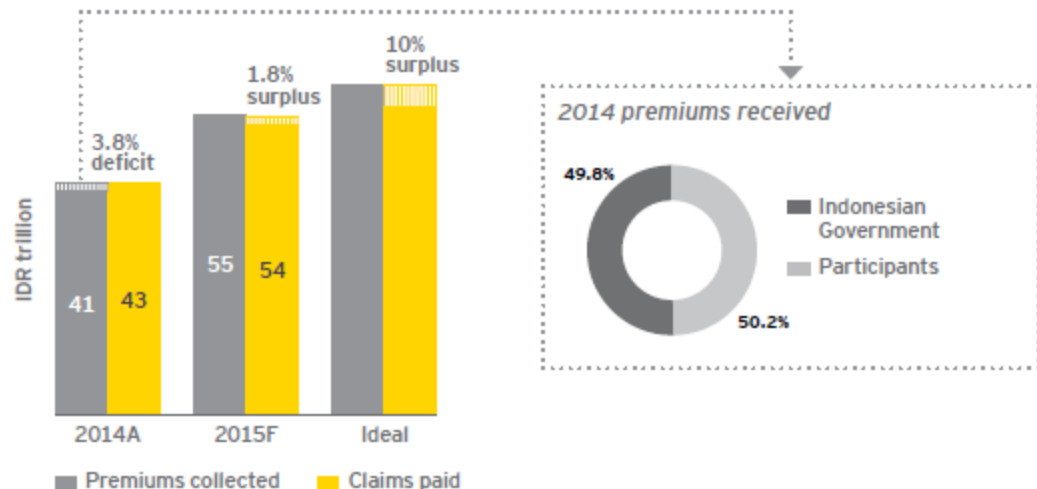
UHC Expenditure in INDONESIA



- Allocated budget for Indonesia UHC (BPJS):
 - 2014: Rp 26 trillion (1.4% of total federal budget).
 - 2015: Rp 20.3 trillion (1.02% of total federal budget).*
 - 2016: Rp 34.2 trillion (1.35% of the federal budget).**
- One of component in the UHC expenses is medicine.
- Medicines use in Indonesia UHC according to National Formulary.



BPJS premiums received and claims paid

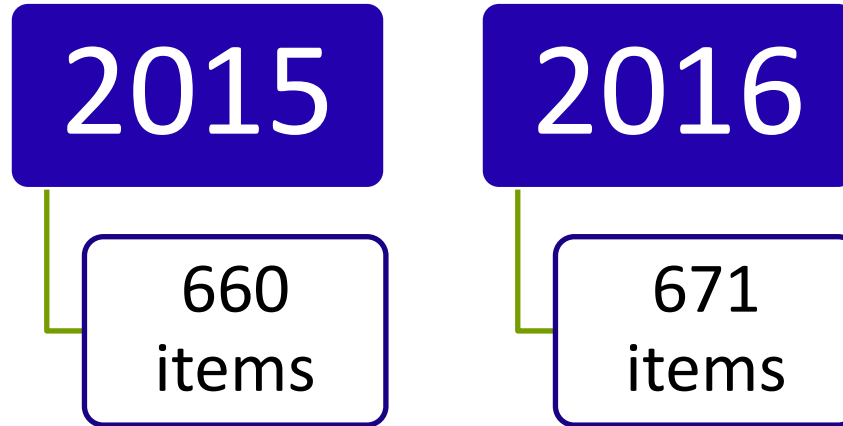


Sources:

* www.republika.co.id, 25 Ags 2015

** www.kompas.com, 31 Mar 2016

Medicines Covered by BPJS in 2015 - 2016

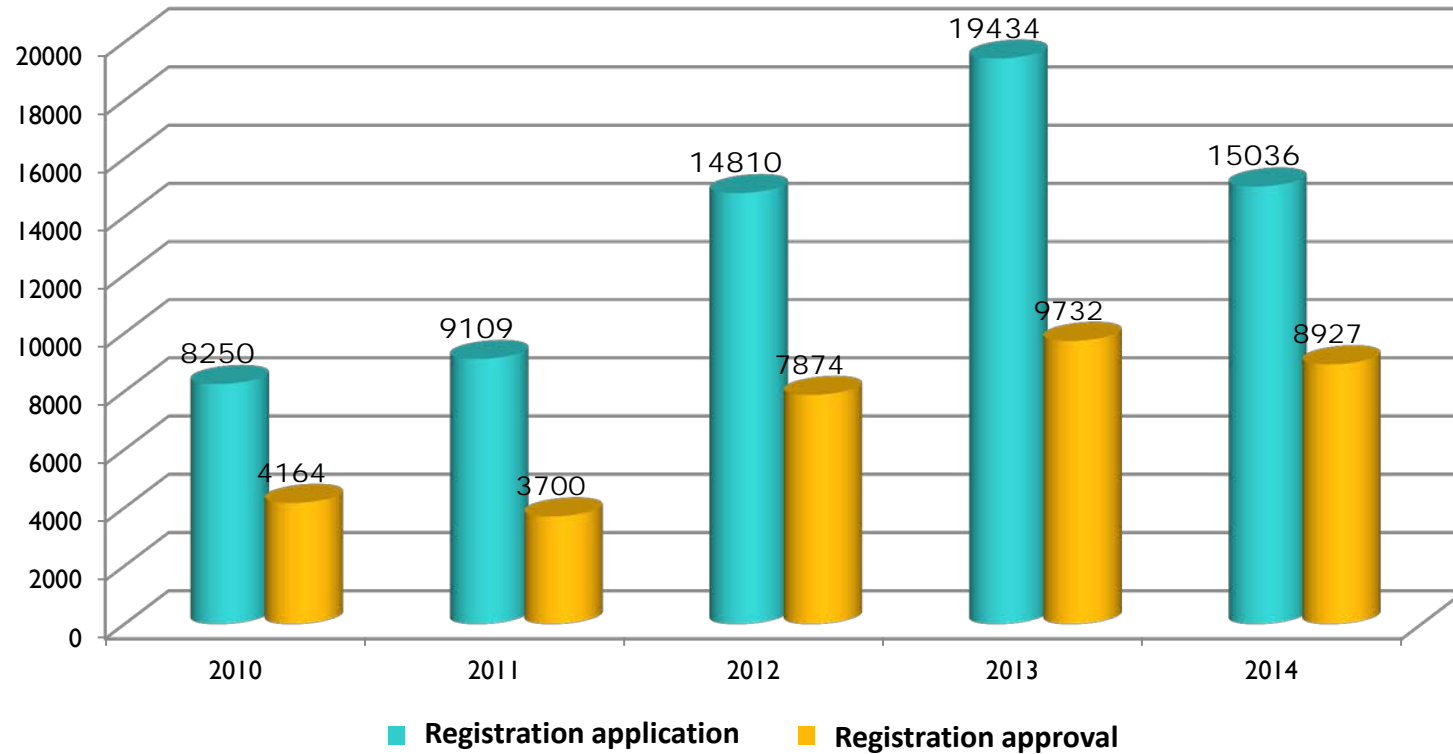


Medicines use for UHC preferably locally manufactured medicines, **however, not all items of medicine can be manufactured locally in Indonesia.**



Open opportunity for investment in Indonesia

Drug Registration Profiles



Source: Badan POM

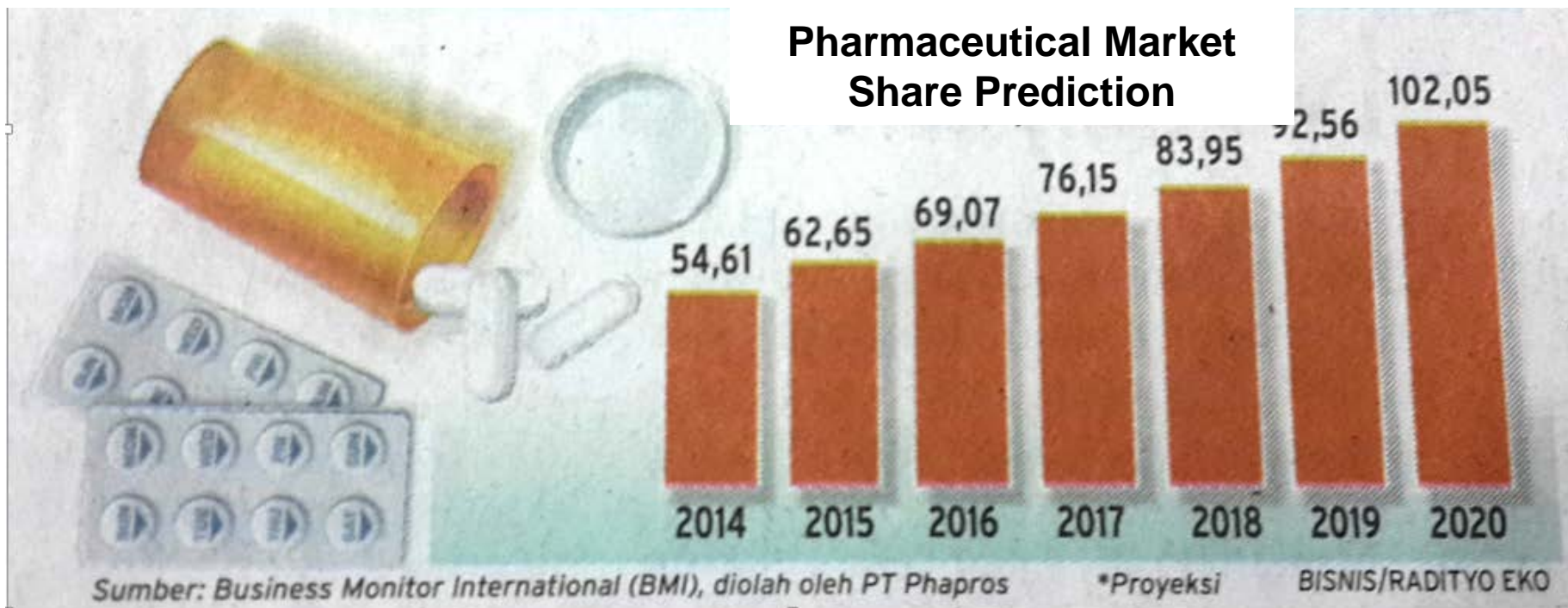


The Pharmaceutical Industry's Development in Indonesia

Indonesia Pharma Market Forecast



Pharmaceutical Market Share Prediction

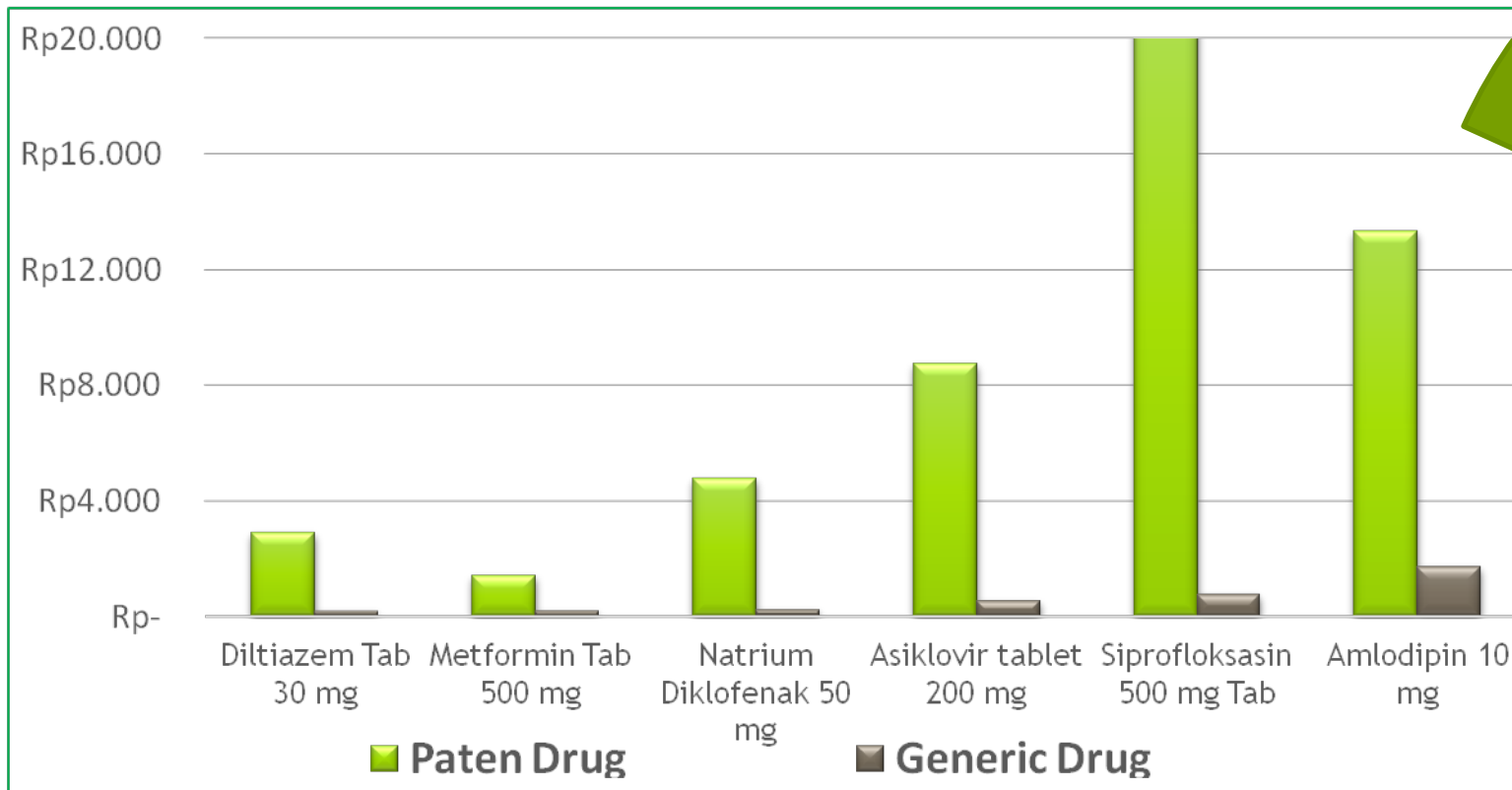


Indonesia pharma market grows up until 2020

Source: Business Monitor International (BMI), in Bisnis Indonesia, 5 September 2014

PRICE COMPARISON OF PATENT & GENERIC DRUG

The price of patent drugs ranges between **8 - 27** times of generic drug, example (*):



It's important to get the first generic drugs

(*) It's chosen from drugs which is widely circulated and used in the long term.

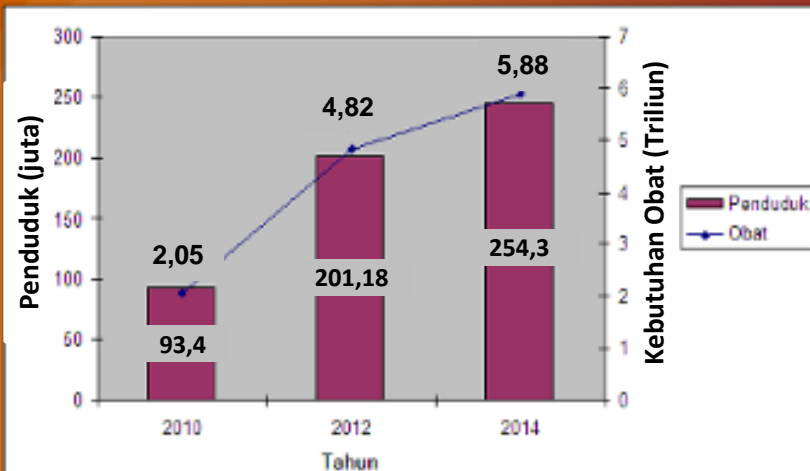
Source: quarterly reports of pharmaceutical industry (2015)

Biotech Product Market Overview

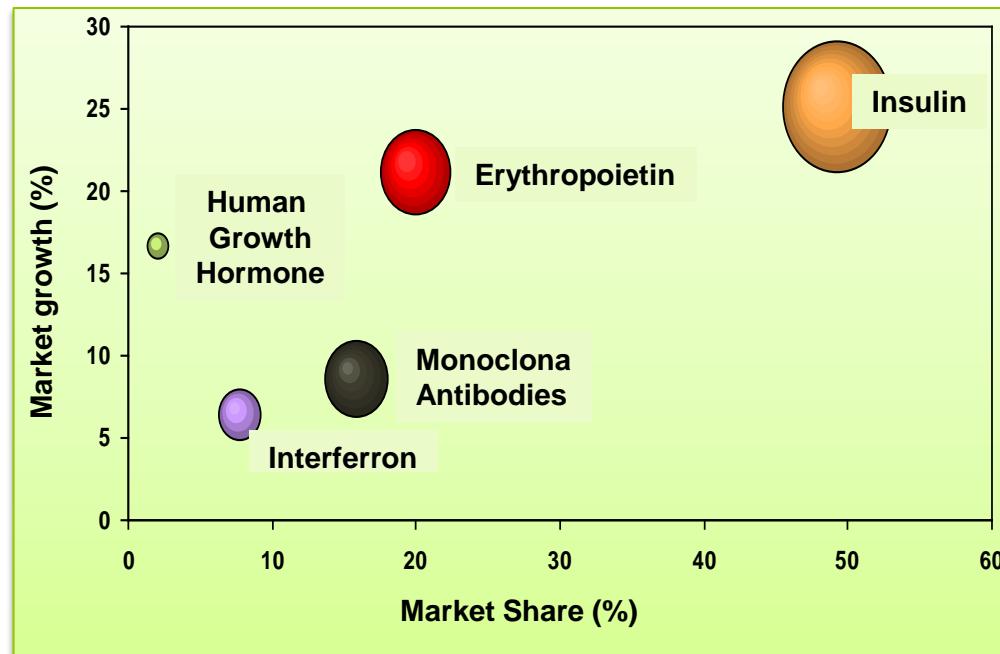


Market overview - Indonesia

PREDIKSI KONSUMSI OBAT UNTUK UNIVERSAL COVERAGE



Market share 2011



Intertribal Monitoring Association on Indian Trust Funds (ITMA), 2011

- *Biotech market in Indonesia is still relatively small but keeps growing*
- *Erythropoietin (EPO) for Renal therapy and Growth Colony Stimulating Factor (GCSF) are listed in ASKES DPHO*
- *With universal healthcare coverage implementation in 2014, pharma market is estimated to grow at least 3 times fold*
 - *Generic - Low price*
 - *Local content preference*

Trend pharmaceutical industries in Indonesia tends to increase



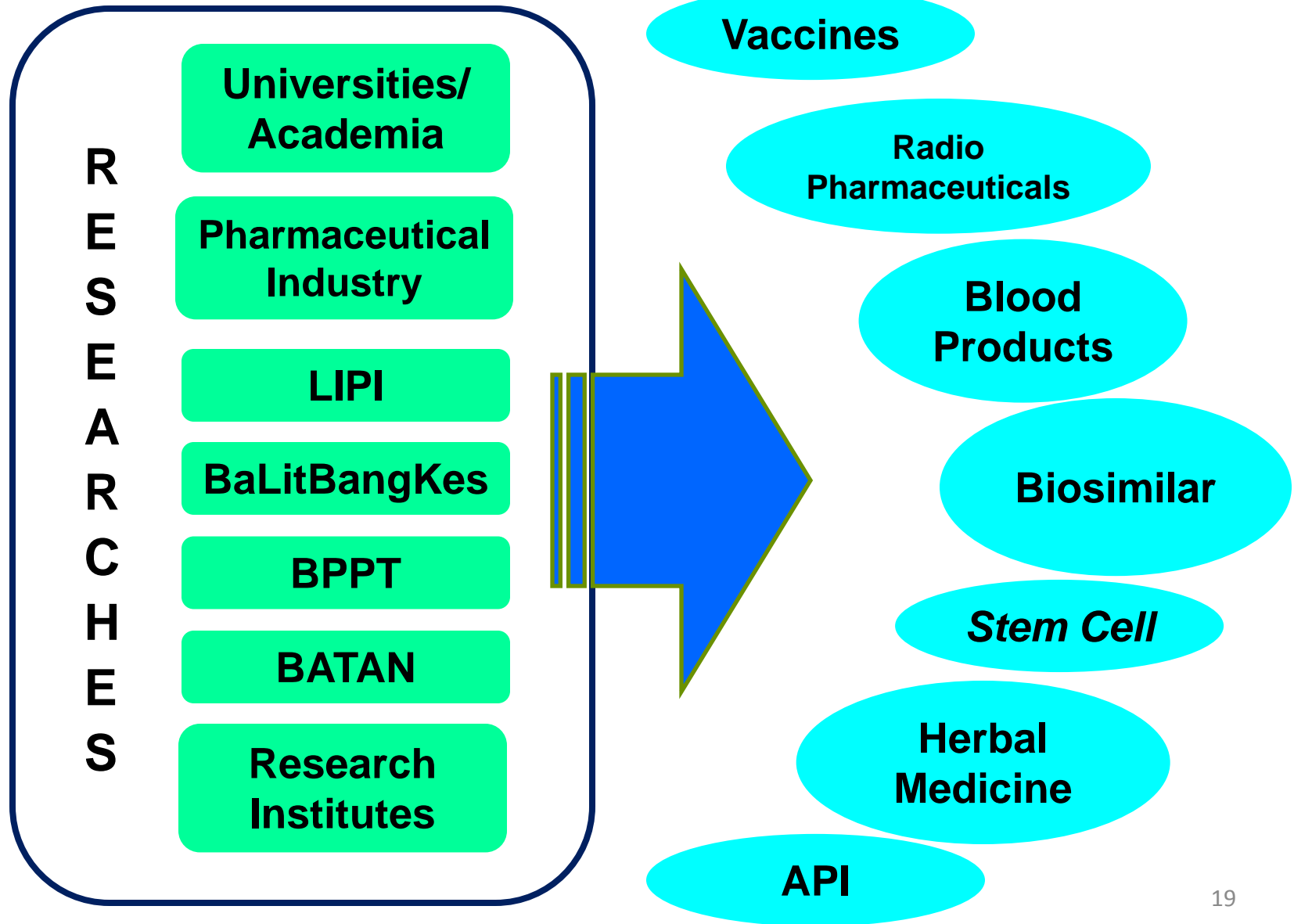
*: Data in 2016 until March 2016

Source: Badan POM 2016



Innovative Medicine Position

Current Drug Researches & Developments in Indonesia



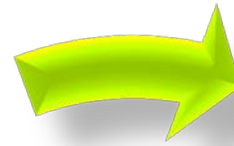
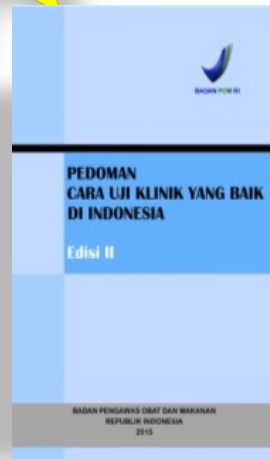


BPOM Encourages New Drug Development

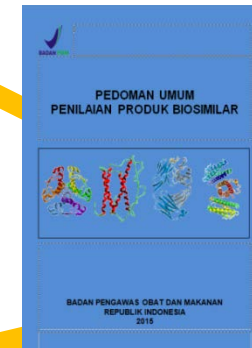
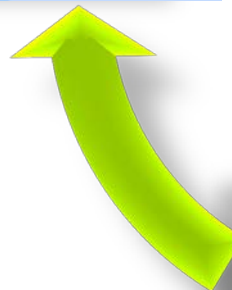
- Badan POM facilitates communication between drug developer (Research Lab / sponsor) for regulatory assistance to avoid inappropriate step during drug development.
- Indonesia accepts foreign clinical trial but foreign CT study may not sufficient to support the registration. Regulatory assistance is needed to disseminate the requirements for registration.

Regulatory Involvement since Drug Development to Marketing Authorization

December
2015



Drug
Evaluation



Badan POM Roles in Product Life Science Development



Badan POM



**Life Science &
Research
Development**



**Life Science
Products**

(Drug & Biological
Product, including
vaccines & biosimilars)



**Public /
Community**



Regulatory involvement through out the product development stages to meet the regulatory requirements (Mechanism of *IND-like system*)



Provide guidance to support new drug development and evaluation for marketing authorization. (e.g.: IND, Biosimilars and vaccines)



Regulatory advocacy and dissemination of regulation for drug evaluation

Examples of Life Science Products through IND Mechanism

In Development Process

- 5 Vaccines
- 2 Biosimilars

In Evaluation Process

- 1 vaccine
- 1 Biosimilars

Marketing Authorization

- 2 Vaccines

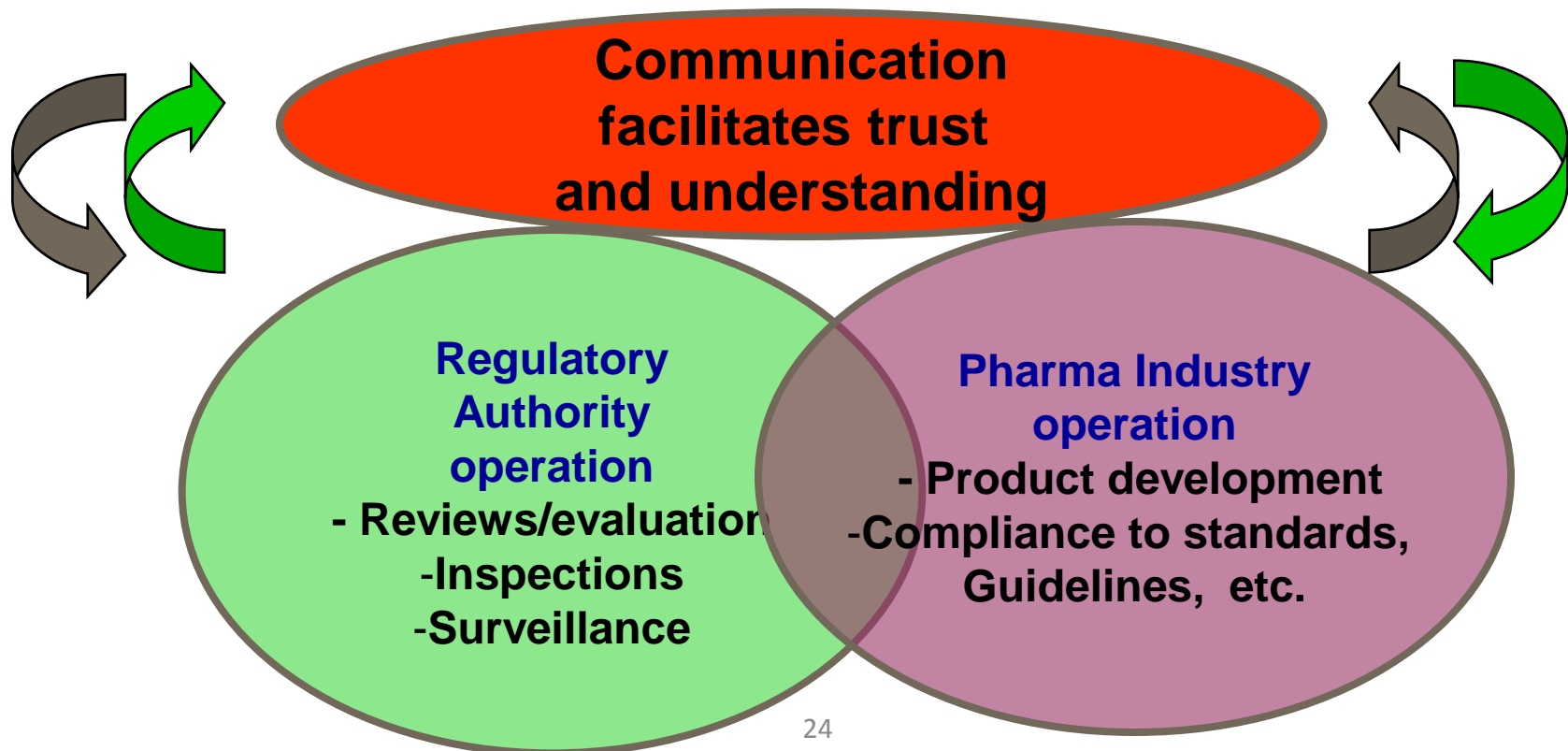


Keyword for Good Relationship Between RA and Pharma Industry in the Life Sciences Sector



MUTUAL TRUST AND UNDERSTANDING

Through Quality risk management





CONCLUSION



CONCLUSION (1)



- Indonesia is a potential pharmaceutical industry hub for ASEAN and global market.
- The Indonesia Universal Health Coverage (UHC) provides opportunities for investors to develop the health care sector.
- Indonesia government support the Pharmaceutical Industry's Development and investment in Indonesia in order to improve National Public Health.

CONCLUSION (2)



- Badan POM encourages New Drug Development and committed to facilitate the new drug development through IND-like system.
- Good climate for innovation could be achieved by implementation of Good Regulatory Practices.
- Badan POM welcomes the synergistic cooperation with academia, business operator and society for the pharmaceutical development.

