



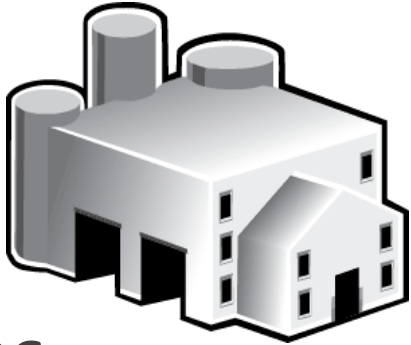
GP.FARMASI INDONESIA

# Presentation Business Engagement - Pharmaceutical

The Indonesian Pharmaceutical Association

24 January 2019

# Summary : Indonesian Pharmaceutical Market



**206** Pharmaceutical Company  
(**4** Govt, **178** Domestic Co,  
**24** Multinational)



**95% Raw Materials imported**  
(Roughly USD 2,2bio in 2017)



Market Size (2017)  
**Rp 70 trillion**  
(+/-USD 5 bio)

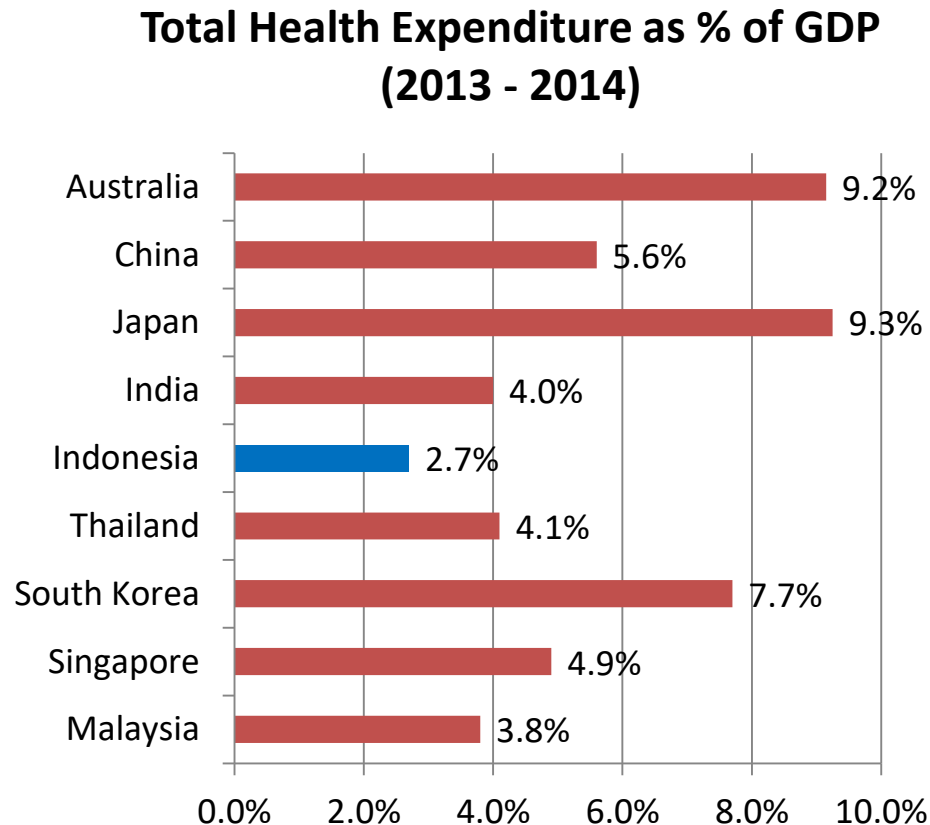
CAGR: **8%**

**73%** value of the market  
dominated by Domestic  
Company



**27%** of ASEAN market  
is in Indonesia

# Total Health Expenditure as % GDP

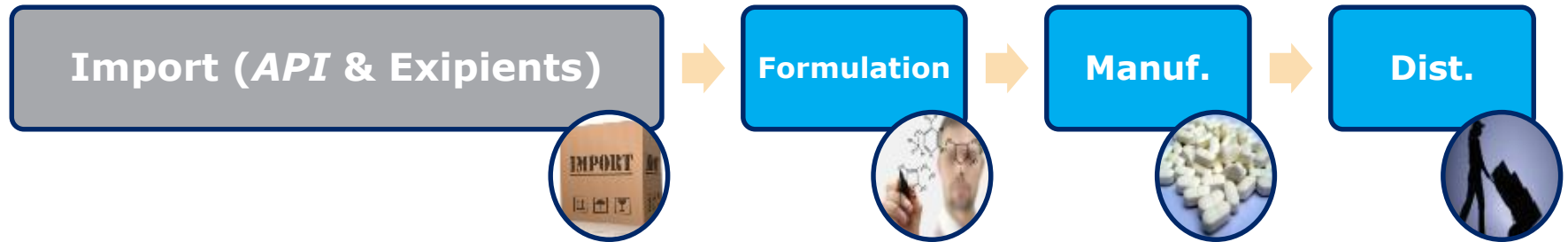


Sumber: Pharmaceutical & Healthcare Countries Report Q2 2014, Business Monitor International; IMS Asia Pacific Insight, 2013

# Transformation of Indonesian Pharma Industry

From formulation-production to Integrated Pharma Industry

## Current Business Model



## Future Business Model



# Potential Business Opportunity for Indian Pharma Companies

Project No 1 : Investment

**Pharmaceutical Raw Materials**

# Considerations for Indian API Manufacturer in Indonesia

## **1. Indonesian Government “push” for API Manufacturer to reduce import of API :**

- ✓ 95% of raw materials API still imported
- ✓ Allowing 100% Foreign Investment in production of Pharma API manufacturer. No local partners needed. Proprietary technology can be secured.

## **2. Replacing other API suppliers, which is having a substantial portion in Indonesian API business.**

- ✓ Since 1 Jan 2016, Local FDA requires DMF for API, Indian company have better knowledge and skills in developing and following proper DMF.
- ✓ Assurance of API supply for Indonesian pharma producers.

## **3. Ease of access to Indonesian Market**

- ✓ Marketing foothold for superior Indian products to be introduced to 178 Indonesian local manufacturer. (USP, EP, DMF)
- ✓ Support technical data required for DMF and other requirement by local FDA (COA, impurities, etc)

# Potential Business Opportunity for Indian Pharma Companies

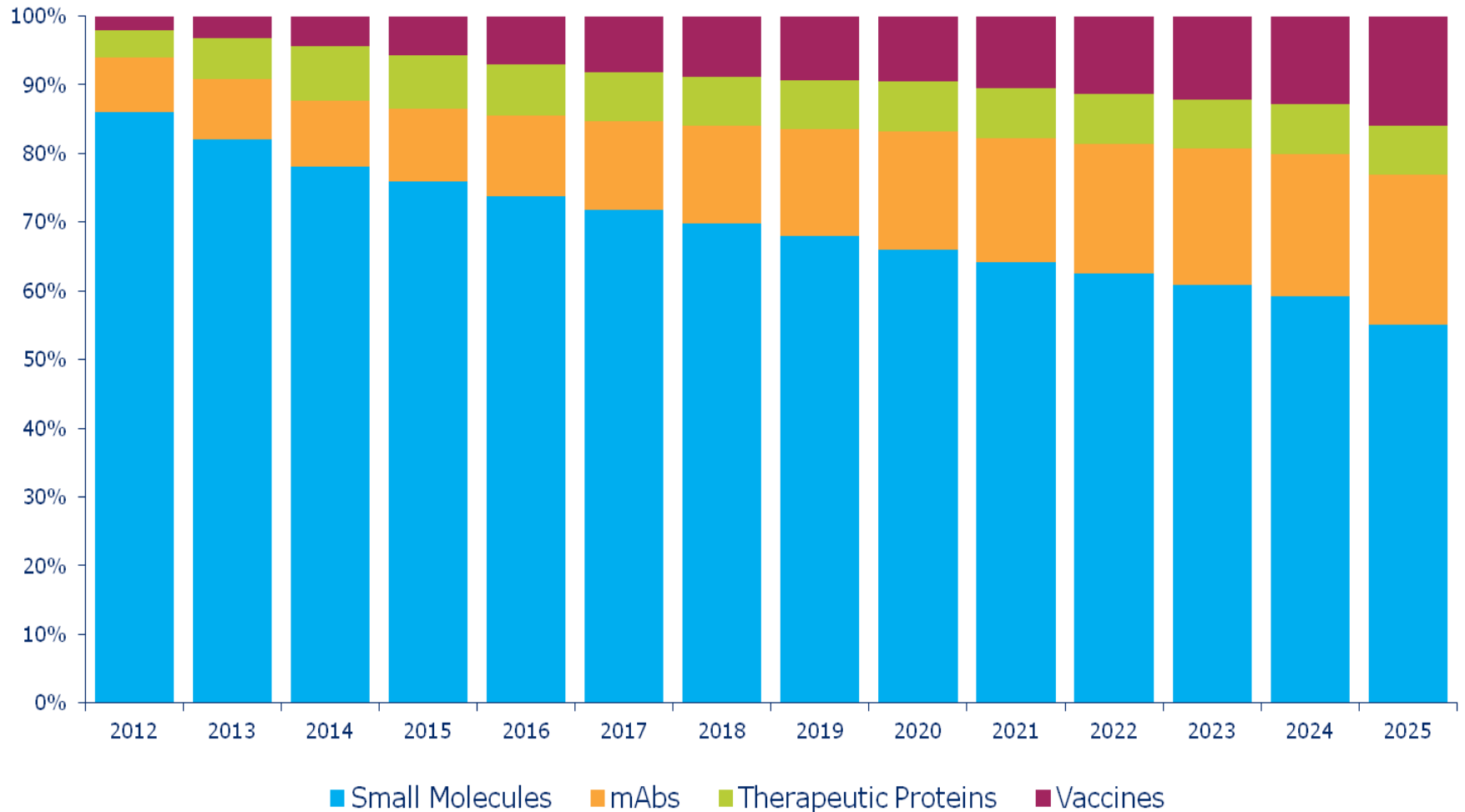
## Project No 2 : Trading (Export to Indonesia)

Hightech Products

(Biotech, Cancer, Blood-related, mAbs, ARV etc)

# IMS : Biopharmaceuticals: Big Molecule is the Global Trend

Global Trend by Bio-Pharmaceutical Market







# Rapid Developed Segment in Pharmacy Industry

## Global top 10 products 2011-13

**5 among Top 10 Global Blockbusters**



-  Small molecule products
-  Biologic products

|    | 2011     | 2012     | 2013     |
|----|----------|----------|----------|
| 1  | LIPITOR  | LIPITOR  | SERETIDE |
| 2  | PLAVIX   | SERETIDE | HUMIRA   |
| 3  | SERETIDE | PLAVIX   | CRESTOR  |
| 4  | NEXIUM   | CRESTOR  | ENBREL   |
| 5  | CRESTOR  | HUMIRA   | NEXIUM   |
| 6  | SEROQUEL | NEXIUM   | REMICADE |
| 7  | ENBREL   | ENBREL   | ABILIFY  |
| 8  | HUMIRA   | REMICADE | LANTUS   |
| 9  | REMICADE | SEROQUEL | CYMBALTA |
| 10 | ZYPREXA  | ABILIFY  | MABTHERA |

# Biopharmaceuticals in Indonesia : Indian Company has advantage to penetrate Indonesian Market

|                          | Sales 2013 (Rp mio) | Growth 2012-2013 |
|--------------------------|---------------------|------------------|
| VACCINES                 | 686,965             | 20.9%            |
| ANTIVIRALS EXCL ANTI-HIV | 250,640             | 1.5%             |
| ERYTHROPOIETIN PRODUCTS  | 188,438             | 21.5%            |
| IMMUNOSTIM AG EX INTFRON | 37,365              | 8.8%             |
| INTERFERONS              | 1,390               | -51.8%           |
| HUMAN INSULIN+ANALOGUES  | 486,834             | 20.5%            |
| GROWTH HORMONES          | 20,991              | 35.3%            |
| ALL OTH. ANTINEOPLASTICS | 445,016             | 22.7%            |
| ANTI-TNF PRODUCTS        | 12,653              | 2.3%             |

*TNF : Tumor Necrosis Factor*

- Biopharmaceuticals market in Indonesia is still in infant phase, except for vaccine market lead by Biofarma, Bandung.
- ***Indian technology is needed to reduce drugs price/expenditure, especially for products supplied by multinationals.***

Source : ITMA, 2013

# Opportunities for Indian Biotech Products

## Top 10 Cancer related drugs (National Insurance)

2014

| NO. | NAMA GENERIK OBAT | JUMLAH KASUS | JUMLAH OBAT | BIAYA (RP)     |
|-----|-------------------|--------------|-------------|----------------|
| 1   | Docetaxel         | 9,659        | 19,463      | 34,471,614,352 |
| 2   | Paclitaxel        | 10,145       | 46,789      | 30,471,620,870 |
| 3   | Trastuzumab       | 1,158        | 1,239       | 24,070,102,848 |
| 4   | Bevacizumab       | 673          | 2,794       | 13,439,158,948 |
| 5   | Capecitabine      | 4,755        | 349,698     | 12,046,944,380 |
| 6   | Oxaliplatin       | 3,015        | 7,575       | 12,017,540,800 |
| 7   | Rituximab         | 728          | 942         | 8,959,004,724  |
| 8   | Imatinib Mesylate | 407          | 41,900      | 8,354,777,513  |
| 9   | Gemcitabine       | 3,058        | 7,351       | 6,604,030,958  |
| 10  | Cetuximab         | 356          | 1,752       | 6,248,096,203  |

2015

| No | Drug Name    | No cases | Unit Drugs | Cost (Rupiah)  |
|----|--------------|----------|------------|----------------|
| 1  | Docetaxel    | 8,848    | 38,954     | 38,777,809,080 |
| 2  | Paclitaxel   | 11,484   | 52,641     | 22,712,395,148 |
| 3  | Capecitabine | 6,098    | 457,355    | 12,788,486,145 |
| 4  | Trastuzumab  | 789      | 842        | 8,734,222,165  |
| 5  | Cetuximab    | 561      | 3,218      | 7,996,329,139  |
| 6  | Ifosfamide   | 1,015    | 5,923      | 7,883,230,273  |
| 7  | Oxaliplatin  | 3,438    | 6,970      | 5,136,475,700  |
| 8  | Vinorelbine  | 859      | 4,151      | 5,109,274,028  |
| 9  | Bevacizumab  | 397      | 1,539      | 5,101,605,698  |
| 10 | Gefitinib    | 821      | 15,958     | 4,794,166,900  |



= Biotech Products provided by MNC

# Opportunities for Indian Biotech Products

| RANK | HOSPITAL PRODUCTS<br>(IMS Q1 2016) | Potential VALUE |        |
|------|------------------------------------|-----------------|--------|
|      |                                    | (USD.Mio)       | %G     |
| 1    | imatinib                           | 18,7            | 235,0% |
| 2    | bevacizumab                        | 17,3            | 238,8% |
| 3    | trastuzumab                        | 17,2            | 101,1% |
| 4    | insulin                            | 16,0            | 7,2%   |
| 8    | docetaxel                          | 13,3            | 12,7%  |
| 9    | rituximab                          | 11,9            | 107,6% |
| 10   | albumin                            | 11,8            | -6,8%  |
| 11   | gefitinib                          | 11,7            | 263,9% |
| 16   | nilotinib                          | 10,6            | 247,1% |
| 18   | paclitaxel                         | 10,5            | 89,1%  |
| 19   | erithropoetin                      | 10,1            | 15,0%  |
| 22   | docetaxel                          | 9,2             | 3,7%   |
| 28   | capecitabine                       | 7,5             | 42,2%  |

# Current Regulations on Drugs in Indonesia :

## PICs standard : applied to domestic and import

| API                                        | GMP                                                    | Registration Dossier                                            |
|--------------------------------------------|--------------------------------------------------------|-----------------------------------------------------------------|
| Drug Master File                           | Site Inspection<br>(infrastructure & QA documentation) | Common Technical Dossier format                                 |
| Halal Certificate for all raw-mats. (2019) | PICs guidelines                                        | EP/BP/USP                                                       |
|                                            |                                                        | 3 consecutive production batches, with complete validation data |
|                                            |                                                        | Stability Data                                                  |
|                                            |                                                        | Biotech : Clinical Trial Phase III by CRO GCP, GLP              |
|                                            |                                                        | Halal Certificate (2019)                                        |

# Conclusion

---

- 1.Indonesia provides more investment flexibility for foreign company to invest in an API facility in Indonesia.
  - 2.Leadng Indian Pharma-biotech companies have competitive advantage to export its biotech products to Indonesia.
  - 3.Indonesian FDA is imposing equal standard to local and imported products, with strict PICs standard.
-

---

# Thank you



GP.FARMASI INDONESIA

---