



# Safety product in Pharmaceutical Market

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Jakarta, 12 November 2019

## Introduction

- Pharmaceutical market usually based on one or more of the following strategies:
  - Biomarkers and / or surrogate end points
  - Results from interim analyses
  - Reduced size safety database

## Pharmaceutical Market

- Benefit
  - Earlier access to potentially live saving or otherwise severe conditions
  - Unmet medical need

## Pharmaceutical Market

- Risks
  - Avoid exposing unnecessary risks
  - Possibly ineffective treatments

## Innovation for improving market

- Innovative financing mechanism
- Risk Sharing
- Service bundling
- Alternative product branding
- Patient access programmes
- Market entry agreement
- Demand generation initiative

#### Characteristics of Indonesian Pharma Providers

#### Indonesian Manufactures

- Predominantly produce out of patient / generic products, OTC, fitofarmaka
- High volume, low margin products
- Low drive towards finding new compounds, research instead target for product expansions

#### Characteristics of Indonesian Pharma Providers

#### **MNCs**

- Mainly expand through research based innovative medicines
- Older, proven established medicines are still keeping some market
- Research are essential, although driven through global initiative

#### Access Barriers to Medicines

- Affordability
  - Patient and family
  - Payers
- Profitability
  - Pharma companies
  - Distributors
  - Outlets

### Access Barriers to Medicines

- Regulatory
  - Legalities
  - Socio cultural

Strategy

## Implementation Market Access

• In many countries, policymakers utilize health technology assessment (HTA) methodologies to direct investments in health care to obtain the maximum benefit for the population as a whole

## Implementation Market Access

- To illustrate potential benefits of using HTA approach:
  - Demonstrates how a new treatment for patients although more expensive than the current standard of care - improves clinical outcomes
  - Represents a cost effective of public health resources

## Implementation Market Access

• If aligned with the prevailing cultural and ethical considerations and with the necessary investment in expert staff resources, HTA promises to be a valuable tool for development of the healthcare sector

## Patients Reported Outcomes

• Increased focus on patient reported outcomes (PROs) in medical research in recent years has heightened the awareness of the patients perspective of health outcomes

## Patients Reported Outcomes

 Pros are useful for physicians, pharmacists and patients for the assessment and improvement of the therapy

## Summary

 More extensive and earlier epidemiologic assessment of risks and benefit of new products: will create a new standard of evidence for industry and regulators more effective and balanced regulatory actions, thereby affording better care for patients

## Summary

 Whereas patients are able to receive treatments that adhere to their needs and expectations

# Thank You