



Safety product in Pharmaceutical Market

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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