

# Enhancing Local Manufacturing Capacity: Pharmaceuticals and Quality Control

International Federation of Pharmaceutical Manufacturers  
& Associations (IFPMA)



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1. The global environment that surrounds health issues
2. What is expected of the pharmaceutical industry?
3. What structure should the pharmaceutical industry have in the future?

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# 1. The global environment that surrounds health issues

# Changing Times, Our Challenge

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- The rise of Emerging Developing Countries
  - Emerging developing countries' voices get louder. Opposition at the WHO gets more severe.
- Dividing line between R&Ds and generics becomes blurred
  - Major R&D-based companies enter generics business in developing countries.
  - 'Originator drugs vs. generic drugs' is becoming old.
  - Shifts of type of competition
    - 'top brand, high quality, large-scale production vs. domestic production'
    - Which to choose? Government health policy plays an important role.
    - Quality, price, reliability are key for success
  - Spread of substandard medicines becoming more of an issue

# Changing Times, Our Challenge

- Growing number of Non-Communicable Diseases in developing countries
  - Shift from communicable diseases to non-communicable diseases (diabetes, cardiovascular diseases, chronic respiratory diseases, mental diseases)
  - Need for health policy for the emerging developing countries
  - Need for new business model for the R&D-based industry
- Pandemic Influenza and Vaccine problem
  - Hopes for vaccine manufacturing capacity building in developing countries
  - Expectations to get “IP Protected Technology ” from major vaccine companies (SMTA)
  - Vaccine supply system to Least Developed Countries

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## 2. What is expected of the pharmaceutical industry?

Capacity building & technology transfer  
What are the fundamental problems?  
Differential pricing  
Patent Pools  
Shared Commitment for Global Health

# Capacity Building & Technology Transfer

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- Key strategy : Differentiate between Least Developed Countries (LDCs) and Low- Middle- Income countries
  - For Least Developed Countries(LDCs):
    - ✓ Production of essential drugs
    - ✓ Establishment of regulatory infrastructure for quality management
    - ✓ Acquisition of basic technology, knowledge transfer
  - For low- and middle-income countries:
    - ✓ Development of infrastructure to provide high quality, low price essential medicines
    - ✓ Development and consolidation of domestic pharmaceutical companies
    - ✓ Promote investment from global R&D based companies
      - The most efficient way of High tech. Transfer

# JPMA's Experiences in South East Asia

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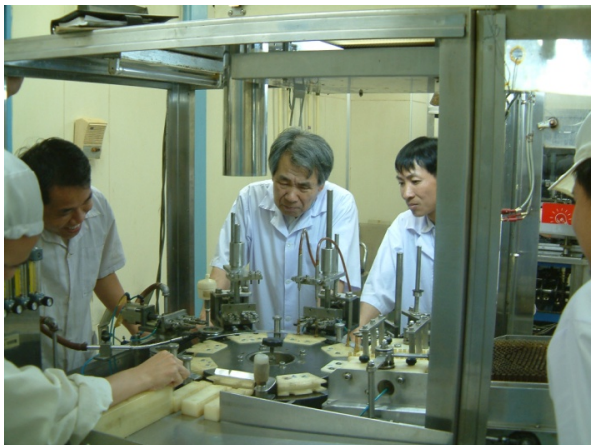
- Common phenomena observed by JPMA at manufacturing sites in South-East Asia
  - National factories and laboratories constructed using Japanese government support were not operating properly.
  - Reasons for this:
    - Lack of basic knowledge and skills
      - Shortage of skills regarding repair and maintenance of machines and equipment
    - The most advanced machinery donated can't be used.
      - Can't understand advanced, Western-style SOPs (in English).
      - Basic knowledge of machinery is lacking.
    - Knowledge of manufacturing control and quality control is insufficient.
      - Lack of GMP and GLP knowledge



# “Accept Reality”: Decisions by the JPMA

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- Simple funding and donation of medicines are not a solution
- Education and practical training on basic knowledge is key for sustainable contribution
- Transfer of basic knowledge and technology is key
- Patience and substantial time is necessary



# Fundamental cause of the access to medicines problem

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Are patents the cause of high price medicines and the access to medicines problem?

**NO! The fundamental problems lie elsewhere**

- Improving health systems
  - Education and training of doctors, other healthcare professionals
  - Establishment of primary healthcare network
- Capacity building (infrastructure)
  - Generic manufacturing capability
  - Establishment of appropriate regulations
  - Basic knowledge for pharmaceutical manufacturing, raising the technology level
  - Construction of a quality management system
  - Construction of a distribution system
  - Create good environment to invite high tech. industries

# Patent Pool

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- Confusing naming
  - If the political objective is to weaken patents, the problem will never be solved.
  - IFPMA member companies fiercely defend patent rights.
- R&D for neglected diseases: create a shared platform where specialists from academia etc can be introduced to compounds owned by industry.
- How about changing the name to "Voluntary Compound Pool"?
  - The key is to build incentives for voluntary contributions from companies.

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3. What structure should the pharmaceutical industry have in the future?

# The Future Shape of the Industry

## Access to Medicine Index

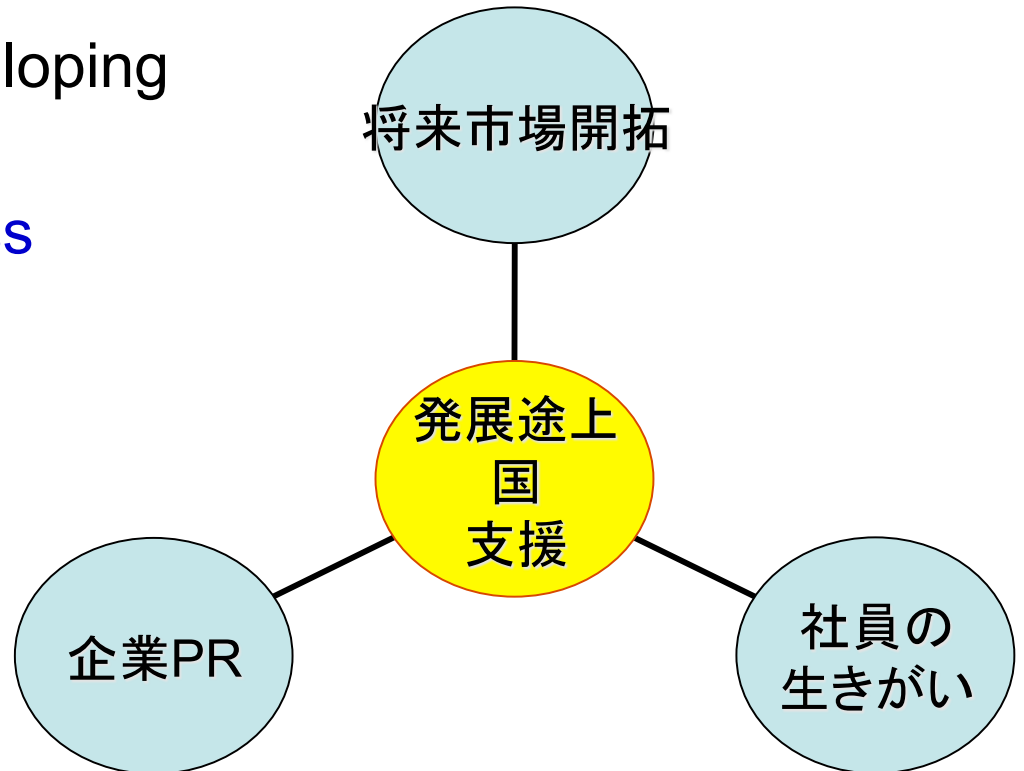
Evaluates contribution of global pharmaceutical companies to developing countries

Contributing to the Medicine Access

Problem highly evaluated.

Merits;

- New market creations
- Good PR
- Provide the best motivation of employee



# Access to Medicines Index

## Pharmaceuticals Evaluated in 7 Areas

- ✓ **Management**
  - **Corporate structure for CSR**
- ✓ **Influence**
  - **Business in developing countries**
- ✓ **R&D**
  - **Numbers of Research Project**
- ✓ **Pricing**
  - **Affordable Pricing policy**
- ✓ **Patenting**
  - **Basic thought on Patent Box**
- ✓ **Capability**
  - **Global quality assurance**
- ✓ **Philanthropy**

	Overall	
1	GlaxoSmithKline PLC	3.7
2	Merck & Co. Inc.	3.1
3	Novartis AG	2.9
4	Gilead Sciences	2.5
5	Sanofi-Aventis	2.3
6	Roche Holdings Ltd.	2.3
7	AstraZeneca PLC	2.2
8	Novo Nordisk A/S	2.1
9	Johnson & Johnson	2.1
10	Abbott Laboratories Inc.	2.1
11	Pfizer Inc.	2.1
12	Boehringer-Ingelheim	1.9
13	Eli Lilly & Co.	1.8
14	Bayer AG	1.8
15	Bristol-Myers Squibb Co.	1.6
16	Eisai Co. Ltd.	1.3
17	Merck KGaA	1.2
18	Takeda Pharmaceutical Co.	0.8
19	Astellas Pharma Inc.	0.6
20	Daiichi Sankyo Co. Ltd.	0.6

# The pharmaceutical industry in the future

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## Model of CSR

(sustainability, transparency, win-win relationship)

1. Era where structure for contributing to patients and society is called for
  - Understanding at CEO and senior management level
  - Creation of a department with specialist responsibility for CSR
  - Does CSR raise the share price?
2. External visibility of philosophy, policies and decision-making system for CSR activities
3. Sustainable CSR activities
  - Contributions in companies' specialist fields
  - Long-term benefit rather than short-term success
  - Win-Win relationship: benefit for both recipient countries and companies

# Trends underway at the IFPMA

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Conflict → Dialogue

Isolation → Collaboration

“Shared Commitment for Global Health”

## ■ For patients around the world

- Seek a strategy for mutual understanding and benefit with emerging developing countries
- Support for LDCs (e.g. Capacity Building)
- Pandemic Influenza Preparedness
- Work together on WHO health policies







Thank You!

