Main Points of New Drug Industry Vision

Changes in environment

- **Research trends in life sciences**
  (antibody drugs, molecular markers)
- **Further globalization**
  (Multinational clinical trials, government-level global research competition)
- **Increase in M & A**
- **Expansion of related industries**
  (Boom in venture firms, increase in various forms of outsourcing)

Drug Industry - Realities and challenges

Realities

O Increase in share of foreign products in Japanese drug market

O 'Drug lag'

Challenges

O No increase in global competitiveness of Japan's drug industry

O Global competitiveness of drug discovery environment and market per se (=global attractiveness) also on the decline

→ **critical situation**

Vision of Industry and Measures for Government Implementation (Action Plan)

Vision of industry 10 years on (differences from previous Vision)

(1) Revise vision of industry in line with global competition status

(2) Clarify importance of **ongoing innovation** for industry expansion

(3) Present vision of wholesale drug industry and functions required

Action Plan
<5-Year Intensive Period>
(2007 ~ 2011)

'5-Year Strategy for the Creation of Innovative Drugs and Medical Devices'
+
Comprehensive Action Plan including development of generic and non-prescription drug market, promotion of more efficient and advanced distribution

Follow-up of measures

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'Panel on Promotion of Drug Industry Policy'
'Public-Private Dialogue for Innovative Drug Discovery'

View of Changes in 5 Years Following Formulation of Drug Industry Vision and Formulation of New Vision

Changes in 5 years following formulation of previous Vision (2002), basic direction of Japan (promotion of innovation and faster growth)

O Greater M & A activity, global expansion, increase in number of clinical trial notifications etc.

⇔ No increase in share of Japan-origin global blockbuster drugs, no blockbusters produced in Japan since 2000 etc.

→ Japanese companies lack global competitiveness

O Drug lag problem, lagging behind in multinational clinical trials

→ Decline in global competitiveness of Japan's drug market

O Acceleration of economic growth rate and promotion of innovation – the political challenges faced by overall government

→ Drug industry in particular is the 'prime' field for generating innovation to contribute to economic growth

Formulation of New Drug Industry Vision

Objective: To boost the global competitiveness of Japan's drug industry and eliminate the drug lag

⇒ Ultimately aspire to become a country with the affluence to 'deliver as quickly as possible and at reasonable prices safe and high-quality drugs in line with healthcare needs'

Requirements for Boosting Global Competitiveness and Eliminating the Drug Lag

O Domestic drug market has shrunk to around 10% of the global

→ **Pharmaceutical companies cannot expand by targeting the Japanese market alone**

→ **Need to boost global competitiveness**

O Drug lag problem (decline in global attractiveness of Japan's drug discovery environment and market)

→ **Barrier to prompt launch of latest foreign therapeutic agents and instant access of public to high-level medical care**

→ **Need to eliminate drug lag**

⇒ **Vital to make Japan's drug discovery environment and market open and globally consistent**

Direction of New Vision Measures

A comprehensive Industry Vision based on the '5-Year Strategy for the Creation of Innovative Drugs and Medical Devices' with the addition of the vision of the industry, the image of related industry expansion and the measures required

Requirements of the Drug Industry

Drugs are life-related products, with high value and heavy burden of social responsibility
→ **Boosting global competitiveness is not the only requirement of pharmaceutical companies**

Requirements of the drug industry

- To respond to unmet medical needs
- To develop and supply unprofitable but vital drugs (agents for refractory diseases with no available therapeutic methods, orphan drugs, vaccines etc.) and drugs to meet the needs in Japan and Asia
- To make social and international contributions through humanitarian assistance to developing countries, crisis management of new influenza strains, natural disasters, bioterrorism etc.

※ **The establishment in Japan of research bases and the development of new drugs originating in Japan by pharmaceutical companies should be welcomed. The grant of government aid to such companies should also be fully considered.**

Vision of Pharmaceutical Industry

On the basis of drug cost increases in line with national healthcare expenditure, in 2015 and 2025 the future drug market could respectively be 1.3 times and 1.7 times that of 2005 .

The global market is increasing at a huge rate → the emergence of a major market is expected

→ Ongoing new drug development, innovation, efforts at global expansion are required for the drug industry to keep up with this rate of increase

→ **Given industry progress in line with the '5-Year Strategy for the Creation of Innovative Drugs and Medical Devices', Japan too could easily become a new drug development base alongside Europe and the US**

Ongoing new drug development, innovation, global expansion require a certain corporate scale

↔

There are limits to the conventional global megapharma model (repeat mergers, concentration on development of major products)

↓

New stage of global competition
(Maturity of existing products, more targeted drug development)

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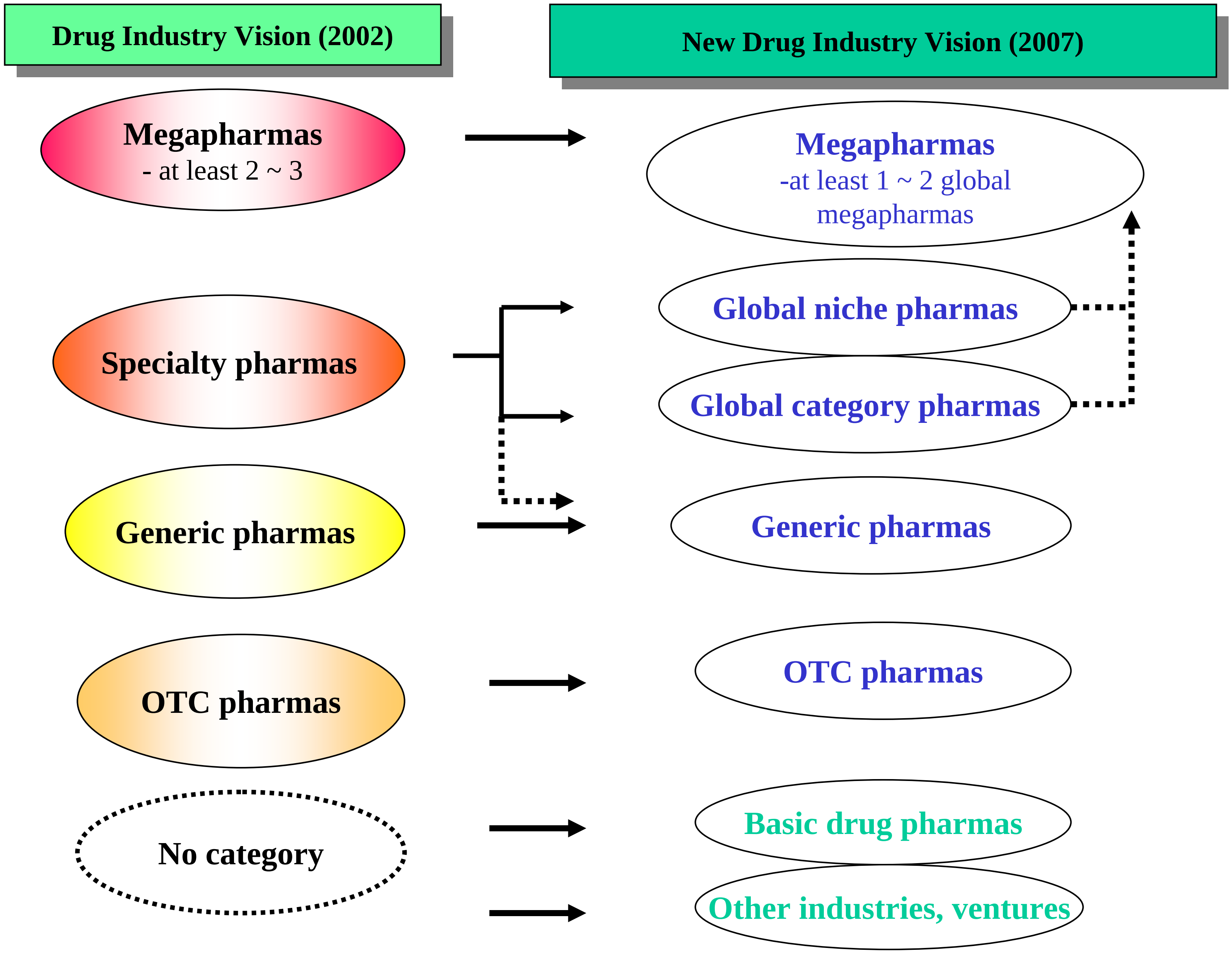
Expansion to the right size, search for fields with global-leader potential, increase in competitive product line-up

⇒
- **O Potential to compete against major global firms in new drug development**
- **O Japan production of at least 1/4 ~ 1/3 of new active ingredients also not impossible**


Drug Industry Vision (2002)
New Drug Industry Vision (2007)
Megapharmas
- at least 2 ~ 3
Megapharmas
-at least 1 ~ 2 global megapharmas
Global niche pharmas
Specialty pharmas
Global category pharmas
Generic pharmas
Generic pharmas
OTC pharmas
OTC pharmas
Basic drug pharmas
No category
Other industries, ventures

Vision of Drug Wholesale Industry

Realities

No. of licensed ethical drug wholesalers: 972 companies

Contractors principally engaged in drug wholesaling
Members of Federation of Japan Pharmaceutical Wholesalers Association **128 (end of 2006)** ← **166 (07/2002)**
Members of Association of Japanese Generic Drug Distributors **64 (01/2007)**

Industry realignment through M & As, speed-up in business alliances, greater concentration

- Progress with modernization of distribution
- Lower drug prices
- Advance of bungyo
- Progress with computerization
- Collective purchasing initiatives

Challenges

Stable Supply

- Need for a more advanced and efficient drug distribution for the‘capillary-style’ system (the detailed services and information required for the supply of an immense variety of drugs to around 220,000 medical institutions, pharmacies and other users)
- Need to establish and promote a crisis management drug distribution framework for crisis situations such as natural disasters and infections

Promotion of IT

- Need for further standardization and computerization of distribution codes to assure safety and traceability

Evaluation of information activities

- Supply of information on package insert revisions and ADRs (the information activities) to enhance the wholesaler value
- Need to improve the quality of the MS, responsible for the wholesaler information activities

Establishment of independence

- Establishment of equal operator status in taking on the diverse needs of the pharmaceutical companies and medical institutions etc.
- Elimination of distribution problems such as ‘pending settlements and provisional deliveries’

Vision

(1)	Integrated	Full-line wholesalers free from manufacturer alliances with a nationwide large-scale distribution network and advanced information services and infrastructure
(2)	Specialized	Wholesalers specializing in specific product areas (e.g. generics), specific users, such as clinics and individual pharmacies, and specific regions, and operating a distribution network and information services in line with these characteristics
(3)	Allied	Wholesalers with specific trading areas, but who form alliances with wholesalers with other trading areas, and as a group can rival the integrated wholesalers
(4)	New cluster	Wholesalers not confined to drug distribution, operating as horizontal integrated (enterprise) or vertical integrated (manufacturing, wholesaling, retailing) wholesalers
(5)	Non-proprietary specialized	Wholesalers who seek efficient business expansion through specialised handling of OTC drugs etc. not covered by health insurance

Independent management and business modernization through functional specialization and reinforcement based on the respective characteristics is also expected to achieve upscaling and greater profitability for wholesalers

Vision of Drug Retailing

Realities

- No. of drug retailers: approx. 86,000 (approx. 51,000 pharmacies, 11,000 drug-sellers with first-class, 13,000 with second-class and 10,000 with third-class license (03/2005)
- Increase in no. of pharmacies through advance of bungyo; decrease in no. of drug-sellers with first-class, second-class and third-class license
- Establishment of risk-proportionate marketing system for non-prescription drugs (PAL revision of 2006)

→ High-risk drugs containing ingredients requiring particular safety precautions … only sold by pharmacies
→ Non-prescription and other relatively low-risk drugs … sold by pharmacies and registered sellers

Challenges and Vision

O Tougher intra-industry competition for drug retailers through diversification of operators and tougher cross-industry competition through deregulation
→ Establish role as local health stations

O Rapid advance of IT
→ Apply IT in distribution for purchasing and inventory management etc.

O Crucial role as local base for the supply of drugs etc. following advance of bungyo and healthcare reforms
→ Respond to local healthcare policies
(Act as primary care pharmacy, implement high-quality bungyo, improve local healthcare etc.)

O Role of primary care pharmacy
→ • Take an active part in minor healthcare services through promoting the use of switch OTC and other non-prescription drugs
• Support home healthcare
• Support promotion of generics

Basic Concept of Drug Industry Policies

Industry expansion should basically proceed within the context of free competition based on the market mechanism. However, there are critical hurdles in the way of improving the healthcare of the nation and gaining its trust, and the government and industry should work together to overcome these.