

Generic Medicines in the International Transaction and Japanese Market

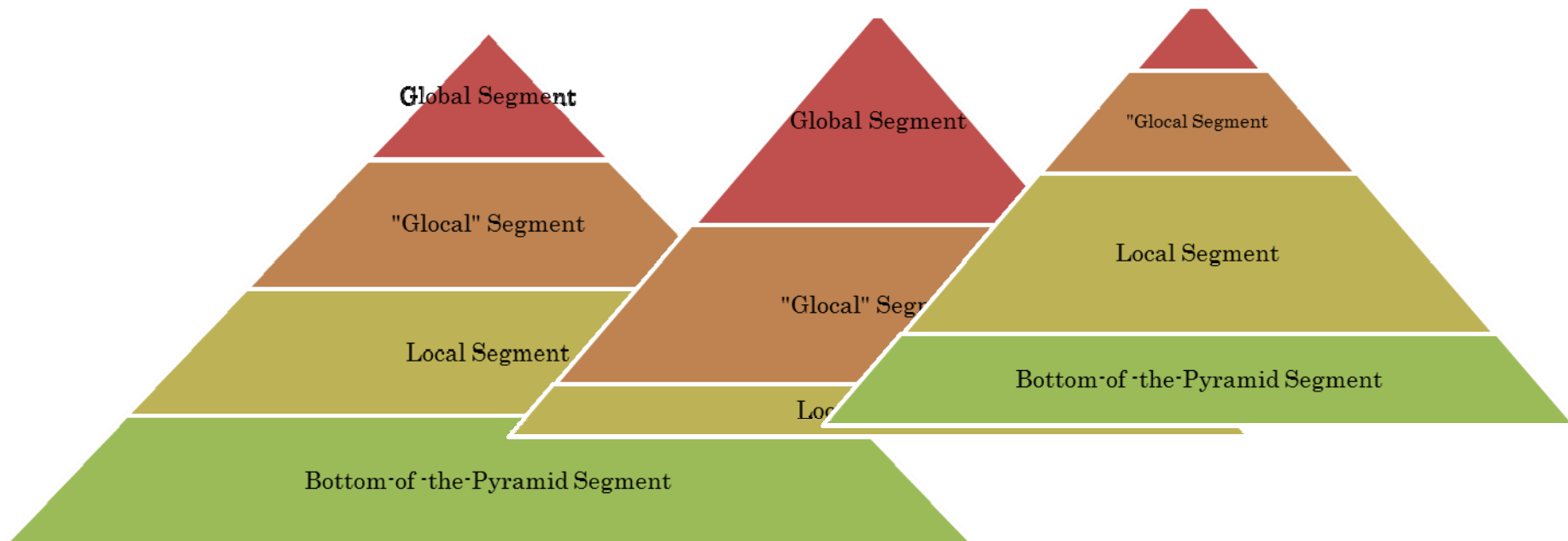
Tamotsu Fujino,
Japan Generic Medicines Association
CPhI March 22, 2012

Japan Generic Medicines Association

- Established in 1968
- President: Mr. Hiroyuki Sawa
- 44 members and some associate members.
Most of them are manufacturers of finished formulations
- There are about the same number of outsiders
- Domestic-oriented. Very little export.

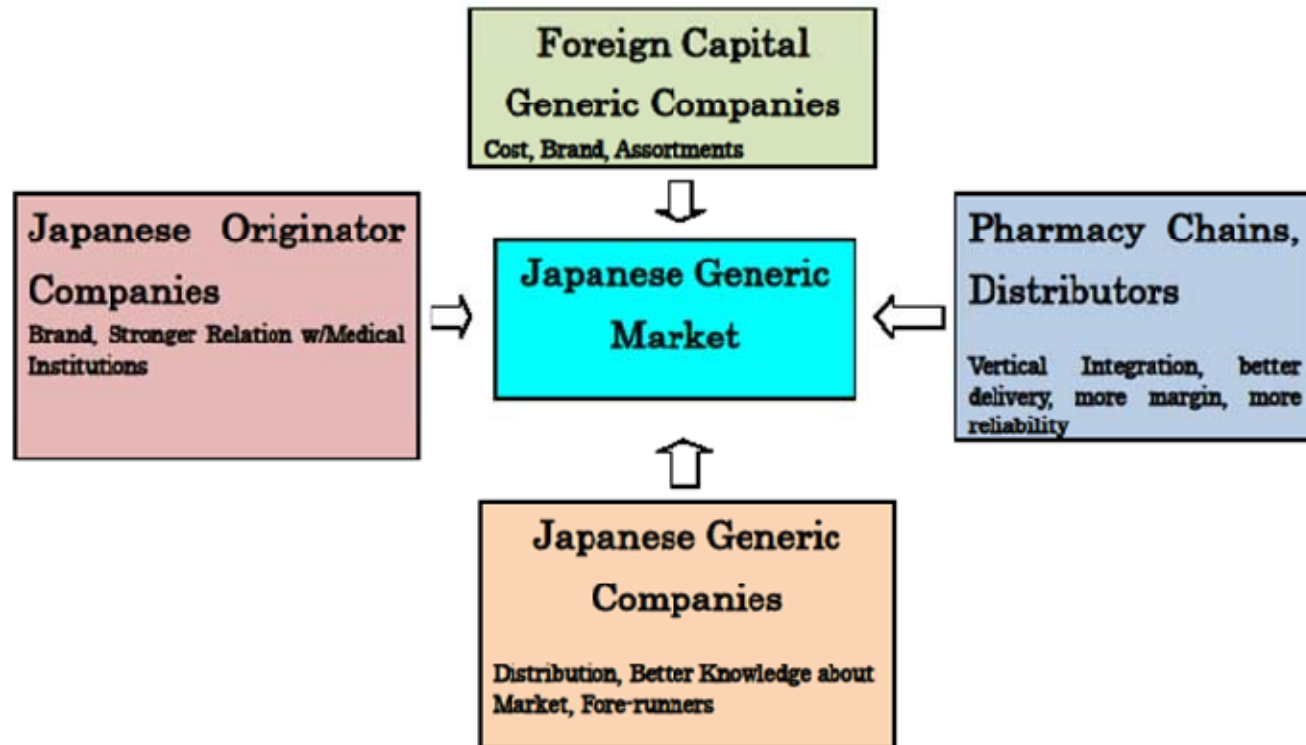
Conceptual Market Structures

There are various patterns of the market structure in each country

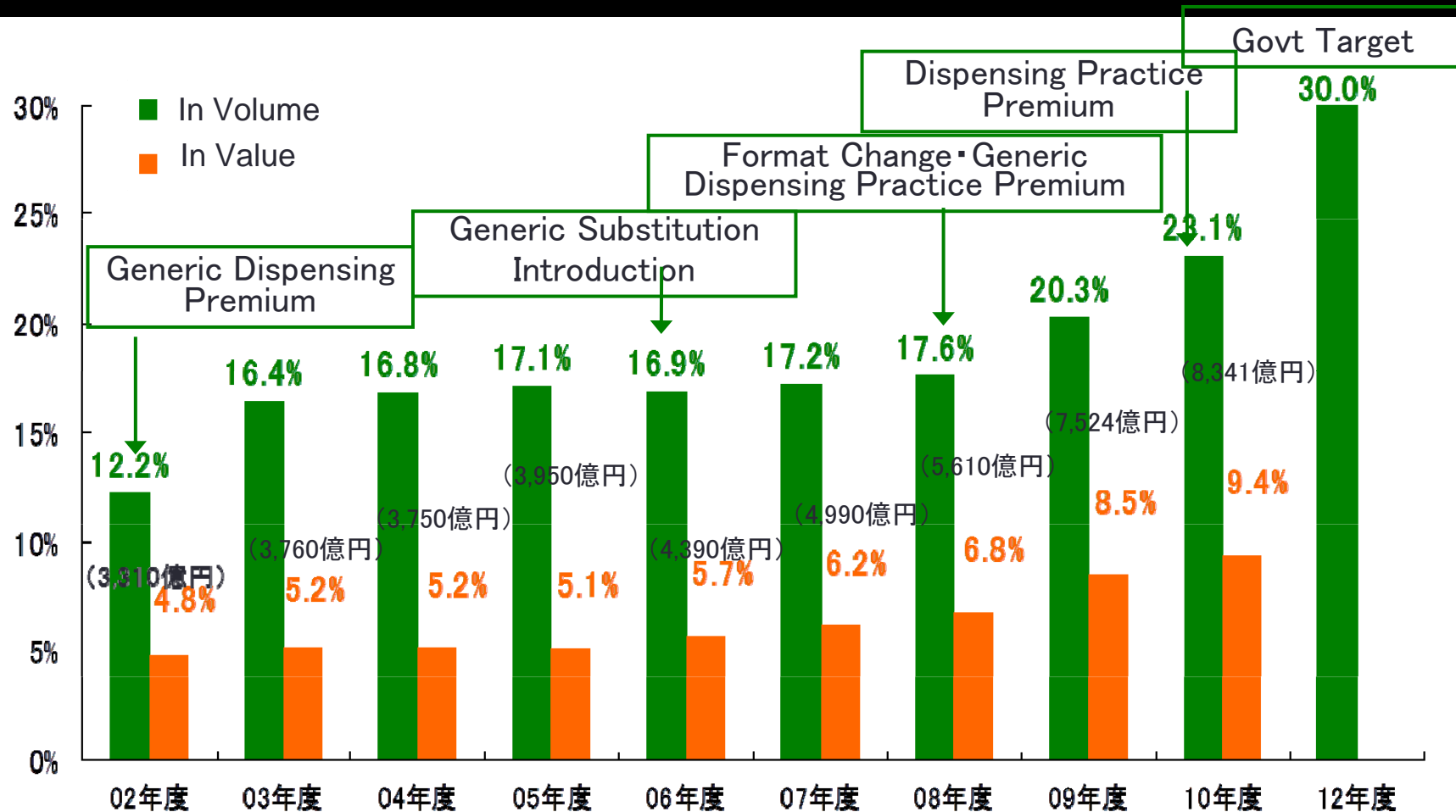


Philip Kotler, Hermawan Kartajaya and Iwan Setiawan, *Marketing 3.0*, 2010

Current Generic Market and Manufacturers



Generic Market Share Evolution



Shares: JGA

Public Price Generic Estimates(): Sawai' Estimate based on IMS

Copyright © 2010 Japan Generic Medicines Association .

Major Issues with Generics (I)

1 Constant Supply

Abandoning of the market resulting from too much price competition. This depends highly on API suppliers as well.

- Only among members, advanced reporting system and mutual rescue operations for those who have inventory problems.

2 Provision of Sufficient Information

Lack of understanding of nature of generics by medical professionals. The same services as innovator marketers are expected.

- Creation of on-line data provision system. And academic literature evaluation efforts are made jointly by industry and Government.

3 High Quality of Products

Lagging impression of the past.

- Adoption of ICH practices improved quality.
- Many cases of contract manufacturing for innovators.
- Voluntary Long-term (3 years) stability data among the JGA members to demonstrate reliable quality.
- Joint industry efforts eliminate bad quality products.

Major Issues with Generics (II)

- Majority of APIs are bought from China, India and EU through importing agents.**(not directly)**
- Adoption of the **Revised Pharmaceutical Affairs Law** requires QC of the suppliers outside of the jurisdiction including inspection by PMDA.
- Adoption of **DMF** would not allow private inspection of the confidential documents and processes while change controls on major process deviations require application in advance to PMDA and MHLW. Suppliers' communications are often insufficient in this regard.

Good Approach to Japanese Market

- First Choose a **reliable in-country caretaker**
- **Communicate well** with the in-country caretaker
- Get sufficient information on **MHLW's moves including good translation of the Ministry's notifications**
- Keep informing the **in-country caretaker as well as the generic manufacturers** especially on the matters related to **quality**

Export of Finished Products

There are several approaches:

- Independent, one by one registration approach is not cost-effective. Since sales volume of each product of generics will be very small to sustain local operation at the beginning.
- **Find a local partner(s) who can register and promote for you.**
- **M & A a local partner(s) who can register and promote**
- **Prepare redundant application dossiers** to cover Japanese requirements as well.

Generic Medicines Market in Japan

- Thank you for your attention