Supply Chain Integrity

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Today’s Agenda

1. What is expected of us?
2. What is Supply Chain Integrity?
3. Challenge and Solution
4. Conclusion
1 What is expected of us?

Common issues developed countries face...

- Increasing medical expenses
- Safety and assurance
- Accountability

...In Japan, the super-aging society accelerates them
1 What is expected of us?

*The pharma industry is expected to*...

- Enhance patient safety - Traceability
- Achieve Efficient medical support - Online Network

*...And Supply Chain Integrity is the solution to meet these expectations*
2 What is Supply Chain Integrity?

Supply Chain Integrity is...

A common platform for the pharmaceutical wholesalers that “enhances patient safety from a patient’s standpoint” and “achieves efficient medical support”
2 What is Supply Chain Integrity?

The Concept

“Cooperation” and “Competition”

Patient Safety
Efficient Medical Support
Supply Chain Integrity

Information Technology (Standardization)
What is Supply Chain Integrity?

Patient Safety

*Shift from “Supply Side” to “Demand Side”*

For example… biological products, JGSP
2 What is Supply Chain Integrity?

Patient Safety

*Why is counterfeit drug not active in Japan?*

- No parallel imports because of administrative direction
- Strict pharmaceutical practice administration/crackdown
- Strict Supply Chain Management by Pharmaceutical Wholesalers
- Strong safety awareness of consumers (purchase only from legitimate channels)
2 What is Supply Chain Integrity?

Personalization + Codification
2 What is Supply Chain Integrity?

Patient Safety

*Safety Management by Alfresa*

- Information gathering (FINE DEM)
- Early Phase Post-Marketing Vigilance
- Provision of Information
- Product Recall
2 What is Supply Chain Integrity?

**FINE DEM is…**

Activities to collect information regarding quality, efficacy and safety of drugs

**Aims**
- To grow drugs
- To contribute to the proper use of drugs
2 What is Supply Chain Integrity?

Example of Package Design Change

**FINE DEM Report**

A vial of Drug A of X company looks very similar in color to drug B of the same company.

Comment from the company:
We received similar report inside and send that to the section concerned.
2 What is Supply Chain Integrity?

Efficient Medical Support

For example…Online network
2 What is Supply Chain Integrity?
Relationship between Drug Networks in Japan

Manufacturers

JD-NET

JD-NET Council

Wholesalers

PRO-NET

PRO-NET Council

Medical Institutions

JPMA
FPMAJ
JPWA

418 members
60 million Transactions /mth

280 Wholesalers
38000 Medical institutions
15 million Transactions /mth

JPMA : Japan Pharmaceutical Manufacturers Association
FPMAJ : Federation of Pharmaceutical Manufacturers Association in Japan
JPWA : Japan Pharmaceutical Wholesalers Association
## History of Drug Networks in Japan

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<th>HM-NET</th>
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**Established in Apr. (planned):**
- PRP-NET (‘06.10~)

**Manufacturers (~ Medical service Providers):**
- HM-NET
- HCM-NET
- T-NET
- CM-NET
- KOS-VAN
- JM-NET
- TMS-NET
- K-NET
- HOSTY-NET
- KMS-NET
- JD-NET

**Wholesalers:**
- PRO-NET

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2 What is Supply Chain Integrity?
2 What is Supply Chain Integrity?
Flow of Claims for Medical Treatment Fee

- **Medical Institution**: 1.2 bio papers p/a
- **Audit & Payment Institution**: Paper Receipt 77%
- **Medical Insurers**: 1.6 bio papers p/a

5 hundred times higher than height of Tokyo Tower (333m) if piled

- **Digital Device**: 23%
- **Online Receipt**
3 Challenges and Solutions

**Challenge in maximizing IT potential**

- Standardization requirements
  - Technical Aspect
  - Conceptual Aspect
    - Shift from traditional to new paradigm
3 Challenges and Solutions

Technical Issue

Towards Standardization…

Data Structure

Develop common rules for supply chain participants

E.g.
- GTIN (Global Trade Item Number)
- Application Identifiers
- GLN (Global Location Number)

Data Carrier

Build structure to linking products and various information

E.g.
- RSS
- JAN/EAN/UPC
- UCC/EAN-128
- RFID
- EDI, XML

Source: GS1 Standard System
Accepting standardization is nothing but an inhibition of free competition.

Standardization is a threat. In order to protect the territories, unique criteria and labeling is sufficient.
3 Challenges and Solutions

Conceptual Aspects

New Paradigm

- Standardization based on total optimization
4 Conclusion

“Cooperation” and “Competition”

Patient Safety
Efficient Medical Support
Supply Chain Integrity

Information Technology (Standardization)
Thank you