

Japan-Indonesia Symposium Presentation Material

At Jakarta
2013/1/21

Drug Distribution and GDP in Japan

(社)日本医薬品卸業連合会 薬事制度委員会 委員長
一條 宏 (バイタルネット)

Hiroshi ICHIJO

Chairperson of the Pharmaceutical Regulation Committee
the Federation of Japan Pharmaceutical Wholesalers
Association

(Director of VITAL-NET, Inc.)

Japanese Drug distribution

- 医薬品卸企業の数91社 (JPWA加盟)

91 Drug Wholesalers affiliated with JPWA

(Japan Pharmaceutical Wholesalers Association)

- 医療用医薬品 売上高8兆円

The sales of Rx drugs : 8 trillion yen.

- 医薬品卸売業を経由の販売が97%

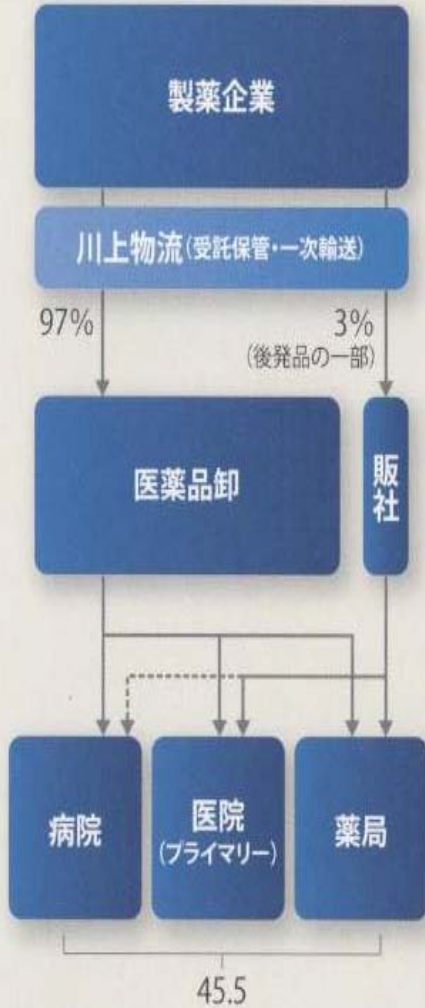
97% of Rx drugs are sold through Drug Wholesalers.

- 従業員数5.5万人

The number of employees are 55,000.

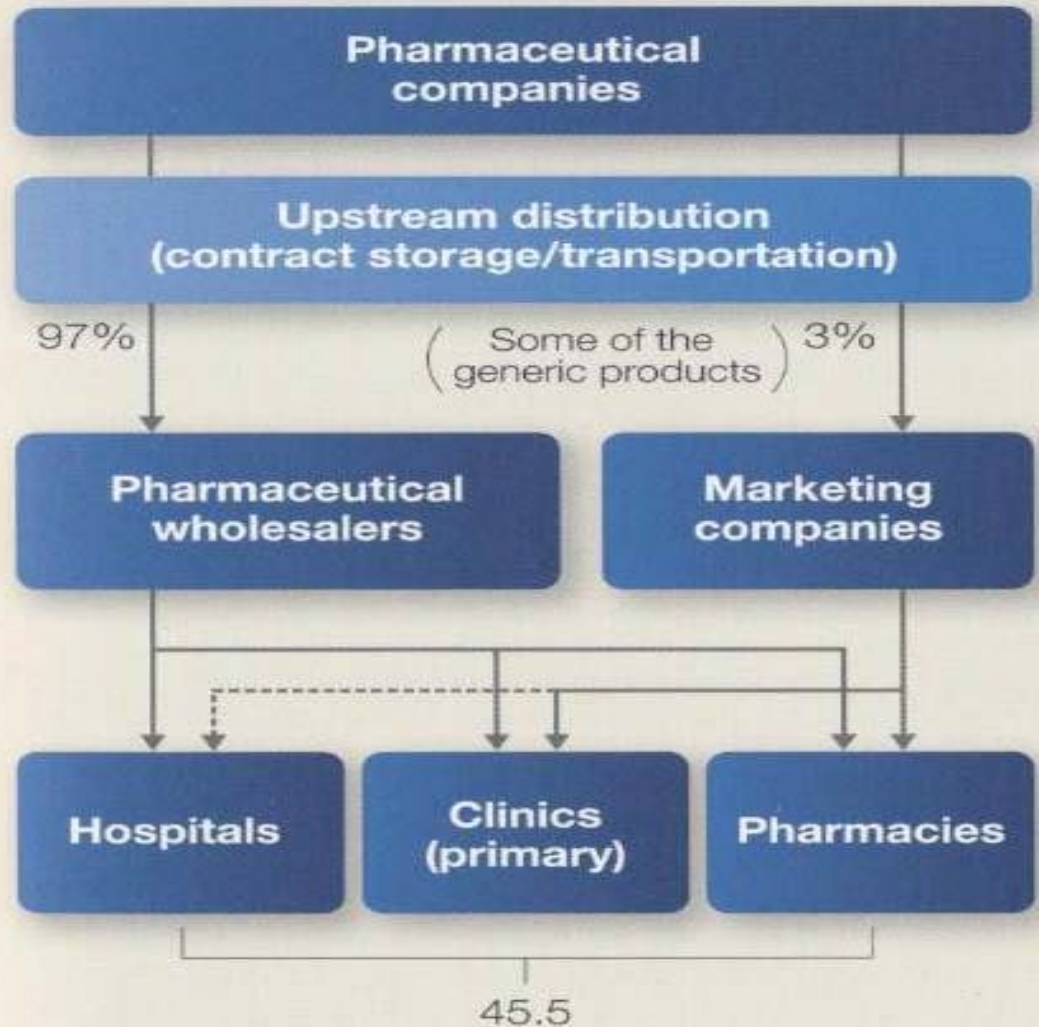


日本
市場規模*: 7.1兆円



配送回数/軒/月

Japan
Market size*: JPY7.1 trillion



Number of deliveries/site/month

Five functions of pharmaceutical wholesalers

	Function	Japan	US	Europe
Distribution function	Order processing and handling	✓	✓	✓
	Procurement	✓	✓	✓
	Packing and shipping	✓	✓	✓
	Delivery	✓	✓	✓
Financial function (account management)	Price negotiations	✓	✓	✓
	Credit management/ debt collection	✓	✓	✓
Promotion function	Promotion to pharmacies	✓		
	Promotion to prescribers	✓		
Information function	Collection/ provision of safety information	✓	✓	✓
	Provision of regional prescribing/ stock information	✓	✓	✓
	Operation of order/ inventory management system	✓	✓	✓

* Crisis management function was added as the 5th function to respond to disasters, pandemics, and terrorism

Pharmaceutical products wholesale association 1894~



大阪製薬同業組合 1902年設立
Osaka Pharmaceutical Trade
Association founded in 1902



大阪薬種卸商組合1894年設立
Osaka Pharmaceutical
Wholesalers Association
founded in 1894

日本の医薬品流通の特徴

The feature of Japanese drug distribution

① 毛細血管型供給体制 distribution system like capillaries

供給拠点の多さ many distribution centers.

医療機関・・・23万か所

the number of medical institutions is 230,000

取扱アイテムの多さ variety of items.

薬価銘柄別収載品目・・・15000品目

Rx drugs・・・15,000 items

アイテム数・・・45000数

the numbers of items include medical supplies etc・・・45000items

② MS (MARKETING SPECIALIST) の存在・・・20000人体制

Existence of MARKETING SPECIALIST→20000

経済合理性の追求・・・少量多頻度配送の実態

Pursuit of the economic rationality

・・・ frequent delivery with small quantity

③ JGSPに基く管理 薬剤師関与の供給管理・・・2000人体制

Wholesalers employ 2,000 Pharmacists who are
in charge of the drug distribution

JGSP : Japanese Good Supplying Practice :
Industry norms and voluntary standards

医療用医薬品の供給と品質管理に関するガイドラインで薬事関連法規をもとに
日本医薬品卸業連合会が策定した自主管理規範

MSとその機能 The function of MS

- * マーケティング・スペシャリスト(・・・20000人)

20000 MARKETING SPECIALIST

- * 医薬品卸売業の営業担当で医療機関や薬局を訪問し医薬品の販売活動に従事

MS who sells Rx drugs to hospital, clinic, and pharmacy.

- * 販売活動を円滑にするため、担当している医療機関や薬局が、必要としているものは何かを素早く把握し、ニーズに合ったものを確実に提案・提供していく仕事

The role of MS;

- to know what the customer want quickly
- to deriver and sell

医薬品卸企業の薬剤師が果たすべき役割

Pharmacists' roles in pharmaceutical wholesalers

Wholesalers employ 2,000 Pharmacists

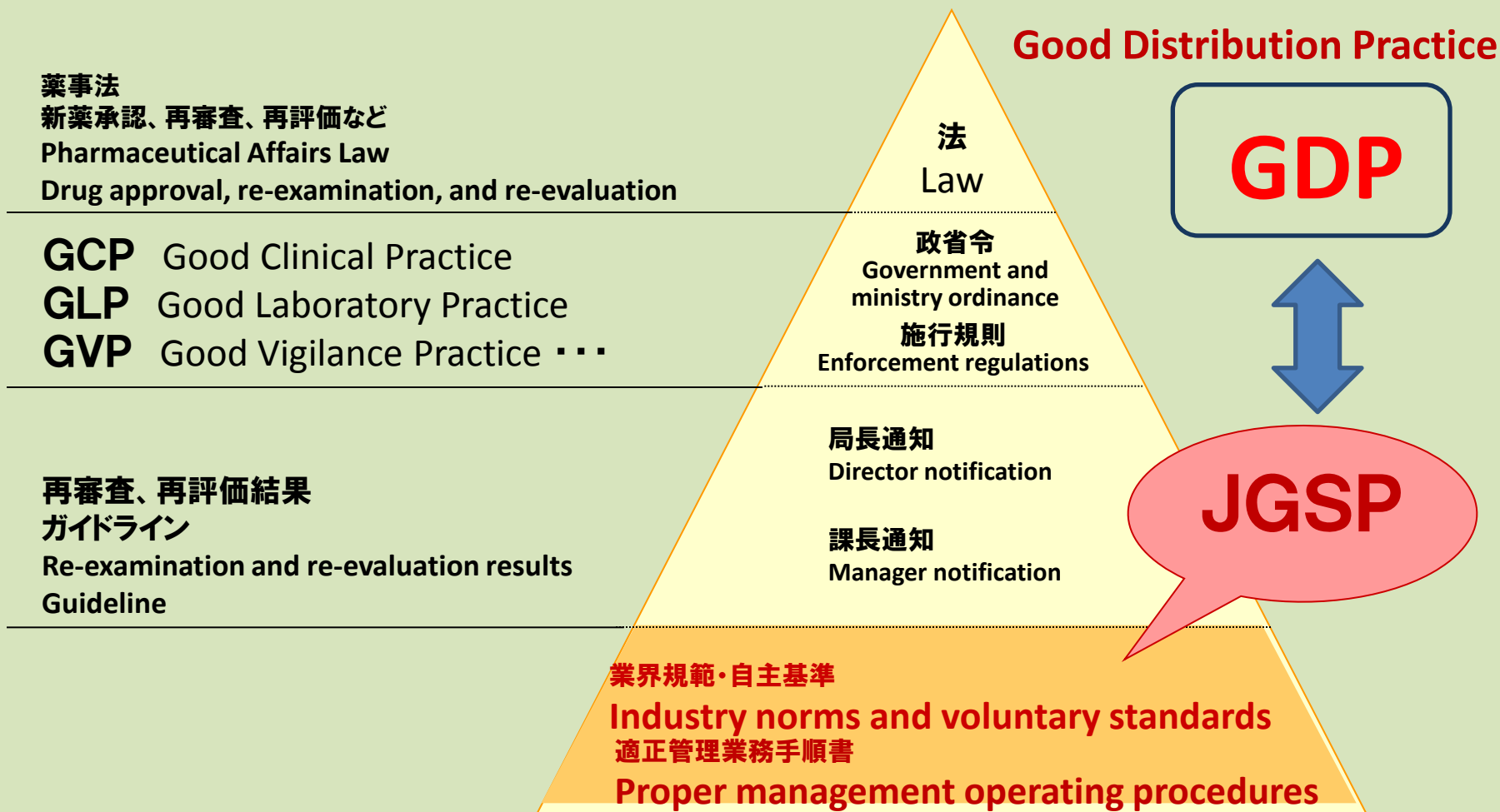
- 医薬品流通における安定供給と専門性の確保
- Ensuring stable supply and expertise in drug distribution
- 品質の確保と安全確保業務への対応
- Ensuring quality and security
- JGSPの取組み
- JGSP's activities



- 医薬品卸企業の薬剤師業務
- Pharmacists' activities in pharmaceutical wholesalers
多様化と高度化
Diversification and sophistication

JGSPの位置づけ

JGSP's positioning



GDP in Japan

Pharmaceutical Affairs Law
Law
(Obligations of wholesalers to comply with)
Paragraph 2 of Article 36



Regulations for Buildings and Facilities of Pharmacies, etc.
(Buildings and facilities of wholesalers' sales offices)
Article 3



Pharmaceutical Affairs Law
Enforcement Regulations
(Ensuring Proper Control of pharmaceuticals)
Article 155



the Pharmaceutical Regulation Committee the Federation of Japan Pharmaceutical Wholesalers Association



JGSP
Japanes Good Supplying Practice



pharmaceutical wholesalers

Requirements for drug distribution under the Pharmaceutical Affairs Law

Proper Control

1. Development of guidelines for the performance of the services,
2. Providing training programs for employees,
3. Establishment of a framework for accident report,
4. Preparation and application of Standard Operating Procedures, and,
5. Gathering information on Proper Control and response with improvement measures



What is JGSP?

JGSP is a non-legally binding code of management developed voluntarily by JPWA

JAPANESE GOOD SUPPLYING PRACTICE

“A practical standard for drug distribution and quality control”

- JGSP is established under the fundamental philosophy to put **quality maintenance in distribution** above commercialism, which pharmaceutical wholesalers easily autocratic
- JGSP is placed as a requirement that pharmaceutical wholesalers need to comply with in distribution and quality control

JGSP(JAPANESE GOOD SUPPLYING PRACTICE)

医薬品の供給における品質管理と安全管理に関する実践規範

第1章 JGSPの意義と役割

Chapter 1. Significance and role of JGSP

第2章 組織と任務

Chapter 2. Organization and mission

第3章 医薬品の供給と品質管理

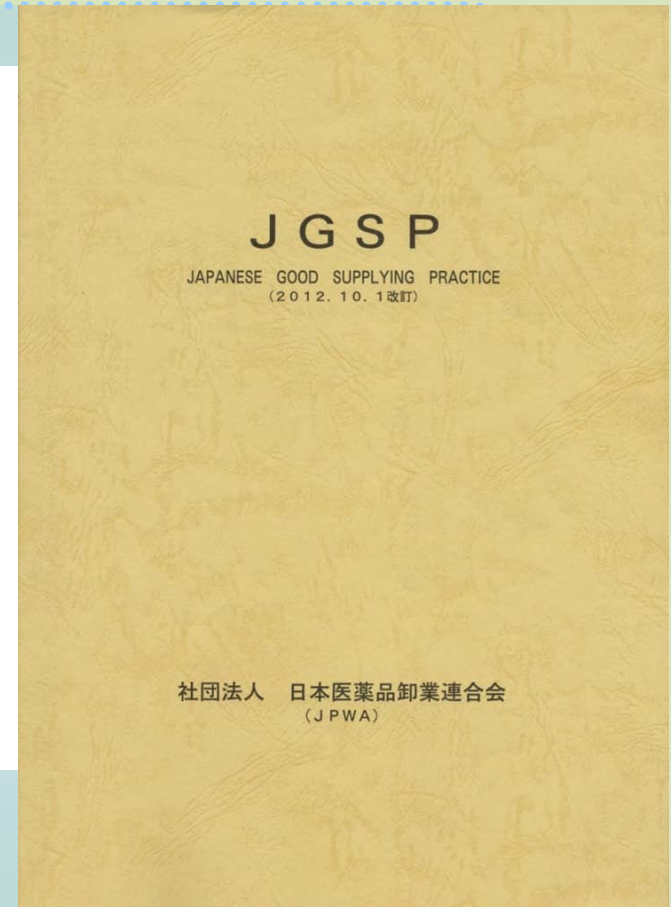
Chapter 3. Supply and quality control of
pharmaceuticals

第4章 安全確保業務

Chapter 4. **Safety assurance**

第5章 教育訓練

Chapter 5. Education and Training



Chapter 1 Significance and role of JGSP

■ Basic philosophy

Stable supply

安全な品質管理 Robust quality control

Ensuring compliance

Chapter 2 Organization and mission

*** Establish an organization that is appropriate to be in charge of accurate distribution service, proper quality control, and safety management in line with relevant laws and regulations, and assign personnel to carry out the missions thereof**

*** An organizational structure that equipped with check-and-balance system**

A function to supervise and prevent commercialism and efficiency

Chapter 3 Supply and quality control of pharmaceuticals

Section 1 Environment for drug distribution

* The Pharmaceutical Affairs Law sets forth the regulations for buildings and facilities

←JGSP provides specific requirements

The building and facilities of wholesalers must meet the requirements listed below, in order to ensure quality, efficacy and safety of pharmaceuticals and proper distribution thereof

1.Space

2.Ventilation

3.Separation from the living quarters

4.Lighting

5.Facilities for storing in a cooled condition

6.Storage facilities that can be locked with locks

Section 2 Distribution (service) and quality management

Pharmaceuticals should be supplied on a stable manner, placing top priority on quality control and safety assurance. Also, distribution and sales operations of pharmaceuticals should be conducted in an appropriate and fair manner in accordance with the relevant laws and regulations.

These are economic activities, but pharmaceuticals require special treatment.

*** To ensure safety, all operations involved in distribution must satisfy the conditions that ensure traceability of the products, i.e. what medicine were sold to which medical institution**

1. Shipping/ receiving of products
2. Delivery
3. Work involving the handling of raw materials used to make narcotics, psychotropic substances or stimulants
4. Controlled substances/voluntary controlled substances... Ritalin, thalidomide, etc.
5. Disposal of pharmaceuticals
6. Documenting business operation

Government Required "Statement of Delivery" ensures safety traceability and accountability

Customer address/
The name of customer/
Delivery course

Date of issue/Date of statement/
Method of statement/
Contact person/Slip number

Company name/
Address/
Phone number

Deal classification

D 部店コード E 取引区分
10 お買上

納品仕切書 専用先



株式会社バイタルネット

□□市□□町□□-□□-□□
△△△支店 電話 〇〇〇-〇〇〇-〇〇〇〇

得意先コード 123456
配送コース名一順 ○△コース 1便
〇〇県 □□市
△△町 ◇◇番▽▽号
◆◆◆医院

発行年月日 請求年月日 請求月限 分割担 当者伝 票番号
〇〇△△□□ 〇〇△△□□ 〇〇 〇〇 〇〇 120 02 07 120 123456

整理番号
120123456

商品コード	メーカー名	品名	容量	数量	単価	金額	税額	管理区分	製造番号
076-3044	武田薬品	プロプレス錠4	PTP 500T	3	44,095	132,285	6,614	処	

Merchandise number/
Pharmaceutical company name

Trade name/Content

Quantity

Unit price

TAX

Number of order

Amount

Regulative classification

- Poisonous substance
- Deleterious substance
- Regulated medical equipment
- Prescription drugs
- Refrigerated goods etc

Lot number/
Expiration date

Note /Remarks

合計税額計 総計

23-1101 A46001 00016 393,445 19,672 413,117

管理区分 毒=毒物 劇=劇物 指=指定医薬品 処=処方せん医薬品 #=記帳義務品 冷=保冷品 T=特定保守管理医療機器 Ⅳ・Ⅲ・Ⅱ・Ⅰ=医療機器クラス分類

The total amount of slip 19

Chapter 4 Safety Assurance

Section 1 Collection and provision of safety information

*** Roles of wholesalers in safety assurance**

Wholesalers are responsible for implementing necessary measures based on safety information collected as well as examination results to make contributions in developing partnership between manufacturers and medical institutions. In parallel, wholesalers shall establish a system capable of accepting a contract work that relates to safety management.

*** Collecting safety information**

1) Quality information, 2) Efficacy information, and 3) Adverse event information

*** Provision/distribution of safety information**

- ▪ ▪ Wholesalers shall distribute a document regarding safety information to medical institutions under entrustment from manufacturers

*** Provision/placement of safety information**

- ▪ ▪ Wholesalers shall attach a document such as a revised package insert onto in-stock products

Chapter 4 Safety Assurance

Section 2 Recall

Recall

Upon the manufacturer's recall determination, wholesalers shall confirm the lot numbers of the product to be collected and collect all recalled products from medical institutions quickly without any fail. The collected products will then be sent to the manufacturer along with an written report in a designated form.

第4章 安全確保業務 第3節 トレーサビリティ Traceability

トレーサビリティの重要性は、
取り扱い医薬品を製造番号ごとに把握し
流通履歴を管理すること

The importance of traceability lies in
managing pharmaceuticals using serial
numbers and
maintaining distribution history.

☆生物由来製品については、どこの医療機関に どの製造番号の医薬品を
どのくらい販売したか製造メーカーに報告

☆ Regarding biological products sales, medical institutions, amounts,
and serial numbers should be reported to pharmaceutical company.

すべての医療用医薬品に識別・製造番号・有効期限をバーコードによる表示する検討が進められている！
Identification and serial numbers and expiration dates would be displayed
using bar codes for all ethical drugs!

医薬品の回収 Recall of drugs

2012年4月～3月 不具合による回収件数

Number of recalls due to defects between April 2012 and March 2013

87件／年

87 recalls/year

- 異物混入
- Contamination

- 品質不具合
- Quality defects

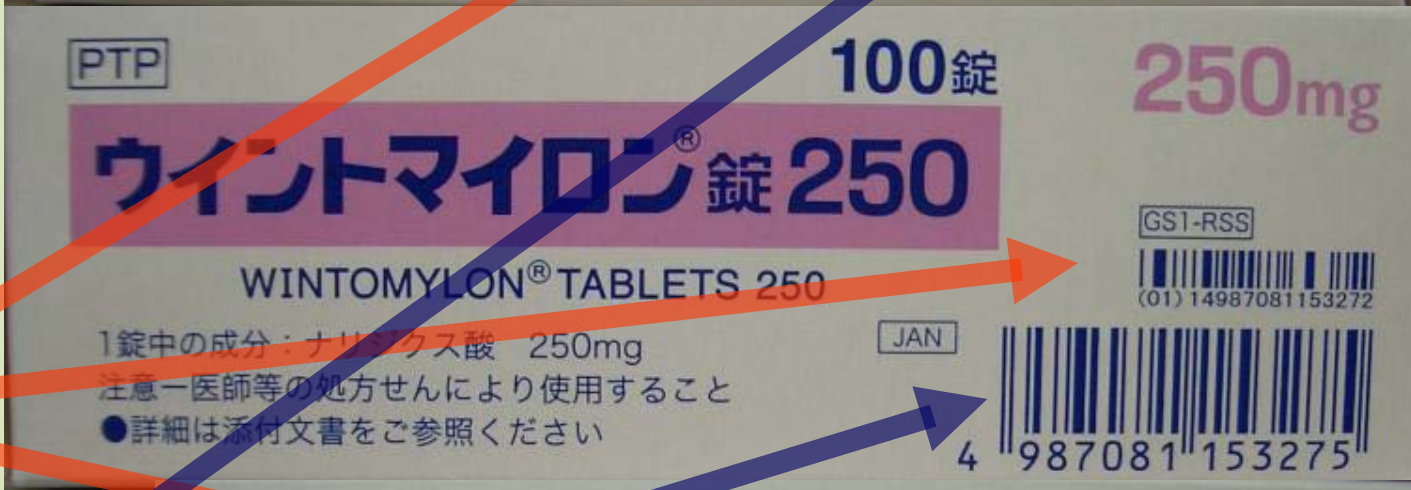
- 表示の誤り
- False indication

- 容器の不備
- Container defects

Levofloxacin, LVFX



Nalidixic acid



識別
製造番号
有効期限
ID

Serial number

Expiration date

RSS Code

JAN Code

識別
ID

Omeprazole



Ampicillin Sodium



調剤包装単位 Prescription unit

医療用医薬品の種類 Kind of the medicine	実施時期 Enforcement	商品コード Product cord	有効期限 Expiration date	製造番号 Serial number
特定生物由来製品 Product derived from blood	A	◎	◎	◎
生物由来製品 Product derived from a creature	A	◎	◎	◎
注射薬 Injection medicine	A	◎	◎	◎
内用薬 Oral medication	B	◎	△	△
外用薬 Medicine for external application	B	◎	△	△

◎ = 必須 Legal regulation

△ = 任意 Arbitrary notation

A = 2008年9月までに表示 2008. 9~ Displayed by September 2008

B = 交渉中 Negotiations

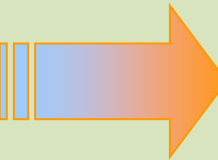
第5章教育訓練(薬剤師による教育訓練)

Education and training by pharmacists

教育訓練

Education and training

- 供給管理業務
Supply management
- 品質管理業務
Quality management
- 安全管理業務
Safety management



『継続研修』を展開
“Continued training”

教育訓練対象者

Staff members who receive education and training

- 営業所長
Directors of sales offices
- MS
MS
- 物流担当者
Persons in charge of distribution

実施計画の作成

Creation of implementation plan

実施時間 導入

Implementation time Introduction

60時間/年 継続:20時間/年

60 hours/year continued: 20 hours/year

研修記録の作成

Preparation of training records



Concerning inflow of counterfeit medicine into Japan

No room for counterfeit medicines to be brought into the official distribution channel managed by pharmaceutical wholesalers

Contributing factors

- * Official distribution channel, which is managed in line with the JGSP, is established as a robust foundation, and,**
- * Supply of pharmaceutical products exceeds demand under universal healthcare system**

Remaining issues

- * Inflow of counterfeit medicines is still possible via private import under the current condition where the Japanese Government permits private import of pharmaceuticals for personal use**

Countermeasures

In response to the online purchases of medicines encouraged by the spread of private import and advancements in globalization, it is necessary to further develop the relating regulations and to improve the environment to standardize identification code, etc. internationally for securing safety of such purchasing activities.

東日本大震災における
被災地での医薬品供給

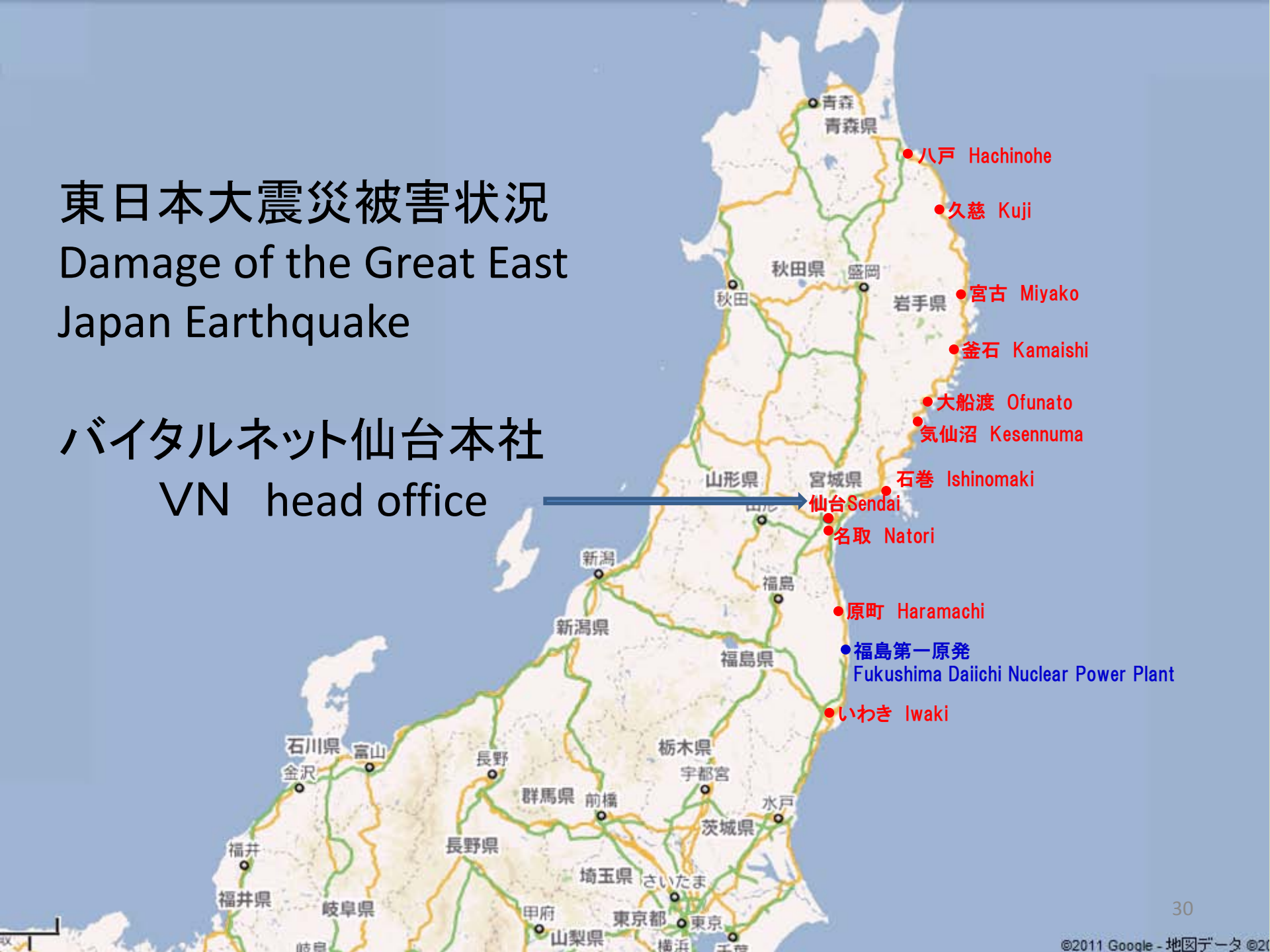
Drug distribution in the stricken area of the Great East Japan Earthquake

2011. 3. 11 東日本大震災発生

March 11,2011 the occurrence of the Great East Japan Earthquake

東日本大震災被害状況 Damage of the Great East Japan Earthquake

バイタルネット仙台本社
VN head office





宮城県名取市 Natori city, Miyagi prefecture

バイタルネット仙台本社5F

VN head office 5th floor



バイタルネット大船渡支店

Ofunato branch





Thanks for all your support of the
Great East Japan Earthquake from all
parts of the world, especially
Indonesian.

**ご清聴
ありがとうございました**

Thank you for your attention.