

Pharma Delegates 34th Healthcare Seminar
“Generics & Biosimilars: Trends & Strategies”

Off Patent Products Market Situation and Takeda-Teva in Japan

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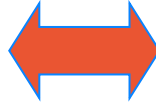


July 1, 2016

- 1. Role and Characteristics of Off Patent Products**
- 2. Expected transformation of the Gx market**
- 3. Takeda-Teva introduction**

Classification of Ethical Drugs

Stage to solidify evaluation
Remaining risks
High drug price for higher efficacy



Established evaluation
Abundant experiences to minimize risks
Low drug price

For Patients who need new treatment

Innovative drugs during patent term
(New drugs)

**Off patent drugs /
Established drugs**

Standard treatment drugs used for many years

Patent-expired innovative drugs
(LLPs) *

Generic drugs
(Gx)

Patent term

Launch

Patent Expiry

*Long listed products

Role and Characteristics of Long Listed Products and Generics

- **More affordable** compare to same class on-patent products
- High reliability based on longtime use (**brand image**)
- Role to maintain and update safety and efficacy data (**base product for generics**)
- Role to meet the additional customer needs (**new indication, new dosage and administration, etc)**

Long listed products (LLP)



Generics

- **More affordable** compare to LLP
- Have advantage to **improve original brand** (dosage form, packaging design etc.) due to follow-on product

- 2nd largest pharmaceutical market in the world
- Continued significant Gx penetration
- Strictly regulated market with strong incentive from government to reduce healthcare expenditures

Expected commercial changes

- **AG** sales become too large to ignore
- Move from **Branded Gx market** to **INN Gx market**
- **High volume Gx growth** is expected (~80% in 5Y) to meet the government penetration target
- Expected intensive price wars leading to relatively **low price environment**
- **Stable supply** is mandatory
- **Blurred lines** between traditional models (**Branded LLP and Gx**)
- **Reduced revenues and OPs** of all stakeholders

Expected structural changes

- New price regulation will re-shuffle the Gx market
- New business models
- Consolidation of industry stakeholders – Gx suppliers, distribution, retail channels
- Increased pharmacists role and importance vs. physicians

The most important KSF for Gx companies are stability of supply and quality

- Government penalizes Gx companies that have supply /quality issues
- “**Zero incidents**” performance is expected from Gx companies
 - stable supply officer to be nominated in companies, API supplier audit, second sourcing and quality improvement measures are mandatory
- We assume the government ultimate goal is to weed out small/medium companies that can't meet market required **quality** and **demand** to assure a reliable Gx industry

Gx Business Model is entering the final stage

- 2007

2007 - 2013

Stage 1

Stage 2

Era of dedicated
manufacturers

Gx of innovator
companies contributed to
high quality, stable supply
and better image.

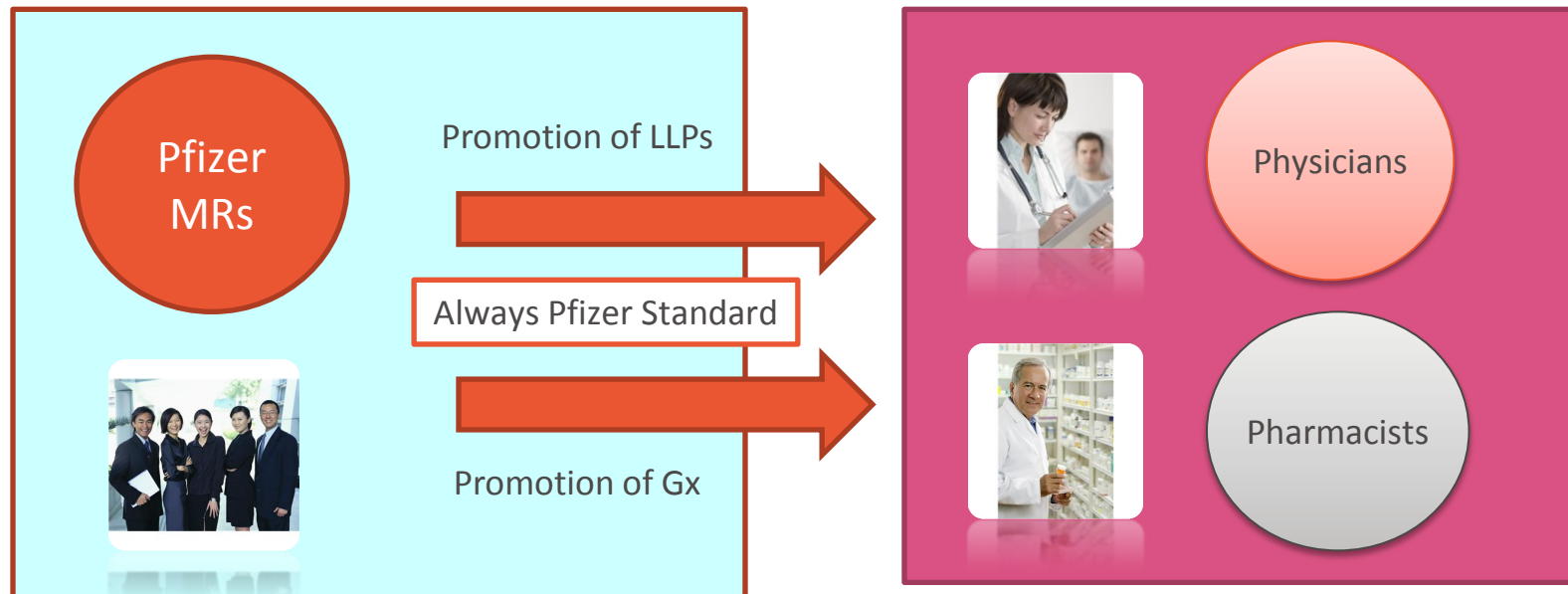
Initial Gx Promotion Program

Action Program

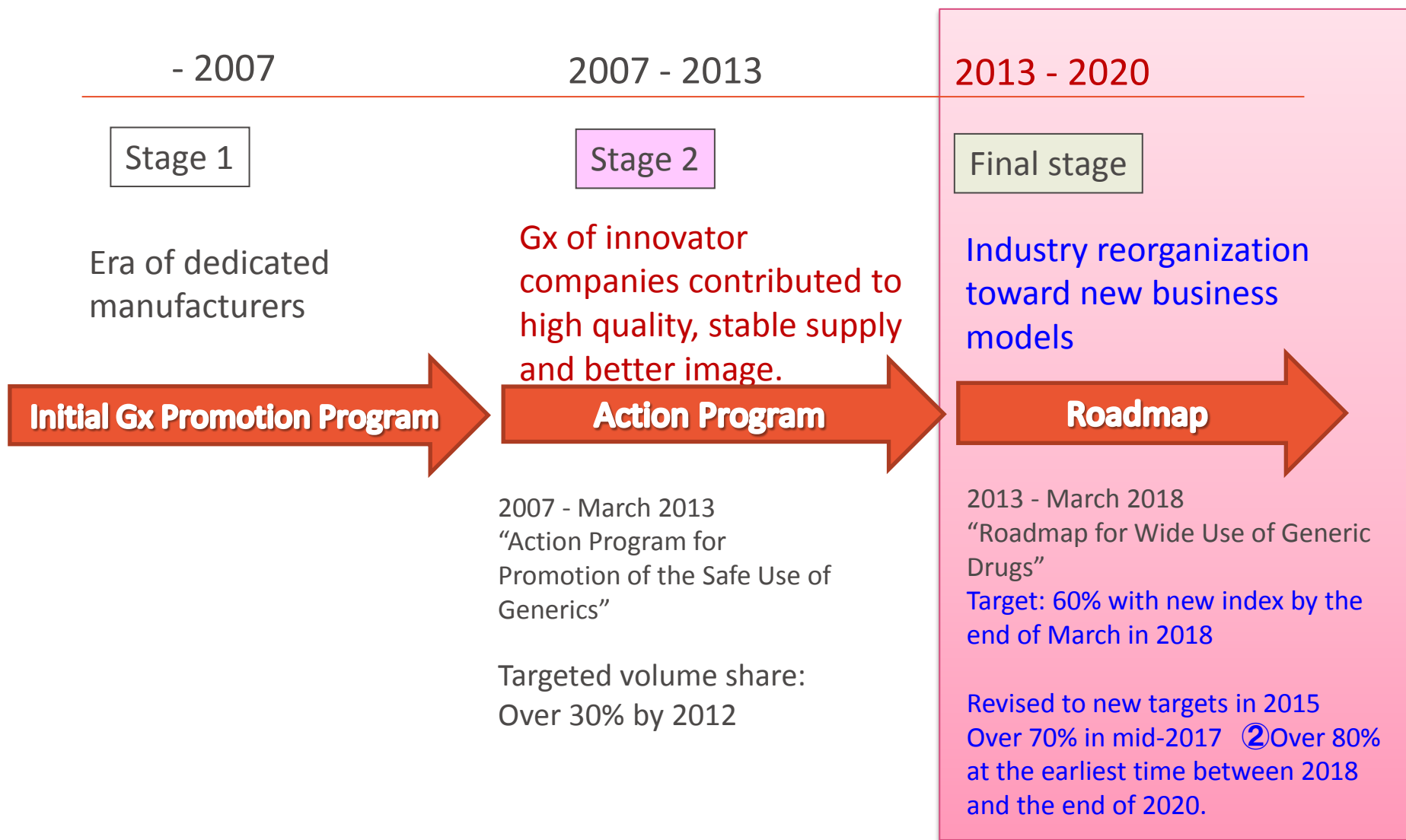
2007 - March 2013
“Action Program for
Promotion of the Safe Use of
Generics”

Targeted volume share:
Over 30% by 2012

- Each MR promotes both LLPs and Gx at the same time.
- Common quality standard across Pfizer as established drugs.
(It's Always Pfizer Standard)



Gx Business Model is entering the final stage



Teva
51% Owner

Takeda
49% Owner

**Takeda Teva Pharma
Board of Directors**

Takeda-Teva Pharma (TTP)
As of October 1st
(Currently Teva Seiyaku)

subsidiary

Takeda-Teva Yakuhin (TTY)
As of April 1st
(used be TYK)

- The highest decision-making body of TT group

- MA holder of **Gx, AG**
- 100% stockholder of TTY

- MA holder of **LLP, (Gx)**

Takeda and Teva Joined Forces

- Largest pharma company in Japan
- Strong brand and reputation with 235 years history
- Outstanding distribution capabilities and relationship with WS



- Largest Gx company in the world with strong API sourcing capability
- State of the art manufacturing and R&D capabilities
- largest foreign Gx company with broad portfolio in Japan

Brand:

Empowered by joining forces with Takeda's strong well established brand and reputation in Japan

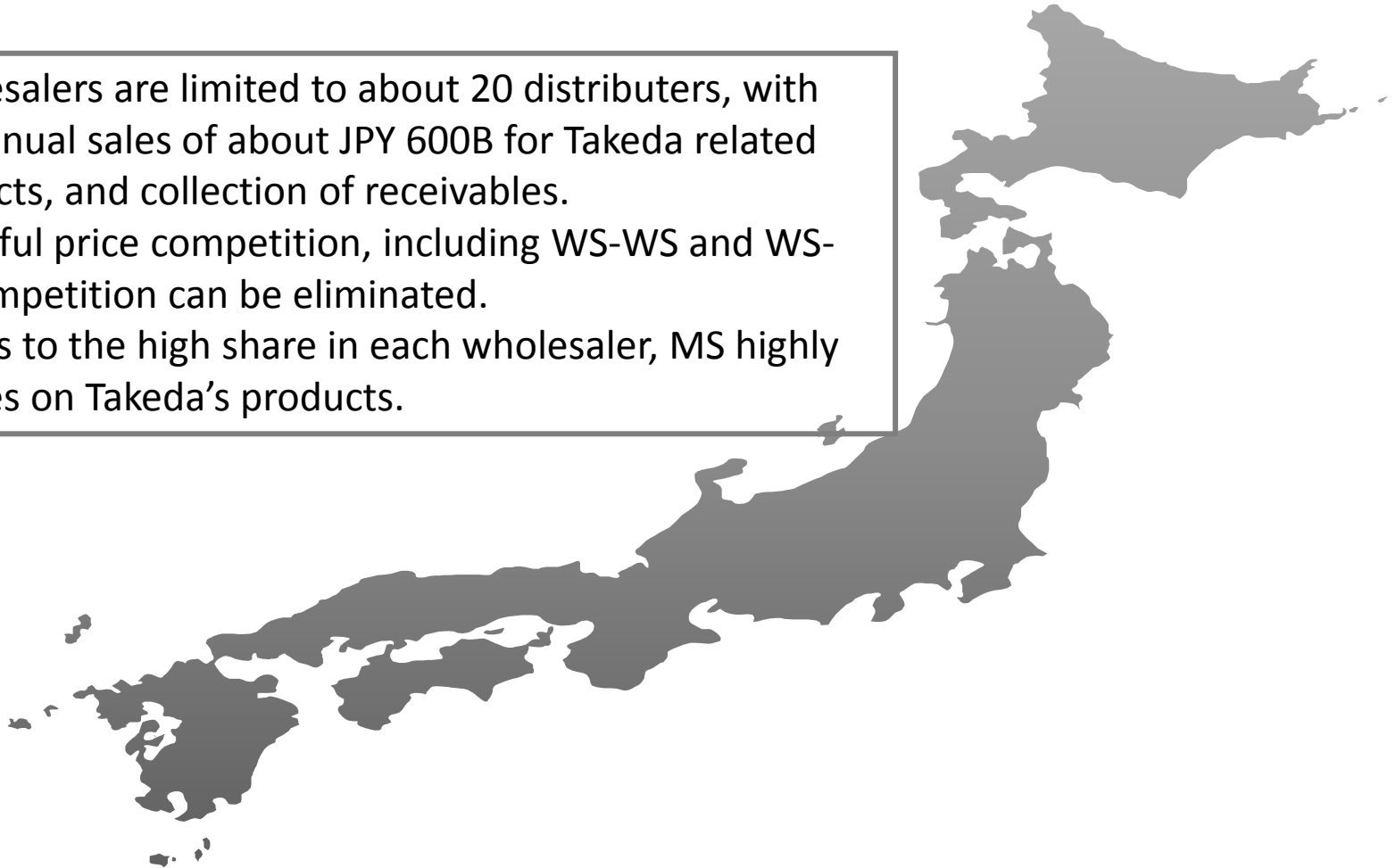
Commercial:

Joint sales force, consists of around 300 MRs, located in 6 Branches (26 district sales offices) across Japan

Unique Distribution Network:

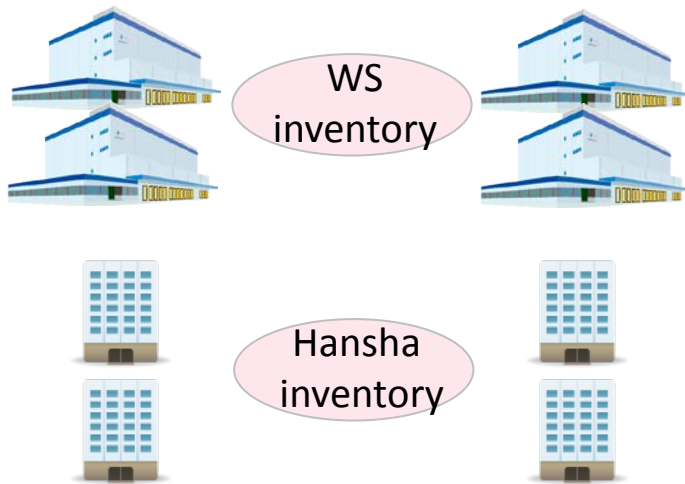
Advanced distribution platform based on Takeda's channels for LLP, Gx & AG Products, outstanding distribution capabilities, relationship with national WS (Alfresa & Medipal) and access to all customer types

- ◆ Wholesalers are limited to about 20 distributors, with the annual sales of about JPY 600B for Takeda related products, and collection of receivables.
- ◆ Wasteful price competition, including WS-WS and WS-HS competition can be eliminated.
- ◆ Thanks to the high share in each wholesaler, MS highly focuses on Takeda's products.



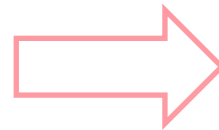
Proper Inventory and Stable Supply System with Integrated Distribution through Takeda's Network

<Current Teva Seiyaku's distribution>

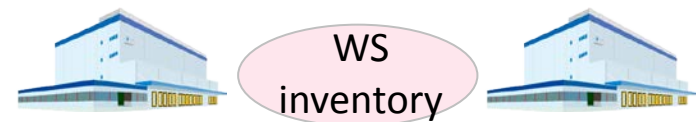


WS(Full line) + over 100 Hansha inventory
Large burden of inventory management
by Teva

**Stable supply
system
construction**



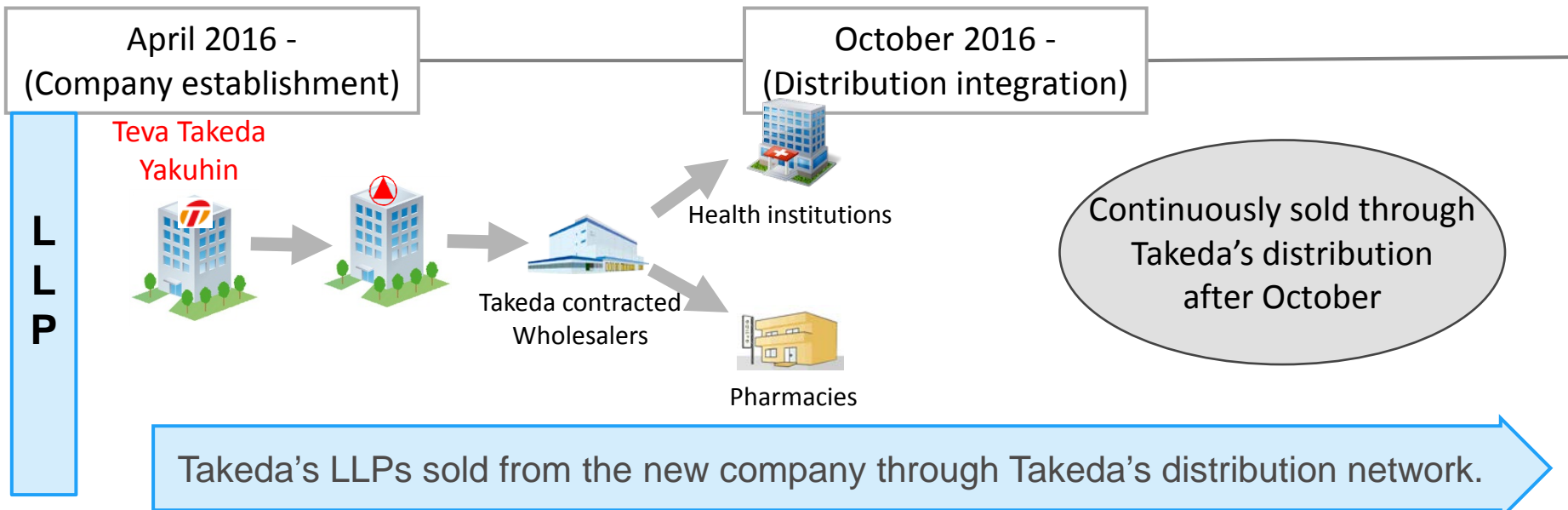
<Takeda's distribution>



Inventory at only about 20 distributors
Less inventory burden for Teva-Takeda

Improved wholesalers' awareness with
inventory management by Takeda

Sales schedule with Takeda's distribution



Portfolio:

- More than 840 different products
- Main TAs: CVS, Oncology, CNS, Alimentary tract, Contrast Media, Anti Inflammatory, Antibiotics
- G-CSF (bio- similar)
- Robust pipeline consists of the major future off patent products in selected TAs



Takayama (in Gifu prefecture)

- **Focus:** Takeda-Teva + CMO
- **Tech.:** OSD, INJ., niche (topical, oral liquid)



Koka (in Shiga prefecture)

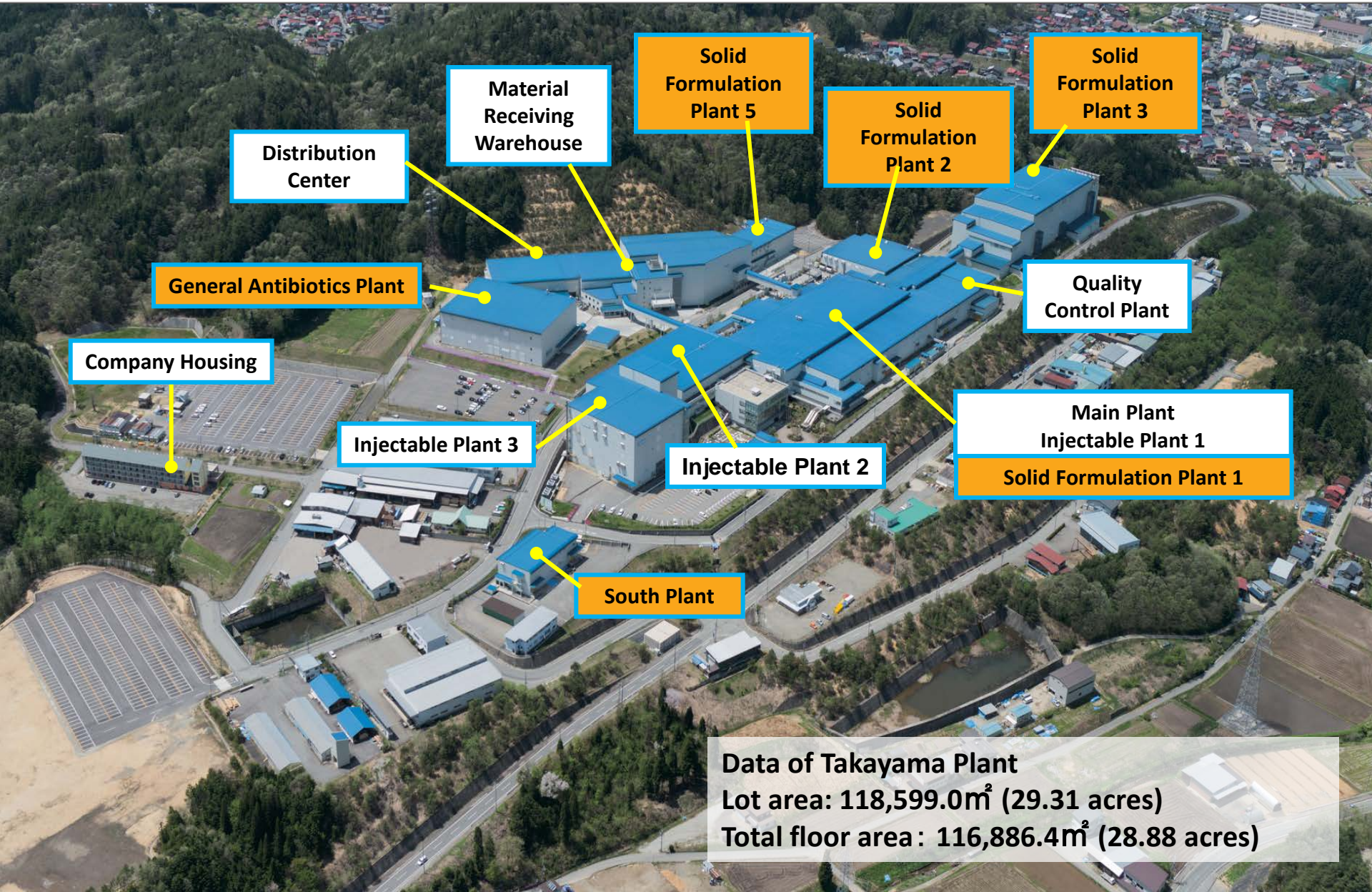
- **Focus:** Takeda-Teva + CMO
- **Tech.:** OSD



Minakuchi (in Shiga prefecture)

- **Focus:** Packaging site

Takayama Manufacturing Site



Data of Takayama Plant
Lot area: 118,599.0m² (29.31 acres)
Total floor area: 116,886.4m² (28.88 acres)

Global Teva have been making every effort to improve stable supply and quality since Taiyo merger



- ✓ Introduced global Teva SOP in operation functions
- ✓ Actively hired capable specialists mainly from innovative pharma to reinforce our organizations
- ✓ Established global standard quality management system (QMS)
- ✓ Introduced global standard Sales & Operations Planning (S&OP) process
- ✓ Started long term stability test under ICH conditions for all products in 2014
- ✓ Started to set release test criteria to all products
- ✓ Proactively discontinued total 179 products based on quality risk assessment

- ✓ Newly launched “Quality and Stable Supply Initiative” as the key pillar of our company-wide “Build Foundation Project”
 - Review all products again form new Takeda-Teva point of view
 - Conduct quality risk assessment for all product
 - Identify the products which needs further improvement to avoid the probable lot rejection
 - Make road map to take necessary actions such as additional discontinuations, quality attributes improvement and manufacturing transfer to other CMO

- Off patent/Established drugs have important role for the next era of super aging
- Gx Business Model is entering the final stage that is industry reorganization stage toward new business models
- Takeda-Teva is the first- mover as new business model with enough capabilities to lead off patent drug market
- Takada-Teva will start full-scale business operation in October after 6 months integration period



Thank you

Always value good drugs used for many years