

April 7, 2017

6th Medium-term Management Policy for FY2017-2021

Kazuhide Nakatomi,
President & COO

Hisamitsu Pharmaceutical's Philosophy and Mission

Management Philosophy :

Improving Quality of Life Around the World



Corporate Mission :

Bringing Patch Culture to the World

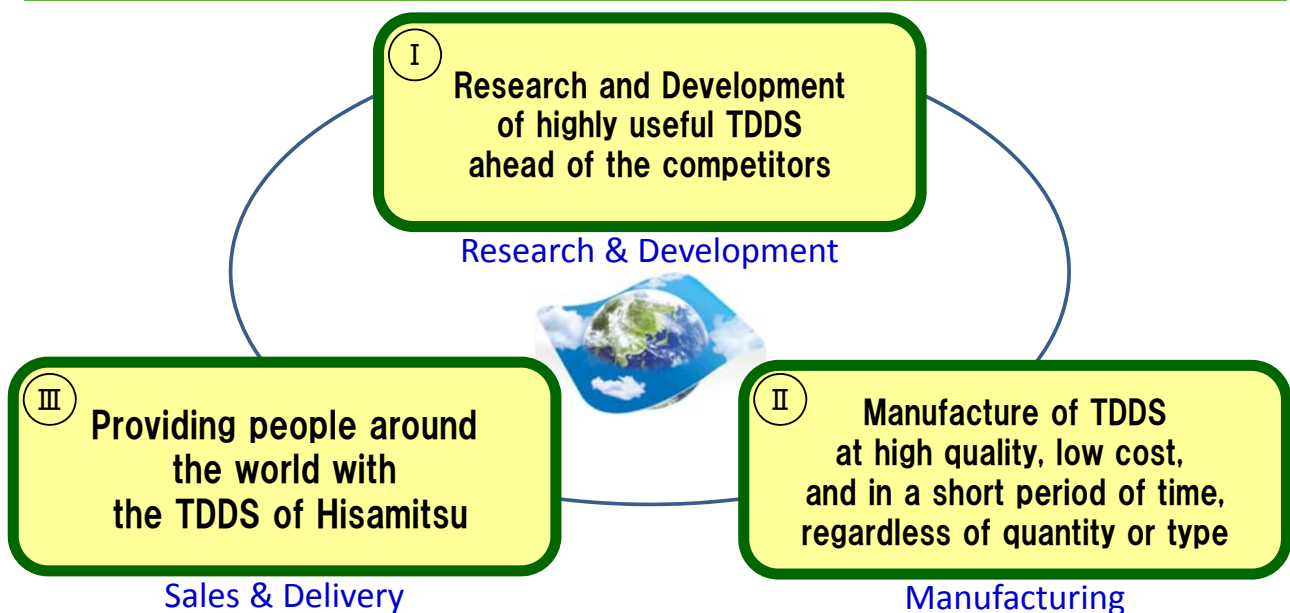


Hisamitsu Pharmaceutical contributes to the health of people around the world through "Research & Development", "Manufacturing", and "Sales & Delivery" of patch treatments that are effective, safe and comfortable



*TDDS: Transdermal Drug Delivery System

- Capturing a 1% share of the global market of "Pharmaceuticals"
- Capturing a 50% share of the global market of "TDDS"



Using "TDDS" as the standard to reinforce individual functions, as well as achieving fast turnover of a series of cycles as a global function to establish competitive superiority

Environmental changes in domestic business and their impact

1. Reinforcement of measures to suppress medical expenditure in Japan and promotion of proper use

- Reinforcement of measures to suppress medical expenditure
 - Permeation and expansion of generic pharmaceuticals
 - Reduction of drug price by continued implementation of reduction in special exemption for long-term listed pharmaceuticals (Z2)
 - Impact of radical reform on drug price system
- Implementation of appropriate provision of compress
 - Limit of 70 sheets per prescription
 - Recording the daily dose and number of days equivalent in medical prescription and medical fee bill

- ◆ Difficulty in maintaining sales for the existing external anti-inflammatory and analgesic TDDS, such as Mohrus[®] Tape

2. Slow growth in Rx new products

- Struggle to differentiate Norspan[®] Tape and Neoxy[®] Tape from competitor products

- ◆ Difficult to make a significant expansion in sales for Rx new products in the future

Environmental changes in overseas business and their impact

3. Change in business strategy of Noven (US subsidiary)

- Slump in sale promotion measures of Brisdelle[®], which was considered to be a driver of growth in the 5th mid-term management policy
 - Closure of sales department (May 2016)
 - Transfer of the right for marketing authorization of Brisdelle[®] and Pexeva[®] (July 2016)
 - Integration of primary functions for production and R&D, and commence establishment of a system for concentrating management resources to TDDS

- ◆ Deterioration of mid-term profit forecast for Noven

**Need arose for modification of sales forecast
in domestic and overseas (US) Rx business**

Progressing aging tendencies in Japan and overseas

- Increased opportunities for use of pharmaceuticals as a result of an increase in disorders and symptoms
- Increase in polypharmacy
- Decrease in treatment compliance
- Promoting a regional comprehensive care system in Japan with the aim of collaboration between medical and welfare care functions
- Increased interest in QOL with economic expansion in various countries, etc.



It is essential to capture "needs for TDDS" with social changes as the background, and act in an accurate and swift manner

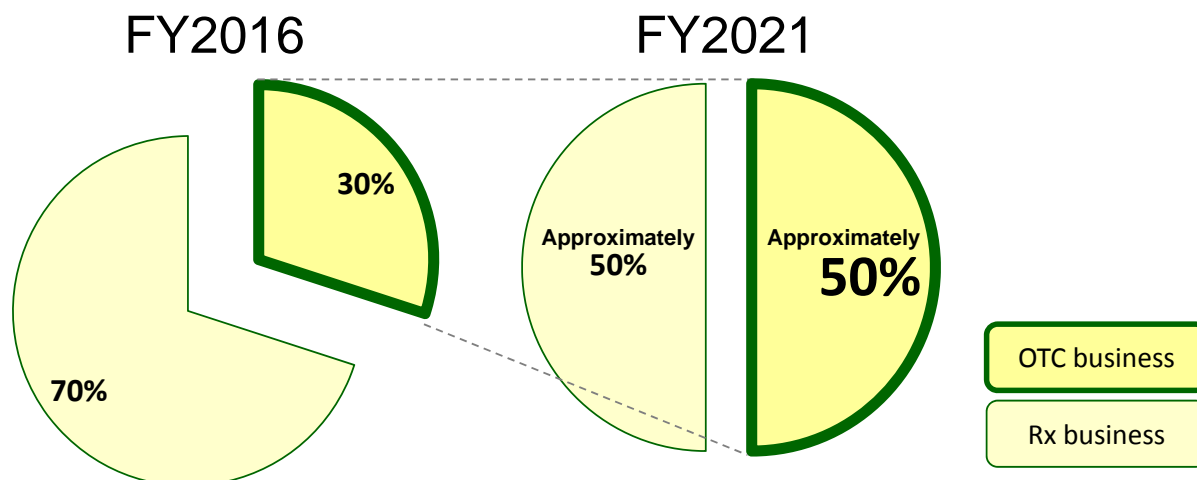
Action Plan for the 6th Mid-Term Management Policy

<p style="text-align: center;">[Sales Activities] (I)</p> <p>Domestic OTC business</p> <ul style="list-style-type: none"> ✓ Creation of values in new and existing areas <p>Domestic Rx business</p> <ul style="list-style-type: none"> ✓ Optimization of business and subsequent expansion <p>Overseas OTC business</p> <ul style="list-style-type: none"> ✓ Concentration of management resource to countries with a base and surrounding countries <p>Overseas Rx business</p> <ul style="list-style-type: none"> ✓ Active advancement into Asian countries and optimization of Noven 	<p style="text-align: center;">[Research and Development Activities] (II)</p> <ul style="list-style-type: none"> ✓ Research and development of TDDS with a clear distinction from existing and competitor products ✓ Promoting the unification of development theme across the Hisamitsu Group ✓ Development of new foundation technology
<p style="text-align: center;">[Production Activities] (III)</p> <ul style="list-style-type: none"> ✓ Pursuing a high-efficiency production system ✓ To improve manufacturing quality and production technology ✓ Expansion of capacity at production bases overseas 	<p style="text-align: center;">[Other Activities] (IV)</p> <ul style="list-style-type: none"> ✓ Increasing operation efficiency ✓ Reinforcement of human resource development ✓ Promotion of ESG in Hisamitsu Group

Implementing action and establishment of a system with the aim of creating corporate values

Sales Activities

Changes in sales composition in domestic and overseas pharmaceutical business

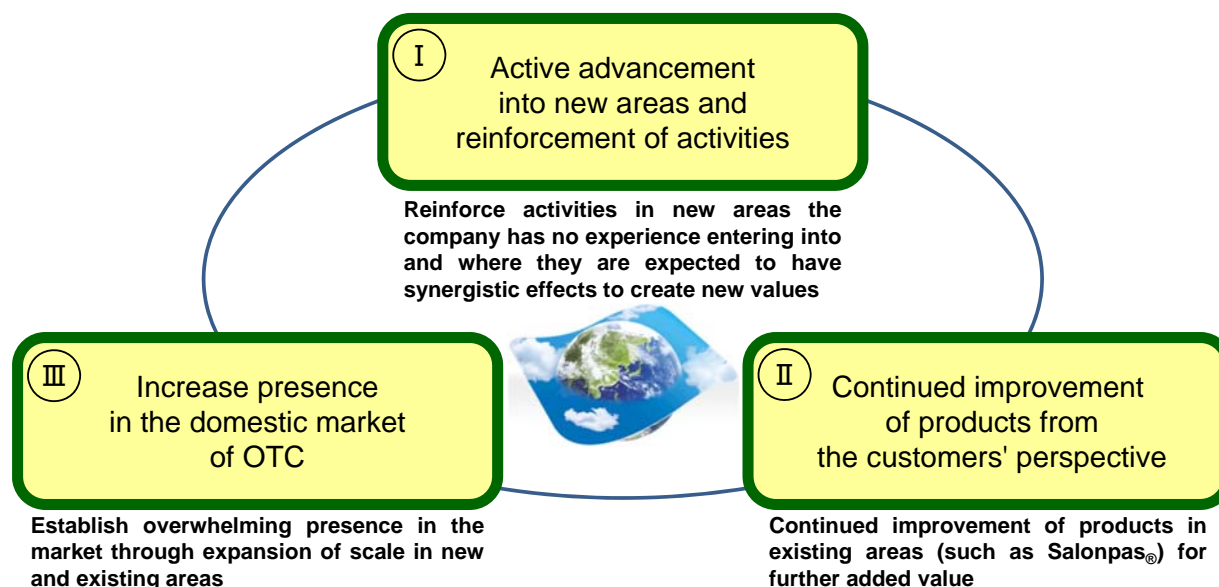


Further focus on activities for OTC business with the aim of stabilizing the profit standard (especially the high sales standard)

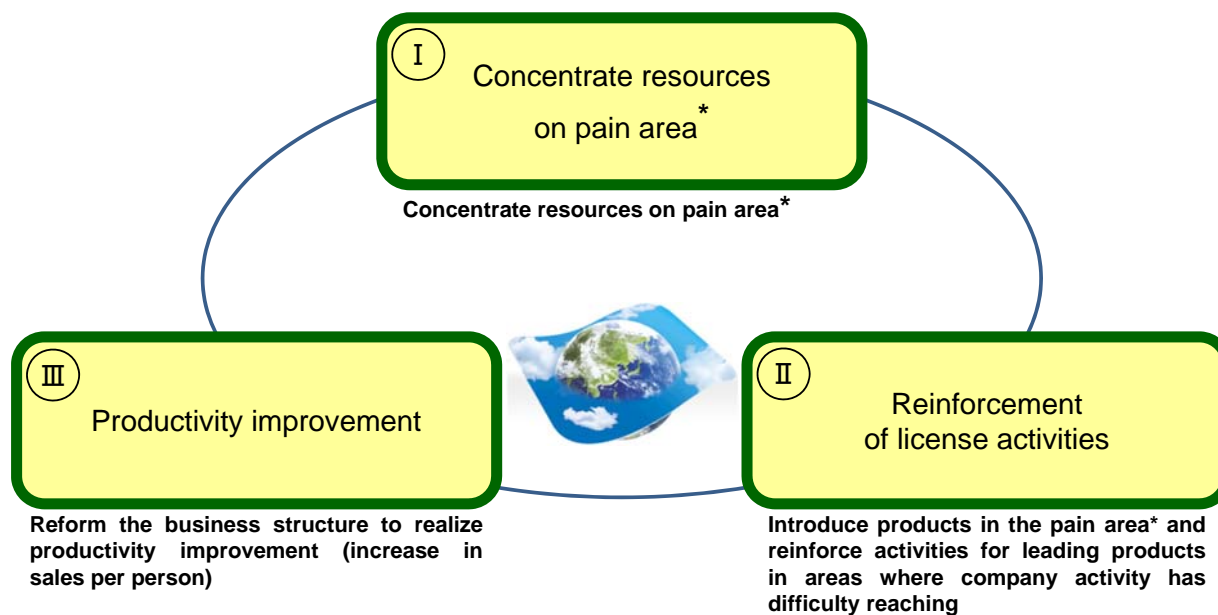
Also, realize increased operation efficacy to prevent profit rate from decreasing

Sales Activities

1. Domestic OTC business

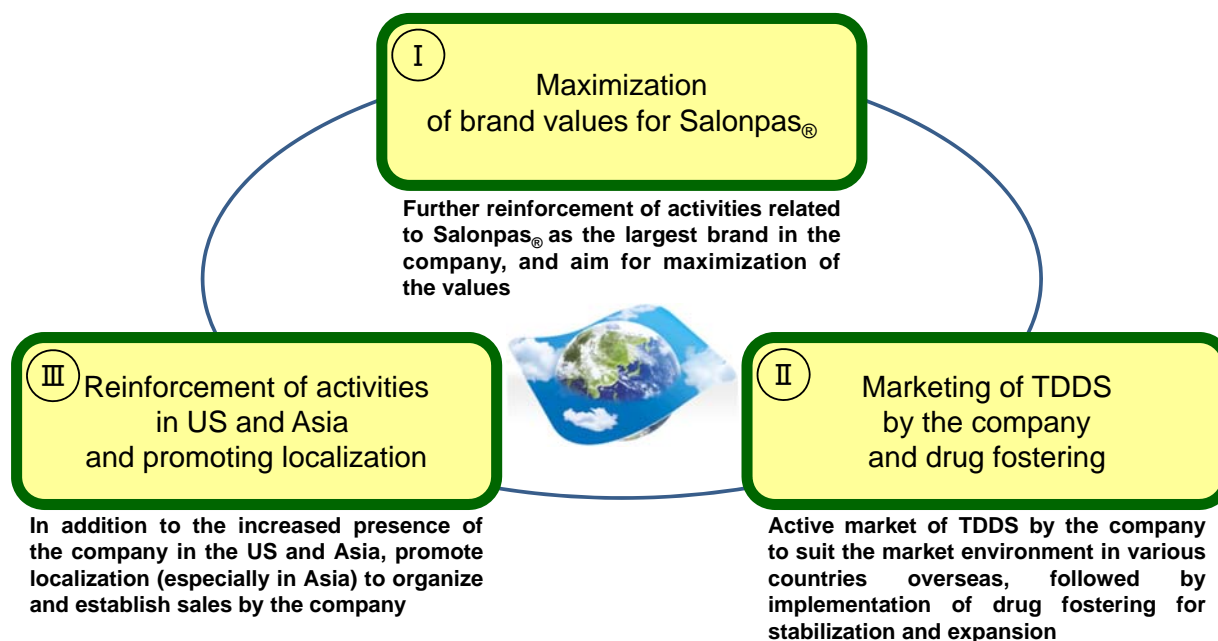


2. Domestic Rx business



^{*}Pain area: Orthopedic surgery, pain clinic, etc.

3. Overseas OTC business



Sales target of Salonpas® (global)

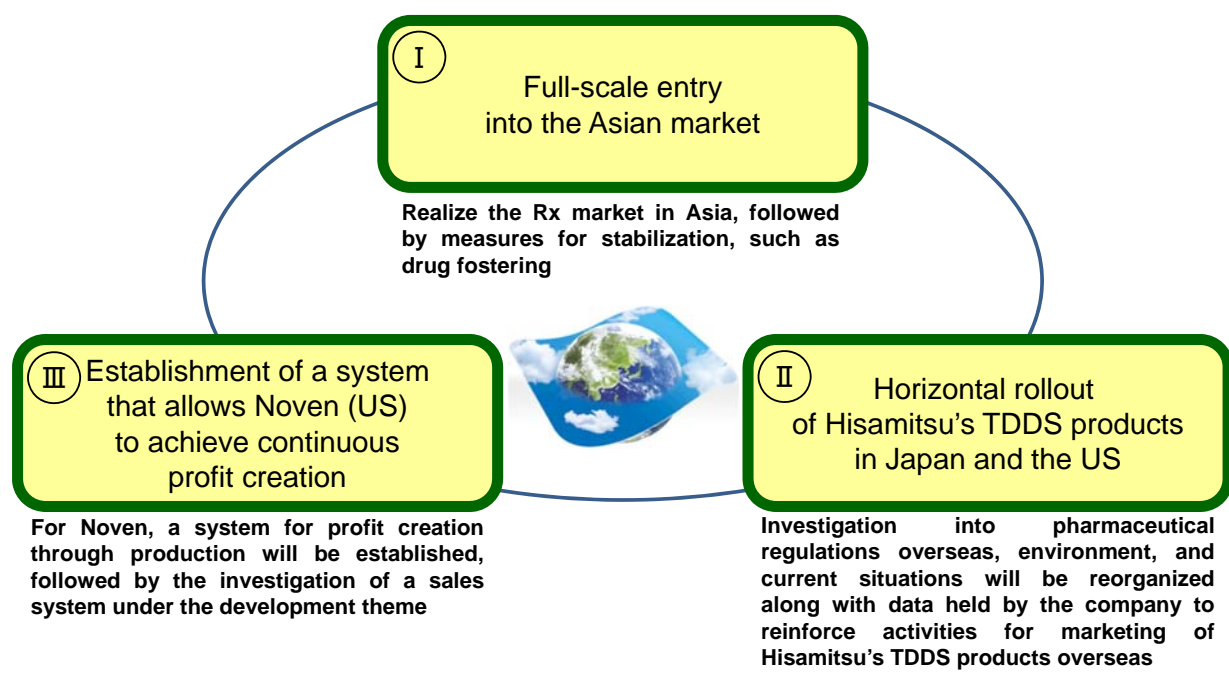
Concentration of resources to countries with bases and surrounding countries



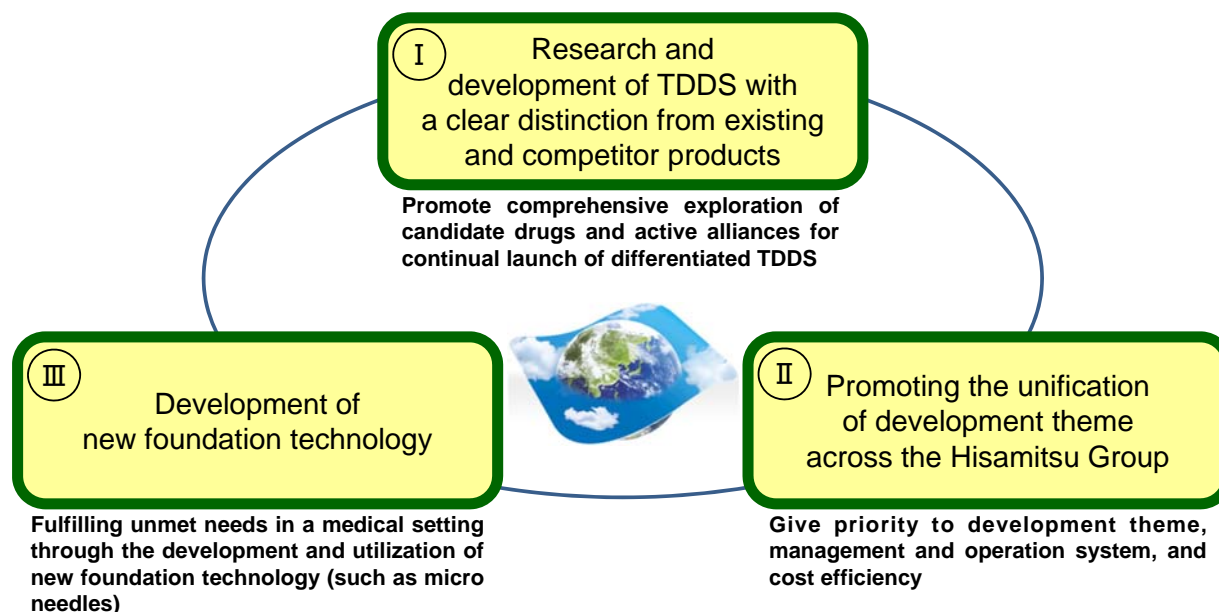
Sales target of Salonpas® (FY2021): 45 billion yen

Sales Activities

4. Overseas Rx business



Research and Development Activities



Research and Development Activities

Forecast for the timing of application for the R&D theme (Rx)

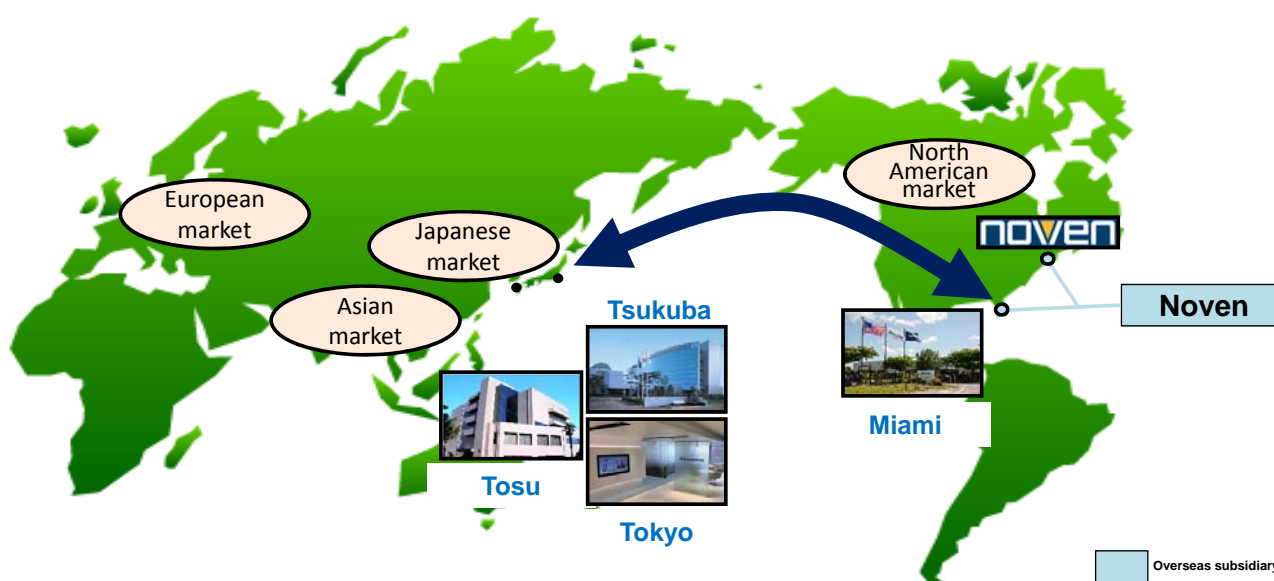
	FY2017	FY2018	FY2019	FY2020	FY2021
Japan	New drug	HP-3000 Ropinirole hydrochloride Parkinson's disease		HP-3150 (non-steroidal) Cancer pain	HP-3150 (non-steroidal) Lower back pain
		Existing drug	Drug fostering Theme 1	Drug fostering Theme 2	Drug fostering Theme 3
US	New drug		HP-3070 Asenapine maleate Schizophrenia	ATS Amphetamine Attention Deficit Hyperactive Disorder (ADHD)	

Continued marketing of differentiated TDDS

Example of differentiated TDDS

HP-3000

- Active ingredient: Ropinirole hydrochloride
- Indication: Parkinson's disease
- Stage: Phase III in progress
- Aim of the development
 - Significant reduction in skin irritation
 - Can be administered to patients with difficulty swallowing

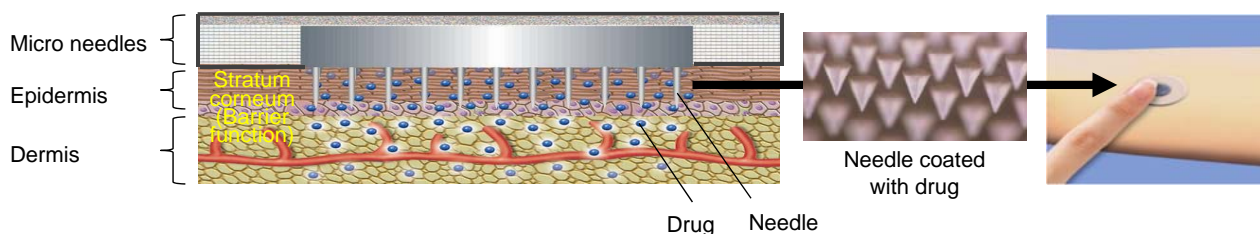


**Unify the development theme across the Hisamitsu Group
and aim for early rollout in Rx markets**

Research and Development Activities

Micro needles

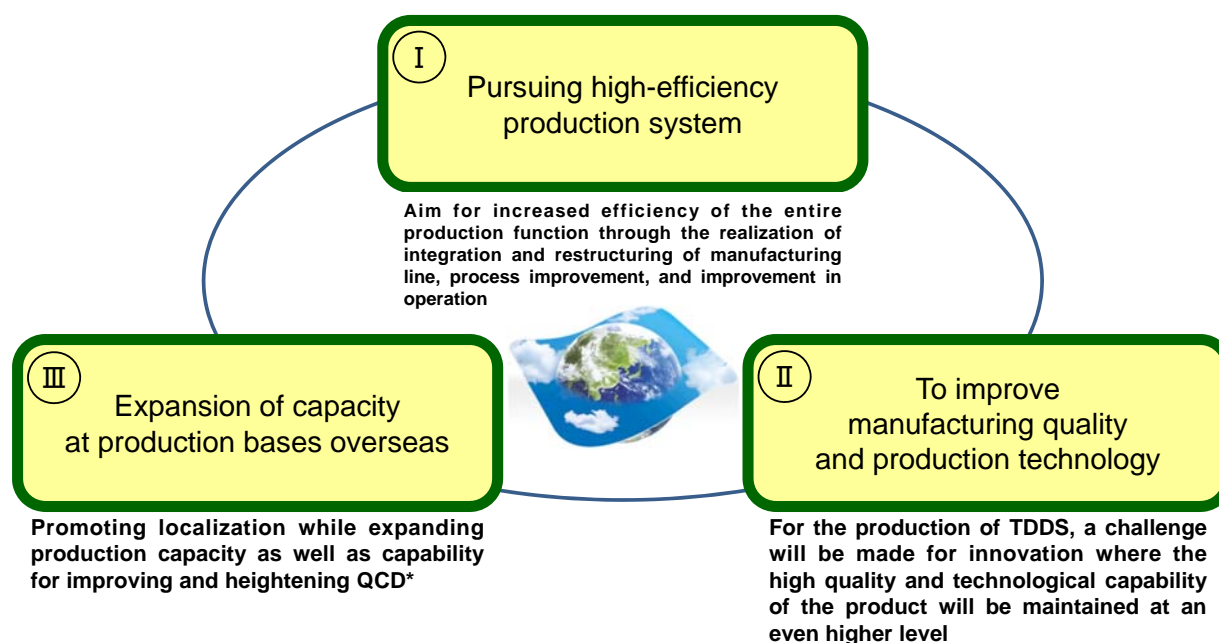
- Under development using multiple drugs including vaccines (some have reached the clinical phase)
- Investigation in progress for the manufacturing method for mass production



- Currently developing micro needles that have a new mechanism with a different drug absorption profile from previous micro needles

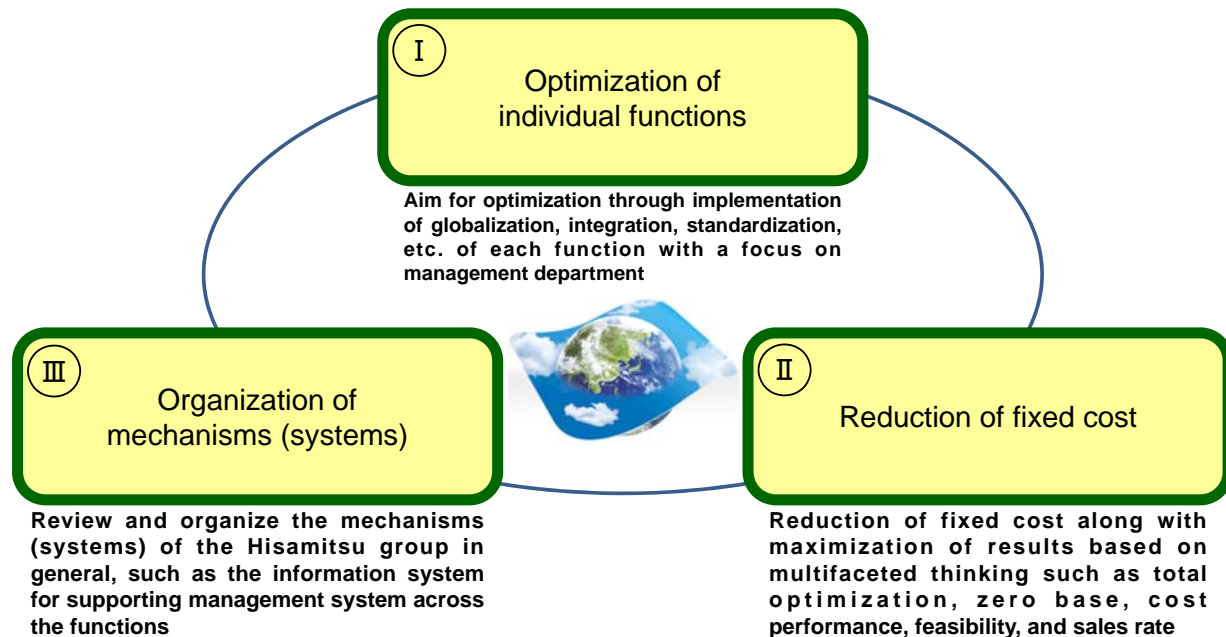
Use of various new foundation technologies to accelerate development, with the aim of commercialization

Production Activities

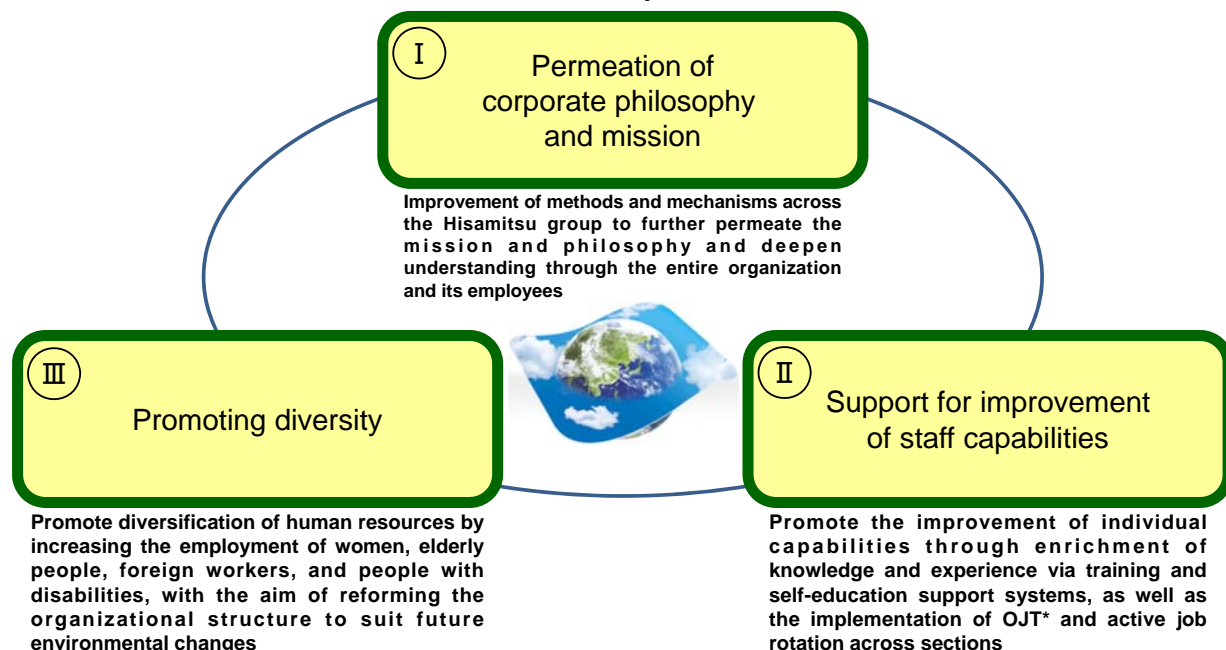


*QCD: Quality, Cost and Delivery

1. Increasing operation efficiency



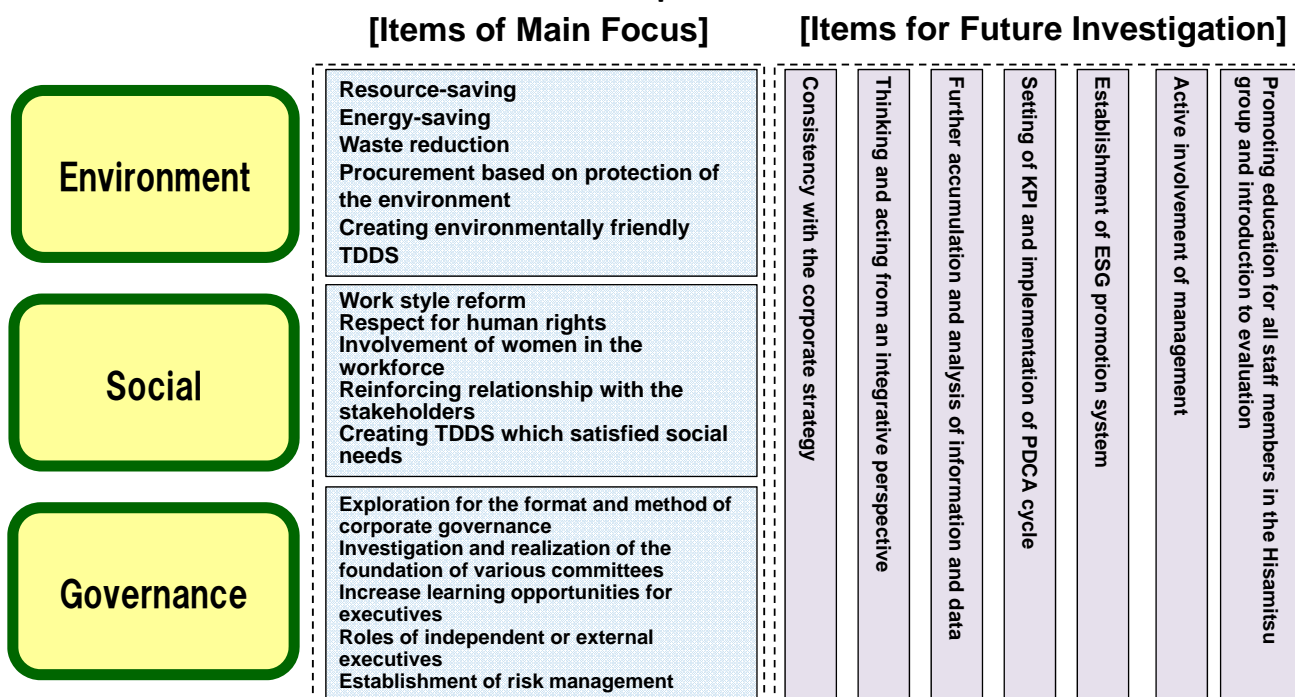
2. Reinforcement of human resource development



*OJT: Training through routine operations (on the job training)

Other Activities

3. Promotion of ESG in the Hisamitsu Group



Management Goal

	FY2016 actual	FY2017 forecast	FY2021 target	5-year average growth rate
Sales	¥145.9B	¥147.0B	¥170.0B	3.1%
CoGs	36.4%	37.9%	35.0%	-
SG&A	45.5%	45.7%	45.0%	-
Operating Profits	¥26.3B	¥24.1B	¥34.0B	5.3%

Total investment
(5-year cumulative)

**At least
100 billion yen**

1. Strategic investment
2. Growth investment
3. Facility investment
4. Investment for improvement of capital efficiency

ROE
(Return on equity)

**FY2021
At least 8.0%**

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