



31/ Oct/ 2014

Separation of Dispensing and Prescribing Drugs in Japan

Katsuaki Ura

General Affairs Division

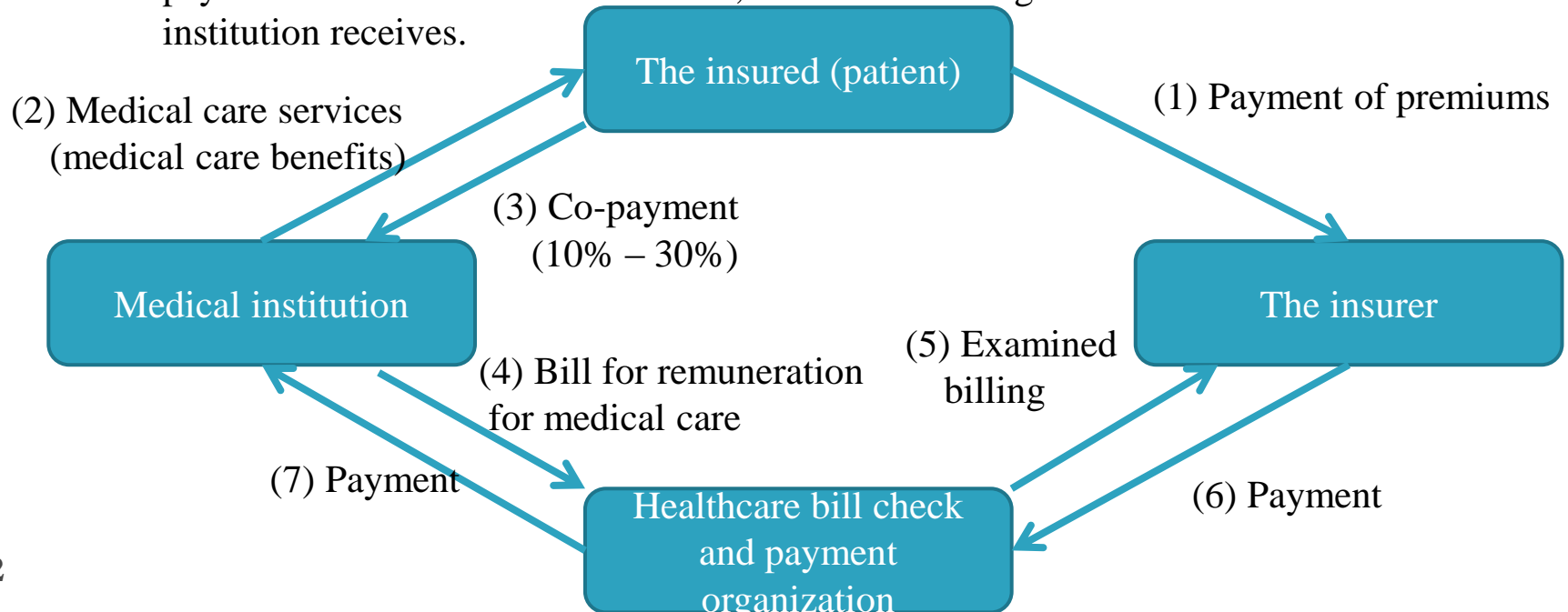
Pharmaceutical and Food Safety Bureau

Ministry of Health, Labour and Welfare

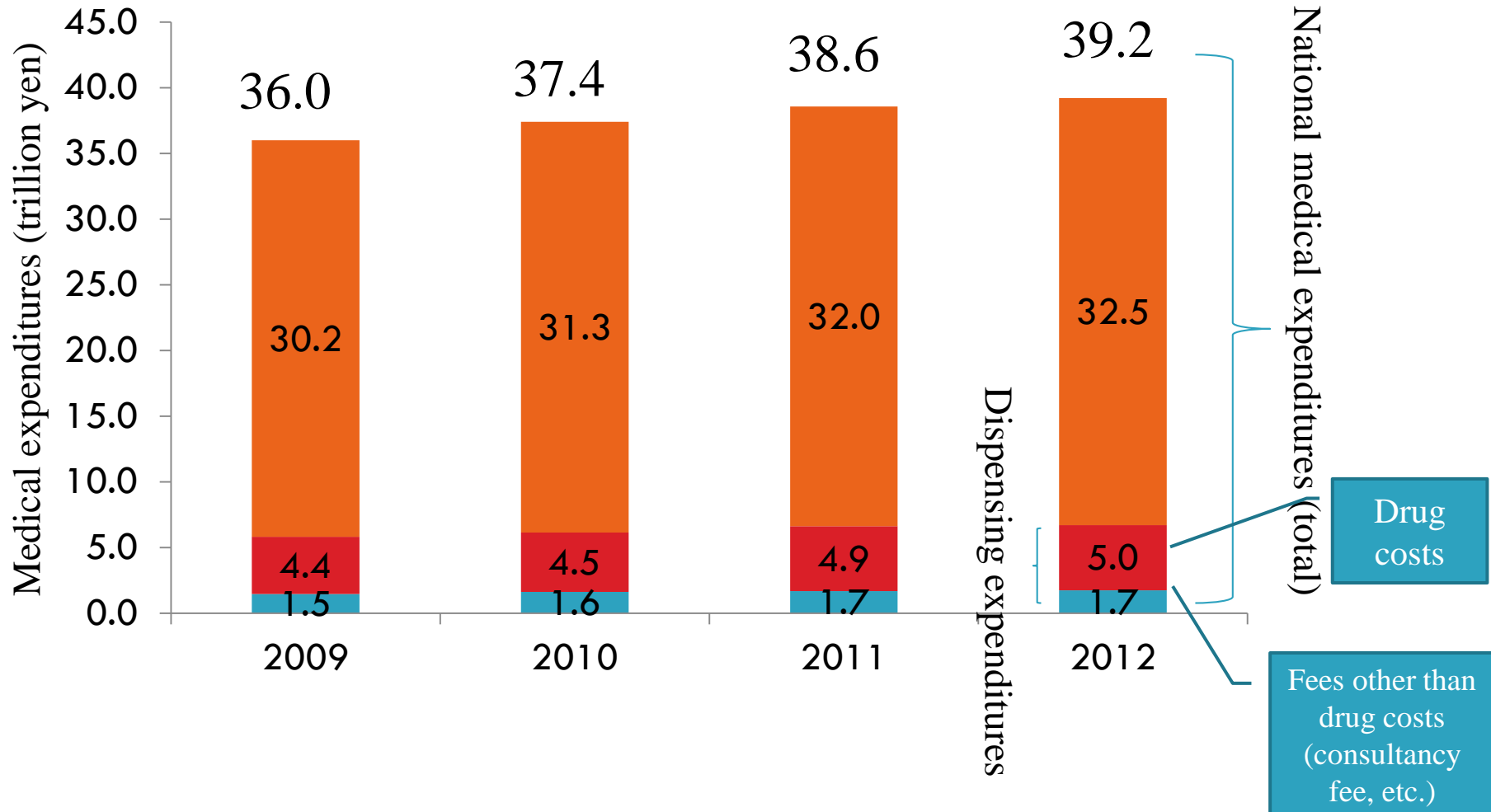
An Illustration of Health Care Services in Japan Provided by Health Insurance

- Remuneration for medical care is determined for each medical practice and paid based on the medical practice carried out. It is a so-called “fee-for-service system.”
- Remuneration for medical care is broadly classified into medical, dental, and pharmaceutical.

Example: If hospitalized for your appendix, items such as the fee for the first medical exam, hospitalization charges according to the hospitalization period, surgery costs for the appendix, laboratory fees, and pharmaceutical charges are added up. The patient’s co-payment is subtracted from that total, and the remaining sum is the amount the medical institution receives.



Shifts in National Medical Expenditures and Pharmaceutical Expenditures



Legal Provisions

Medical Practitioners' Act (Act No. 201 of 1948) (excerpt)

Article 22 Where a medical practitioner finds it necessary to dispense and administer a medicine as a part of a patient's treatment, he/she shall issue a prescription to the patient or a person caring for the patient; however, this shall not apply where the patient or a person caring for the patient reports that it is not necessary to issue a prescription, or in any of the following cases:

(i) – (vii) (omitted)

Pharmacists Act (Act No. 146 of 1960) (excerpt)

Article 23 A pharmacist may dispense medicine for the purpose of sale or provision thereof only according to a prescription issued by a medical practitioner, dental practitioner or veterinarian.

2 (omitted)

Separation of Medical Practice and Drug Dispensing

Objective:

Medical practitioners and pharmacists share duties in each specialization to improve the quality of medical treatment.

Process:

- (1) Medical practitioners provide medical services and issue prescriptions to patients.
- (2) On that basis, pharmacists at pharmacies dispense drugs based on those prescriptions.

Merits:

- (1) A medical practitioner can freely issue prescriptions without being restricted to the medicines he/she has on hand.
- (2) A patient can confirm the prescription contents because the prescription is issued to the patient.
- (3) A pharmacist can double check prescription contents from a position independent from the medical practitioner.
- (4) Even if a patient is seeking consultation at several medical institutions, it is possible to confirm the interaction of medicines and prevent overlapping medications by dispensing medications at a single pharmacy (regularly visited pharmacy).
- (5) Outpatient dispensing duties are reduced, and the ward activities of hospital pharmacists are expedited.

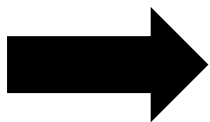
The Effectiveness of Separation of Medical Practice and Drug Dispensing (specific, easy-to-understand examples)

Case 1:

PL granulated medicine is prescribed to a patient receiving treatment for glaucoma. The prescription drug is cancelled due to questions about the prescription.

Case 2:

A medical examination is conducted because of recurring inflammation of the bladder, and a prescription issued. When previously examined, Meiacet was prescribed, but there was a drug rash and the prescription was changed to Cravit. Because the history of drug rash was overlooked and Meiacet was again prescribed, the pharmacist inquired about the prescription and it was changed to Cravit.



Regular pharmacy functions link to the provision of appropriate medicines to patients.

Details of Separation of Medical Practice and Drug Dispensing (1)

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September 1949

- The following recommendations are issued by a delegation of the American Pharmacists Association
 - All possible efforts should be made toward the early realization of the separation of medical practice and drug dispensing through legal, educational, and other means.
 - The job of the medical practitioner should be restricted to diagnosis, issuance of prescriptions, and emergency administration of medicines.
 - The job of the pharmacist should be to secure superior medicines, lawfully store them, and fulfill prescriptions issued by medical practitioners.
- Later, a review was carried out by a “sanshikai,” a consortium comprised of doctors, dentists, and pharmacists, but no conclusion was reached. An investigating committee was established within the Ministry of Health and Welfare.

(From *Annotations to the Pharmacists Act 5th Revision* (Jiho))

Details of Separation of Medical Practice and Drug Dispensing (2)

February 1951

- The following report was submitted by the investigating committee to the Minister of Health, Labour and Welfare.
 - Obligate medical practitioners and dental practitioners to issue prescriptions.
 - Drugs dispensed by pharmacists must be in accordance with a prescription from a doctor, dentist, or veterinarian.

June 1951

- The “law revising portions of the Medical Practitioners’ Act, Dental Practitioners Act, and Pharmacists Act” (the so-called Separation of Medical Practice and Drug Dispensing Act) is established (enforced from April 1, 1956).

Why the Separation of Medical Practice and Drug Dispensing is Presently Advancing (1)

- October 1971
 - Based on the recognition that issues concerning the separation of medical practice and drug dispensing will not be resolved simply by the heretofore assertion of the forced division of labor, the Japan Pharmaceutical Association decided on a policy shift from forced division of labor to discretionary division of labor.

- May 1973
 - In the 1974 revision to remuneration for medical care,
 - Prescription charges were raised (10 pts. → 50 pts.),and a foundation was established to promote the separation of medical practice and drug dispensing, meaning the issuance of outside hospital prescriptions and dispensing of drugs at health insurance pharmacies.

 - Even so, the separation of medical practice and drug dispensing did not thereafter advance to a great degree.

- In 1992 and 1998, prescription charges were raised.

Why the Separation of Medical Practice and Drug Dispensing is Presently Advancing (2)

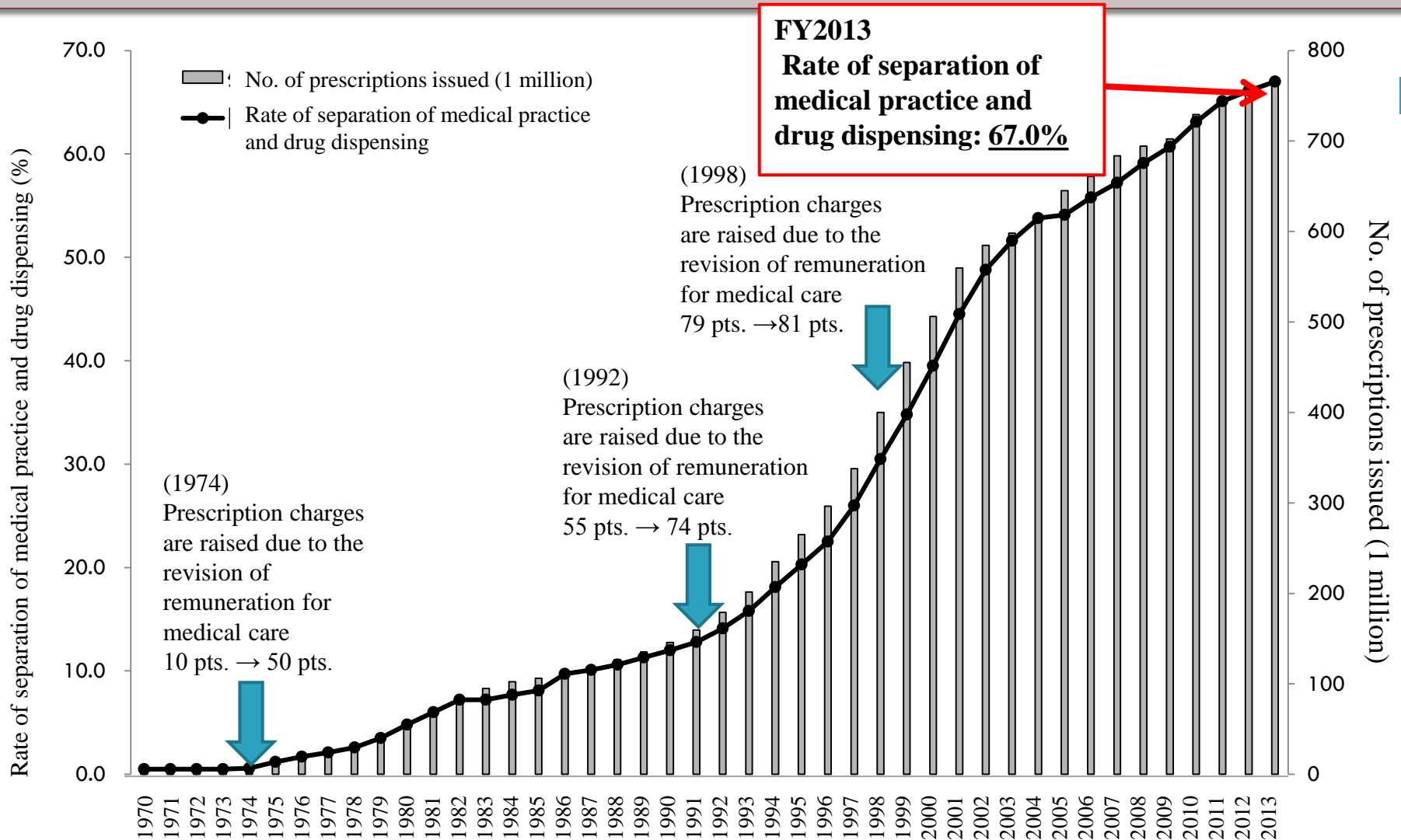
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- From 1975
 - There was a growing opinion denouncing medical treatment that overprescribes medicines, and it was pointed to as the source of price disparities in medicines.

- Therefore, the Ministry of Health, Labour and Welfare successively reviewed the methods for drug price revisions from the 1980s. Drug price disparities were reduced, and doctors' technical fees were raised.
 - Drug price disparities (estimated rate of deviation)
 - 1991: 23.1%
 - 2009: 8.4%

- As a result, the issuance of outside hospital prescriptions gradually advanced.

Annual Shifts in the Rate of Separation of Medical Practice and Drug Dispensing



* Rate of separation of medical practice and drug dispensing (%) = No. of prescriptions issued (No. received at pharmacies) / No. of days of medical consultations (outside of hospitalization) × Rate of prescribed medical medicines + No. of days of dental consultations × Rate of prescribed dental medicines × 100

Publication of Desired Functions in Pharmacies and Their Ideal Form

- “Desired Functions in Pharmacies and Their Ideal Form” was compiled by a Ministry of Health, Labour and Wealth Grants-in-Aid* project **as a guideline for the promotion of the best regularly visited pharmacies based on changes in recent social circumstances** (published by the Japanese Society of Pharmaceutical Health Care and Sciences (JSPHCS), January 2014).

* “Assessment Study on Team Medical Care Undertaken by Pharmacists, Studies on Regional Medical Care, and Outcomes” (Primary Researcher: Masato Yasuhara, professor, Tokyo Medical and Dental University, Department of Hospital Pharmacy, University Hospital of Medicine; president, JSPHCS)

- The Ministry of Health, Labour and Welfare also made the above known to each municipality.
- **Major points**

Basic concept regarding desired functions in pharmacies/pharmacists

1. They are expected to **bear responsibility for medical care** offering optimum drug therapy.
2. From the perspective of ensuring/improving the quality of medical care and ensuring the safety of medical care, they are called on to proactively engage **in team medical treatment in collaboration with medical facilities, etc.**
3. In home medical care, they should ensure/enhance **systems in the community that supply medicines, etc. and provide suitable support for taking medicines.**
4. They are called on to not only fulfill the role as a base offering medicines and medical care/hygienic goods, but also more actively contribute to the **promotion of generic drug usage, and the optimization of medical care that eliminates unused medications.**
5. To promote self-medication, they should actively execute the role of **serving as a base for community-based health information.**
6. They should take responsibility for **overall pharmaceutical management based on lifestyle habits**, rather than just a patient’s medical history.

⇒ This indicates matters under a basic concept that should be ensured or taken on in regard to fundamental systems that pharmacies should provide and the ideal state of pharmaceutical management.

* Regarding publication of “Desired Functions in Pharmacies and Their Ideal Form,” Japanese Society of Pharmaceutical Health Care and Sciences

<http://www.jsphcs.jp/cont/14/0107-1.html>

Primary Functions Desired in Pharmacies

1. Basic functions

Authorization

- Retail drug sales
- Sales of medical equipment

Business Hours

- At least 8hrs./day
- Services on holidays and at night

Pharmaceutical Management

- Ascertaining unused medicines, initiatives to eliminate unused medicines
- Regular confirmation of medications, side effects, etc.

Home Medical Care

- Instruction on managing medicines at home
- Sharing information, collaborating with other professions

Structure/Facility

- Barrier free
- Privacy considerations
- Prohibition of smoking
- Sterile dispensing equipment

Stock/Supply

- Medicines based on community needs (including general/medicines requiring instruction)
- Medical care, hygienic goods
- Nursing care products

Desired Functions

Generic Drugs

- At least a 60% share of stock

Base for Health Info

- Respond to demand for consultation concerning health, nursing care, overall lifestyle habits, etc.

Community Medical Care

- Contribution to community healthcare
- Function as a supply base for medicines in a disaster

Human Resource Functions

- Active initiatives for lifelong learning



Other

- Reports on side effects, etc.

Problems with Current Pharmacies:

- Many do not handle general medicines
- Most pharmacies' business is to dispense drugs based on prescriptions
- A lack of initiatives to become a base for community health development
- Lack of sufficient understanding of separation of medical practice and drug dispensing

● Revised Japan Revitalization Strategy 2014 mid-to-short term progress schedule (June 24, 2014 Cabinet decision; excerpt)

- (1) Promote self-medication that utilizes pharmacies/pharmacists
- (2) Review a framework that publicizes to residents pharmacies that have enhanced consultation systems, facilities, etc.

Promoting model projects that utilize pharmacies/pharmacists

Outsourcing Contractors:
Prefectures (re-entrustment possible)

- Developing projects based on FY2014 projects
- Enhancement/development of effective projects for self-medication

Examples of FY2014 Model Projects:

- ◇ Establishment of consultation points for the proper use of general medicines, etc., and creation/distribution of educational materials on proper use
- ◇ Holding seminars, etc. for the promotion of self-medication (dietary habits, no smoking, heart health, elderly, alcohol, home medical care)
- ◇ Provision of a system for health checks, such as blood pressure
- ◇ Popularization of "electronic medicine handbooks" that aid proper use of drugs, health, development, etc.

Project Examples:

- Based on FY2014 projects,
- Improvement of recognized problems
 - Enlargement of project scale (enlargement of content and number of targeted pharmacies, collaboration with other prefectures, etc.)
 - Introduction of projects in other prefectures, etc.

Reviewing frameworks that publicize to residents pharmacies that have enhanced consultation systems, facilities, etc.

- Pharmacies suitable as health information bases
- Creation of standards** for Health Navigation Stations (provisional name), etc.

Summary of Health Navigation Stations (provisional name)

- (1) A base for supplying all medicines
- (2) Support/consulting functions for creating health among residents
- (3) Functions for residents to conduct health checks on their own that lead to medical examinations
- (4) Collaboration with various professions
- (5) Initiatives for home medical care

Proposed Criteria

- System/facility for health consultations
- Sales system for general medicines/medicines requiring instruction
- Collaboration with other organizations, etc.



Nationally develop even more effective initiatives to promote self-medication among Japanese by enabling citizens to easily access Health Navigation Stations (provisional name).