

# OTC accessibility to consumer

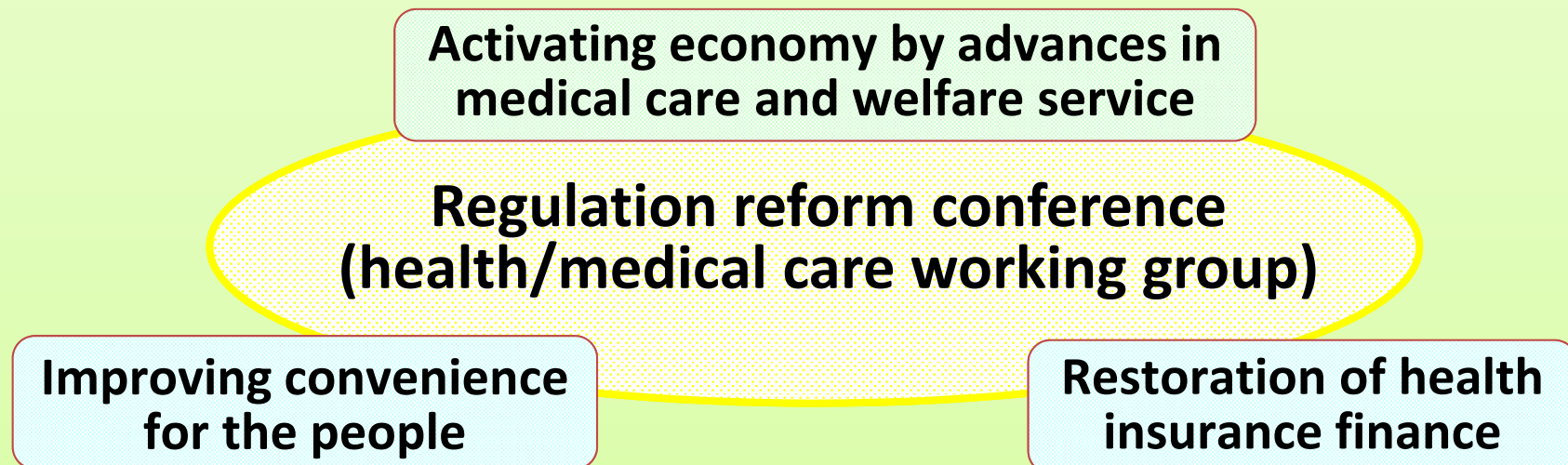


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# Promoting self-care and self-medication

- Living a longer, healthy life with prevention of diseases and nursing care is a common goal of all people. While Japan faces an **ultra-aging society** ahead of the rest of the world, there is an urgent need for realization of a society with healthy longevity where people are able to live long while maintaining health and the quality of life.
- Because of the **progression of an aging society with a declining birth rate**, the **burden on social security** is increasing every year. In order to ensure the necessary medical and nursing care services with limited financial revenues, there is a need for measures, such as health promotion and disease prevention, for the people, as well as increasing efficiency of provision and optimization of cost.



# Contents of activities in Japan

1. Clarifying the roles of parties involved
2. Simplification of approval assessment
3. Promoting Rx-to-OTC switch
4. Revision of Appropriate Advertising Standards on Medical products
5. Establishment of Self-medication tax system (special exemption of medical cost)

# 1. Clarifying the roles of parties involved

In order to promote the proper use of OTC pharmaceuticals by the people before and after attending medical institutions ...



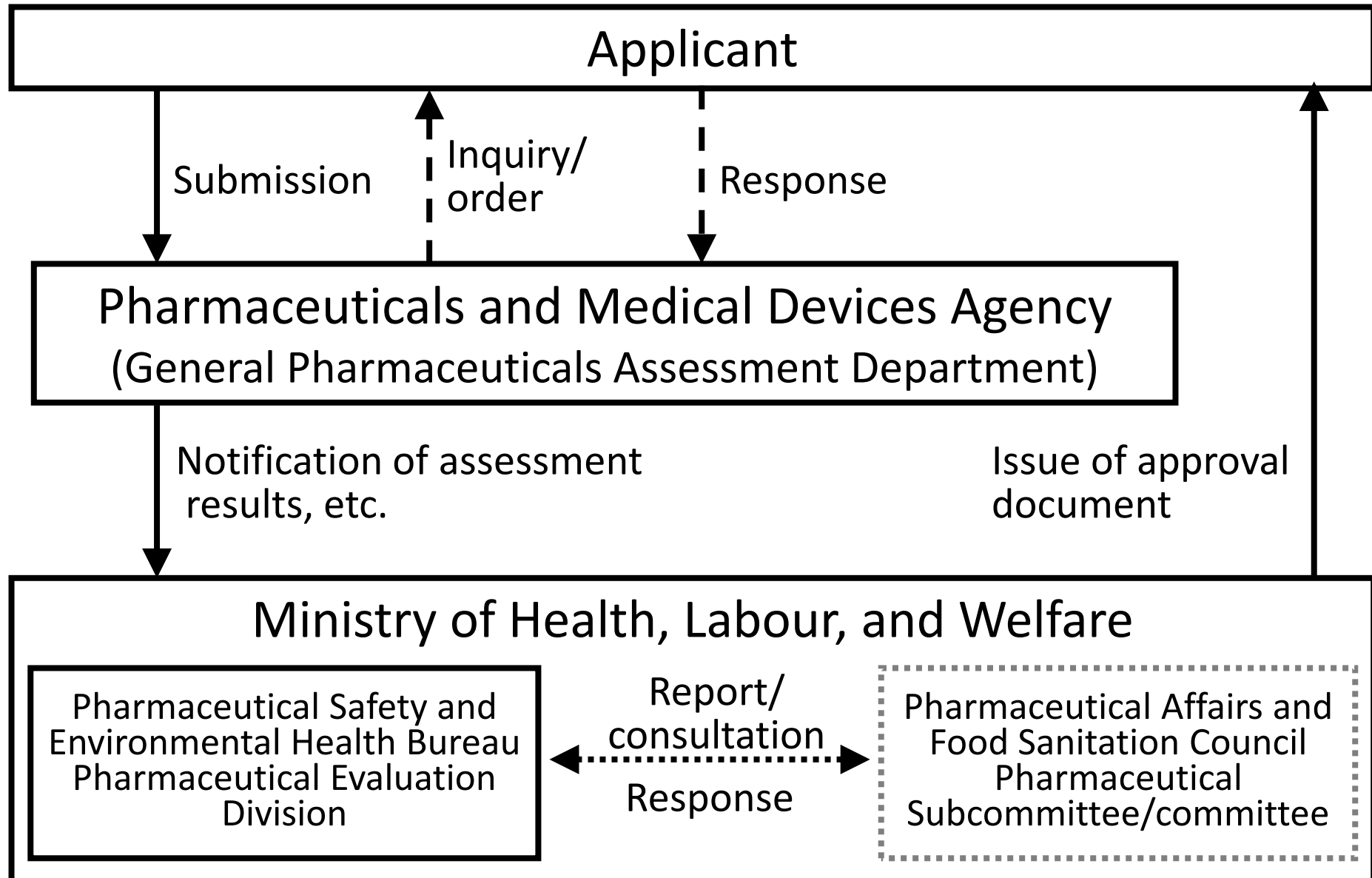
- Enrichment of self-medication promoting activities and provision of information on proper use by companies/industry, health personnel and regulative authorities
- Importance of the people as users in awareness of self-responsibility

**Stipulating the role of relevant parties by law**

(Reference) Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices

**The people** must **use the pharmaceuticals in an appropriate manner** and make an effort **to deepen the knowledge and understanding of their efficacy and safety.**

## 2. Simplification of approval assessment – Expansion and review of items approved by the governor-



# OTC pharmaceuticals (about 11,000 items)

## Approved by the minister

- ❑ Pharmaceuticals not applicable to the standards for approval by the governor

## Approved by the governor

- ❑ Pharmaceuticals applicable to the standards for approval by the governor
  - ❑ Standards for approval by the governor are prepared for the following efficacy groups (15 efficacy groups):
    - Cold remedy
    - Antipyretic and analgesic
    - Antitussive and expectorant
    - Gastrointestinal medicine
    - Laxative
    - Antivertiginous drugs
    - Ophthalmologic drugs
    - Preparations with vitamin as primary agent
    - Enema agent
    - Anthelmintic
    - Nasal drug for rhinitis
    - Oral agent for rhinitis
    - External agent for hemorrhoids
    - Drugs for athlete's foot and ringworm
    - Antipruritic and anti-inflammatory
- (about 4,500 items)

## Period required for approval assessment

Due to the approval standard, the **assessment period is shorter** than the period of approval by the minister.

- Approval by the minister: 7.0 months
- Approval by the governor: 2 to 3 months

## Expansion and review of items approved by the governor

<Advantages>

- Citizens: Expansion of items that meet the needs
- PMDA: Faster assessment of items in new areas due to reductions in the assessment of OTC pharmaceuticals
- Companies: Reduction in burden of development, faster product making

## 3. Promoting Rx-to-OTC switch

“Japan Revitalization Strategy” revised in 2014 – challenges for the future – (June 24, 2014)

Second part: Three action plans

2. Strategic market creation plan

Theme 1: Prolongation of “healthy longevity” of the citizens

(3) Specific measures to be newly considered

ii) Activating the service industry not covered by public insurance

(iii) Promoting transfer from ethical pharmaceuticals to OTC pharmaceuticals (Rx-to-OTC switch)

The following measures will be taken to accelerate the transfer of pharmaceuticals (including diagnostic drugs) from ethical to general use (Rx-to-OTC switch) for promotion of self-medication:

- Speedy assessment should be performed according to the approval application submitted by the companies with reference for data overseas.

In order to achieve this, the forecast ability for approval application by the PMDA needs to be heightened and company development needs to be promoted. For this reason, measures will be implemented in steps from this fiscal year for the setting of the target assessment period in approval assessment and the expansion/enrichment of systems handling inquiries by the companies.

- Mechanisms that reflect the opinions of more diverse bodies, such as the industries and consumers, will be established within this fiscal year with reference to examples overseas (e.g., USA).

Basic policies in economic/financial management and reform (outline) 2014 (June 24, 2014)

Chapter 3: Positive cycle of economic revitalization and financial restoration

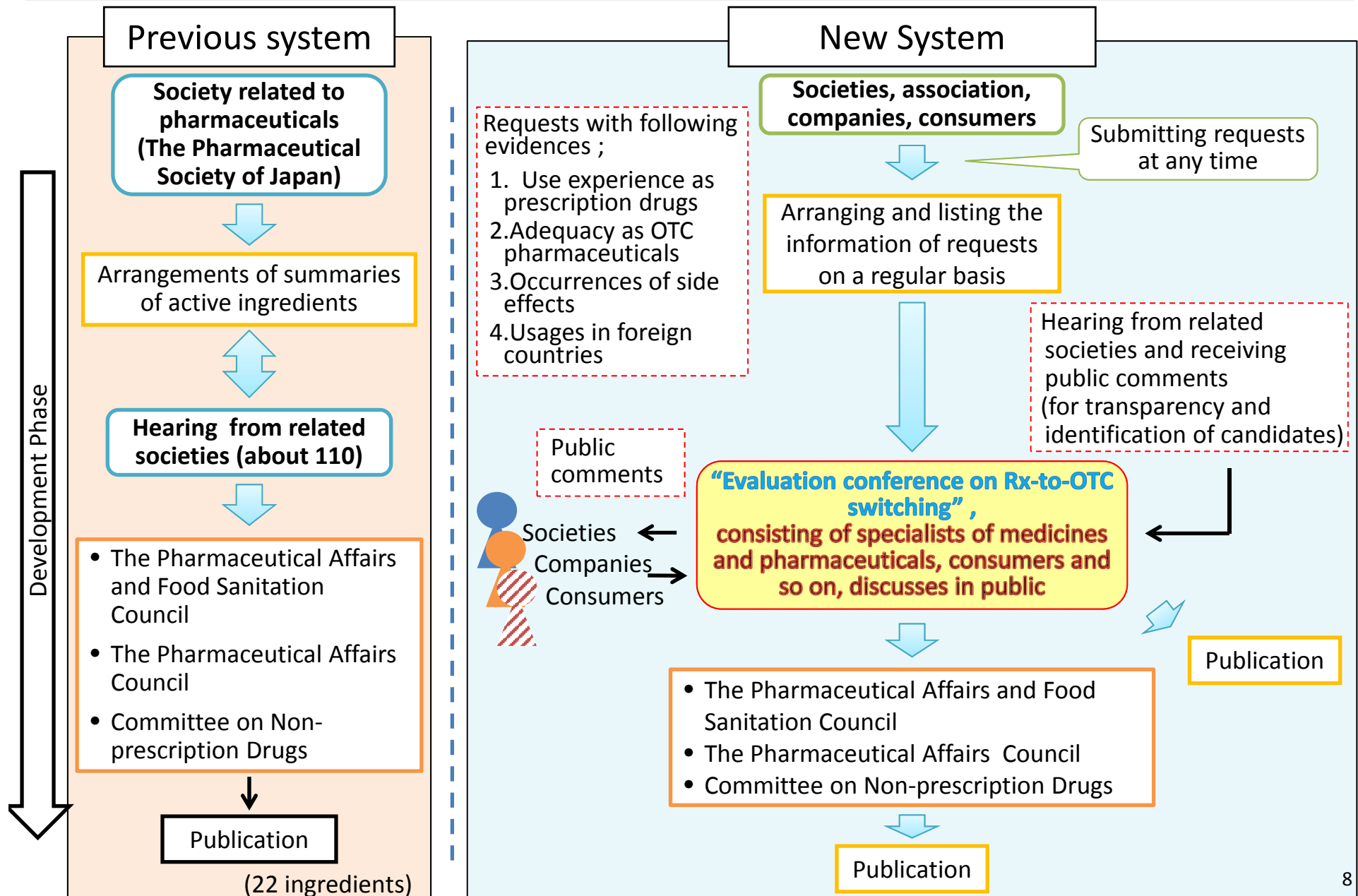
2. Idea on the priority and efficiency in primary areas of expenditure

(1) Social security reform

(Reform of drug prices and pharmaceuticals)

In order to promote self-medication, efforts for accelerating the transfer of pharmaceuticals (including diagnostic drugs) from ethical to general use (Rx-to-OTC switch) should be implemented with the setting of specific goals.

○ To promote the switching of drugs from prescription to OTC pharmaceuticals (included in “Japan Revitalization Strategy” revised in June 2014), MHLW is constructing the new OTC evaluation system where **opinions from various subjects**, referring to systems outside Japan (e.g. USA)





## Requests for Rx-to-OTC switch

### Requests for Rx-to-OTC switch

Start : **August 5, 2016**

**1. Contents :**

The ingredient which is hoped for Rx-to-OTC switch (except for in-vitro diagnostic)

**2. Application period :** At any time

**3. Website :**

<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000127534.html>



### Submitted requests

**1. The ingredient which was requested :**

32 ingredients (August 5, 2016 to June 30, 2018)

**2. Website**

<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000144557.html>

## Request Lists (32 ingredients) part 1

No.	Ingredient	Demanded effect
H28-1	Sodium Hyaluronate	Dry eye, cornea protection
H28-2	Rebamipide	Gastric ulcer, acute gastritis
H28-3	Levonorgestrel	Emergency contraceptive
H28-4	Rizatriptan Benzoate	Migraine
H28-5	Sumatriptan Succinate	
H28-6	Eletriptan Hydrobromide	
H28-7	Naratriptan Hydrochloride	
H28-8	Zolmitriptan	
H28-9	Clindamycin Phosphate	Acne
H28-10	Betamethasone Butyrate Propionate	Rash
H28-11	Omeprazole	Heartburn, gastralgia
H28-12	Lansoprazole	
H28-16	Rabeprazole	
H28-13	Meloxicam	Joint pain, low back pain, neck stiffness
H28-14	Fluticasone Propionate	Seasonal allergic rhinitis
H28-15	Iodine Polyvinyl Alcohol	Sterilization of eyes
H28-17	Clcipotriol	Hyperkeratosis, psoriasis
H28-18	Levocabastine Hydrochloride	Conjunctivitis, itch of eyes
H29-1	Donepezil Hydrochloride	Suppression of dementia progression in Alzheimer-type dementia
H29-2	Galantamine Hydrobromide	
H29-3	Memantine Hydrochloride	
H29-4	Rivastigmine	

## Request Lists (32 ingredients) part 2

No.	Ingredient	Demanded effect
H29-5	Levocetirizine Dihydrochloride	Rhinitis, dermatitis
H29-6	Naproxen	Relieve pain from various conditions such as headaches, muscle aches, tendonitis, dental pain, and menstrual cramps
H29-7	Propiverine hydrochloride	Urinary frequency, urinary incontinence for women
H29-8	Tretinoin tocoferil	Bedsore
H29-9	Tolterodine tartrate	Urinary frequency, urinary incontinence for women
H29-10	Domperidone	Nausea, vomiting
H29-11.1 H29-11.2	Itopride hydrochloride	Heartburn, gastralgia
H29-12	Polycarbophil calcium	Constipation, diarrhea
H29-13	Menatetrenone	Osteoporosis prevention for person whose bone density is lower than normal, but not low enough to be considered osteoporosis.
H30-1	Eperisone hydrochloride	Low back pain, neck stiffness

## 4. Revision of Appropriate Advertising Standards on Medical products

- Regulatory Reform Implementation Plan (Cabinet Decision, 2 June 2016)
- 1 Health and Medical Care
- (1) Point of view and priority area on regulatory reform
- As a measure for achieving healthy longevity society, to address the revision of Advertising Standards on OTC drugs and designated Quasi-drugs based on three basic concept as follows in the range of ensuring safety and relief.
- to improve public convenience
  - to vitalize economic on the basis of development of Health Care and Welfare
  - to ensure National Health Insurance balance

### Specific Revision Issue

1. To modernize “Appropriate Advertising Standards”
2. To disclose the detailed and concrete explanation on the standards
3. To establish a system to minimize administrative guidance difference among prefectures

### (1) Revision of Appropriate Advertising Standards on Medical products (Notification of PFSB No.0929-4, 29 Sept. 2017)

Item	Previous	Purpose and Contents of Revision
Applicable Media	- (No description)	All of media for consumers (various media including websites and emerging ones)
Maintenance of Prestige	Advertisement which would make medical products demeaned wasn't allowed	To declare contents of left column as “Responsibility of Advertiser” (This concept should be applied for advertiser rather than each product)
Branded Products Name	- (No description)	Regarding OTC drugs, to enable to use “common name” of multiple branded products (it would be beneficial for consumer)
Products which have multiple indications	To be described more than two indications, if the product have multiple indications	To accept description of a selected indication (this change doesn't have negative impact for consumers)
Habit Forming Drug	To be described as “Habit Forming” if it was designated by Minister of Health, Labour and welfare	Regarding OTC drugs, to delete this guidance (because there is no Habit Forming Drug in OTC drugs)
Recommendation by professionals.	To exemplify inappropriate professionals to quote *	To add “academic society” (in order to avoid guarantee expression)

\*Physicians, dentists, pharmacists, veterinarians or other professionals and organizations which have an impact to consumer related to indications such as barber, beauty artist, hospital, clinic, official office, school.

## (2) Revision of Appropriate Advertising Standards on Medical products (Notification of PFSB No.0929-4, 29 Sept. 2017)

Item	Previous	Purpose and Contents of Revision
Products' name	Replacement by the other characters from original name wasn't allowed.	To be allowed to be written additional alphabet name (to the extent that product identity cannot be mistaken, consideration is given to consumers who aren't able to read Japanese)
Nickname	To be allowed in the range of permitted in general naming rule	Not to be allowed to use nickname (because there isn't any positive reason.)
Expression of feeling of use	To be allowed expression of feeling of some drugs use such as eye drops	Not to be allowed to emphasis on feeling of use in advertisement (it may cause misunderstanding of products)
Expression of not containing specific ingredients	To be allowed, if the product contains an ingredient which has similar effect to describe	To be allowed to describe containing specific ingredients such as caffeine, sodium, steroid, antihistamine (because it is beneficial information for consumers, but slander of other companies and emphasized expression of safety isn't allowed)
Advertisement for specific age and sex	To be allowed, if there are restrictions of age or sex for regarding the products	To be allowed unless it slander other companies and express emphasizes superiority (because it doesn't cause disadvantage for consumers)
Sales history	Not to be allowed	To be allowed, as long as it doesn't guarantee superiority over other companies' products
Expression of "not cause drowsiness"	- (No description)	To be allowed unless it slander other companies (it would be beneficial for consumer)
Period of "New Release"	6 months since launched	12 months since launched (considered product cycle)
Advertisement of discount	- (No description)	Not to be allowed excessive discount advertising by purchasing amount of products (it may cause unnecessary purchase)

## (3) Update of compliance supervision system

○ **To minimize administrative guidance difference among prefectures, Nationwide Advertisement Monitoring Conference for Medical Products\* addressed as follows.**

\*This conference is consisted of MHWL and 5 prefectures and discusses policies of advertisement monitoring and guidance work and interpretation of violation.

- to publicize the result of conference
- to involve industry for mutual and constructive discussion

## 5. Establishment of Self-medication tax system (special exemption of medical cost)

### 1. Summary of outline

From the perspective of promoting the switch from ethical pharmaceuticals under appropriate health control, **an individual making a certain effort for maintenance/improvement of health and disease prevention who purchased the Rx-to-OTC switch** and the total amount of the applicable purchase in the year **exceeds 12,000 yen**, the excess amount (88,000 yen if the excess is more than 88,000 yen) will be **deducted from the total income**.

### 2. Details of the system

#### ■ Applicable pharmaceuticals : Rx-to-OTC switch

○ Number of Rx-to-OTC switch ingredients: 84 (as of August 1, 2018)

– Examples of efficacies of applicable pharmaceuticals:

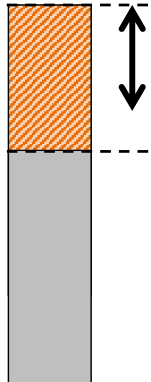
Cold remedies, gastrointestinal medicine, oral drugs for rhinitis, drugs for athletes' foot/ringworm, and patches for stiff shoulder, lower back pain, and joint aches

#### **Visualization of the use of this exemption**

An individual with taxable income of 4 million yen who has purchased 20,000 yen worth of applicable pharmaceuticals in a year (including spouse or relatives living in the same household)

20,000 yen  
(Cost of applicable  
pharmaceuticals  
purchased)

12,000 yen  
(minimum  
cost)



○ **8,000 yen** is deducted from taxable income

Amount of applicable pharmaceuticals purchased : 20,000 yen –  
minimum cost: 12,000 yen = 8,000 yen

○ Amount of tax reduction

• Income tax : **1,600 yen** reduction (deducted amount: 8,000 yen  
× income tax rate: 20% = 1,600 yen)

• Individual Inhabitant's tax : **800 yen** reduction (deducted amount:  
8,000 yen × individual Inhabitant's tax rate: 10% = 800 yen)

# Measures in progress – summary-

## 1. Improving convenience for the people

### ■ Evaluation system for new Rx-to-OTC switch components

Establish a mechanism that will reflect the opinions of diverse bodies (such as consumers) for expectation of the Rx-to-OTC switch approval in new efficacy groups

### ■ Expansion and review of standards of approval by governor

Realize efficacy expressions that are easy to understand from the perspective of consumers.

### ■ Revision of Appropriate Advertising Standards on Medical products

## 2. Restoration of insurance finance

### ■ Self-medication tax system (special exemption of medical cost)



**Thank you for your attention!**

**谢谢了垂闻!**