Recent Progress of OTC Regulation in Japan

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

Information given for the classification and sale of OTC pharmaceuticals according to risk level

**Drug type 1**: Especially high risk
- Drugs with little usage experience as OTC pharmaceuticals etc.
- Drugs containing elements of particular concern for safety reasons (including prescription drugs switched to OTC)

   Number of items: Around 100
   Market size = \( \approx 40\text{bn} \) (Note 1)

**Drug type 2**: Relatively high risk
- Contains elements that could potentially damage health enough to require hospitalization
  * Designated Drug type 2: items in this category that the Minister of Health, Labour and Welfare has designated as requiring special care (must be displayed within 7m of information counters)

   Number of items: Around 7,500
   Market size = \( \approx 610\text{bn} \) (Note 1)

**Drug type 3**: Relatively low risk
- Contains elements that may cause physical discomfort but not to the extent of impeding daily life.

   Number of items: Around 2,800
   Market size = \( \approx 270\text{bn} \) (Note 1)

(Note 1) Number of items: result of drug information database search (October 2015)  Market size are from 2015 (source: market size: INTAGE SDI)

(Note 2) Individuals who qualified a test of credentials introduced by the revision made in 2006

<table>
<thead>
<tr>
<th>Low</th>
<th>Relevant Expert</th>
<th>Pharmacist</th>
<th>Pharmacist or Registered Seller</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information to Purchaser</td>
<td>Obligation</td>
<td>Obligation to make effort</td>
<td>Not required</td>
</tr>
<tr>
<td>Respond to query from purchaser</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Able to sell online?</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>

Ministerial ordinance (before)
Revision of sales regulation of non-prescription drugs

[Before]

Prescription Drugs
face-to-face selling
(Stipulated in Ministerial Ordinance)

Non-prescription Drugs

Drug type 1
face-to-face selling

Drug type 2
face-to-face selling

Drug type 3
Available over the internet

Just-switched drugs
Poisonous drugs

[After Amendment]

Prescription Drugs
face-to-face selling
(Stipulated in the Act)

New Category* Drugs
face-to-face selling

OTC pharmaceuticals

Drug type 1
Available over the internet

Drug type 2
Available over the internet

Drug type 3
Available over the internet

Drugs in new category is to be available over the internet generally 3 years after its switch.

* Face to face selling OTC pharmaceuticals
Label of OTC Pharmaceuticals Classification
Label of OTC Pharmaceuticals Classification must be described on the immediate container or capsule of a pharmaceutical (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices Article 50 (vi)(vii), Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices Article 209-2 and 209-3).

Face to face selling OTC pharmaceuticals

Drug type 1
Drug type 2
Drug type 3

Change of OTC Pharmaceuticals Classification
Based on the post-marketing surveillance of pharmaceuticals, the OTC Pharmaceuticals Classification is determined after consultation of Pharmaceutical Affairs and Food Sanitation Council Pharmaceutical Subcommittee/committee.

With regard to Label of OTC Pharmaceuticals Classification, if pharmaceuticals were designated by the MHLW as those whose labels of OTC Pharmaceuticals Classification need to be changed and which have been marketed before the change, it is not necessary to provide the labels of OTC Pharmaceuticals Classification after the change for the period designated by the MHLW. (Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices Article 216-2)

There will be a one-year transitional measure.
# 2. 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) Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals 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.***
3. Simplification of approval assessment – Expansion and review of items approved by the governor-

applicant

Submission → Inquiry/order → Response

Pharmaceuticals and Medical Devices Agency
(General Pharmaceuticals Assessment Department)

Notification of assessment results, etc. → Issue of approval document

Ministry of Health, Labour, and Welfare

Pharmaceutical Safety and Environmental Health Bureau
Pharmaceutical Evaluation Division

Report/consultation → Response

Pharmaceutical Affairs and Food Sanitation Council
Pharmaceutical Subcommittee/committee
OTC pharmaceuticals (about 19,000 items)

Approved by the minister
- Pharmaceuticals applicable to the standards for approval by the governor
- Standards for approval by the governor are prepared for the following efficacy groups (17 efficacy groups):
  - Cold remedy
  - Antipyretic and analgesic
  - Antitussive and expectorant
  - Gastrointestinal medicine
  - Laxative

(about 8,000 items)

Approved by the governor
- Pharmaceuticals applicable to the standards for approval by the governor
- Standards for approval by the governor

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 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

Pharmaceuticals applicable to the standards for approval by the governor
- Cold remedy
- Antipyretic and analgesic
- Antitussive and expectorant
- Gastrointestinal medicine
- Laxative

Standards for approval by the governor are prepared for the following efficacy groups (17 efficacy groups):
- 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
- Kampo products
- Crude drug products

<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
Preparations with vitamin as primary agent
• Revision to easy understanding indication

<Example>

<table>
<thead>
<tr>
<th>Pharmaceuticals</th>
<th>New indication</th>
<th>Old indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparations with vitamin A as primary agent</td>
<td>Nyctalopia (hemeralopia, <strong>night blindness</strong>)</td>
<td>Nyctalopia (hemeralopia)</td>
</tr>
</tbody>
</table>

• Addition of new active ingredients (Mecobalamin, Hepronicate, Red Ginseng, Chinese Angelica Root, Sinomenium Stem and Rhizome)

Gastrointestinal medicine
• Revision of name and classification of Creosote

Others
• Revision of active ingredient name according to JP revision
4. 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)

Previous system

Society related to pharmaceuticals (The Pharmaceutical Society of Japan)

Arrangements of summaries of active ingredients

Hearing from related societies (about 110)

• The Pharmaceutical Affairs and Food Sanitation Council
• The Pharmaceutical Affairs Council
• Committee on Non-prescription Drugs

Publication (22 ingredients)

New System

Societies, association, companies, consumers

Submitting requests at any time

Arranging and listing the information of requests on a regular basis

Hearing from related societies and receiving public comments (for transparency and identification of candidates)

Requests with following evidences:
1. Use experience as prescription drugs
2. Adequacy as OTC pharmaceuticals
3. Occurrences of side effects
4. Usages in foreign countries

Public comments

“Evaluation conference on Rx-to-OTC switching”, consisting of specialists of medicines and pharmaceuticals, consumers and so on, discusses in public

• The Pharmaceutical Affairs and Food Sanitation Council
• The Pharmaceutical Affairs Council
• Committee on Non-prescription Drugs

Publication
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 (Japanese version only):
   http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000127534.html

Submitted requests

1. The ingredient which was requested:
   35 ingredients (August 5, 2016 to June 30, 2019)

2. Website (Japanese version only):
   http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000144557.html
<table>
<thead>
<tr>
<th>No.</th>
<th>Ingredient</th>
<th>Demanded effect</th>
<th>〇 (indications needs to be changed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>H28-1</td>
<td>Sodium Hyaluronate</td>
<td>Dry eye, cornea protection</td>
<td></td>
</tr>
<tr>
<td>H28-2</td>
<td>Rebamipide</td>
<td>Gastric ulcer, acute gastritis</td>
<td></td>
</tr>
<tr>
<td>H28-3</td>
<td>Levonorgestrel</td>
<td>Emergency contraceptive</td>
<td>×</td>
</tr>
<tr>
<td>H28-4</td>
<td>Rizatriptan Benzoate</td>
<td>Migraine</td>
<td>×</td>
</tr>
<tr>
<td>H28-5</td>
<td>Sumatriptan Succinate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H28-6</td>
<td>Eletriptan Hydrobromide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H28-7</td>
<td>Naratriptan Hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H28-8</td>
<td>Zolmitriptan Hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H28-9</td>
<td>Clindamycin Phosphate</td>
<td>Acne</td>
<td>×</td>
</tr>
<tr>
<td>H28-10</td>
<td>Betamethasone Butyrate Propionate</td>
<td>Rash</td>
<td>×</td>
</tr>
<tr>
<td>H28-11</td>
<td>Omeprazole</td>
<td>Heartburn, gastralgia</td>
<td>×</td>
</tr>
<tr>
<td>H28-12</td>
<td>Lansoprazole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H28-16</td>
<td>Rabeprazole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H28-13</td>
<td>Meloxicam</td>
<td>Joint pain, low back pain, neck stiffness</td>
<td>〇</td>
</tr>
<tr>
<td>H28-14</td>
<td>Fluticasone Propionate</td>
<td>Seasonal allergic rhinitis</td>
<td>〇</td>
</tr>
<tr>
<td>H28-15</td>
<td>Iodine Polyvinyl Alcohol</td>
<td>Sterilization of eyes</td>
<td>〇</td>
</tr>
<tr>
<td>H28-17</td>
<td>Clcipotriol</td>
<td>Hyperkeratosis, psoriasis</td>
<td>×</td>
</tr>
<tr>
<td>H28-18</td>
<td>Levocabastine Hydrochloride</td>
<td>Conjunctivitis, itch of eyes</td>
<td>〇 (indications needs to be changed)</td>
</tr>
<tr>
<td>H29-1</td>
<td>Donepezil Hydrochloride</td>
<td>Suppression of dementia progression in Alzheimer-type dementia</td>
<td>×</td>
</tr>
<tr>
<td>H29-2</td>
<td>Galantamine Hydrobromide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H29-3</td>
<td>Memantine Hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H29-4</td>
<td>Rivastigmine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H29-5</td>
<td>Levocabastine Hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H29-6</td>
<td>Naproxen</td>
<td>Relieve pain from various conditions such as headaches, muscle aches, tendonitis, dental pain, and menstrual cramps</td>
<td>〇 (indications needs to be changed)</td>
</tr>
<tr>
<td>H29-7</td>
<td>Propiverine hydrochloride</td>
<td>Urinary frequency, urinary incontinence for women</td>
<td>〇 (indications needs to be changed)</td>
</tr>
</tbody>
</table>

※ 〇: Approved as OTC Pharmaceuticals candidate in the conference.
※ ×: Not approved as OTC Pharmaceuticals candidate in the conference.
<table>
<thead>
<tr>
<th>No.</th>
<th>Ingredient</th>
<th>Demanded effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>H29-8</td>
<td>Tretinoin tocoferil</td>
<td>Bedsores</td>
</tr>
<tr>
<td>H29-9</td>
<td>Tolterodine tartrate</td>
<td>Urinary frequency, urinary incontinence for women</td>
</tr>
<tr>
<td>H29-10</td>
<td>Domperidone</td>
<td>Nausea, vomiting</td>
</tr>
<tr>
<td>H29-11.1</td>
<td>Itopride hydrochloride</td>
<td>Heartburn, gastralgia</td>
</tr>
<tr>
<td>H29-11.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H29-12</td>
<td>Polycarbophil calcium</td>
<td>Constipation, diarrhea</td>
</tr>
<tr>
<td>H29-13</td>
<td>Menatetrenone</td>
<td>Osteoporosis prevention for person whose bone density is lower than normal, but not low enough to be considered osteoporosis.</td>
</tr>
<tr>
<td>H30-1</td>
<td>Eperisone hydrochloride</td>
<td>Low back pain, neck stiffness</td>
</tr>
<tr>
<td>H30-2</td>
<td>Mosapride citrate hydrate</td>
<td>Heartburn, gastralgia</td>
</tr>
<tr>
<td>H30-3</td>
<td>Nutrition 31 ingredients (Sodium Caseinate, Sodium Calcium Caseinate, Soy Protein Isolate, Corn Oil, Soy Lecithin, Dextrin, Sucrose, Retinol Palmitate, Cholecalciferol, Tocopherol Acetate, Phytonadione, Ascorbic Acid, Thiamine chloride Hydrochloride, Riboflavin, Pyridoxine Hydrochloride, Cyanocobalamin, Choline Chloride, Folic Acid, Nicotinamide, Calcium Pantothete, Biotin, Sodium Bicarbonate, Magnesium Chloride, Potassium Citrate, Tribasic Calcium Phosphate, Potassium Chloride, Sodium Citrate Hydrate, Zinc Sulfate Hydrate, Ferrous Sulfate Hydrate, Manganese Chloride, Cupric Sulfate)</td>
<td>Nutritional supplementation when nutrition is insufficient</td>
</tr>
<tr>
<td>R1-1</td>
<td>Ramelteon</td>
<td>Insomnia characterized by difficulty with sleep onset.</td>
</tr>
</tbody>
</table>

※ ○: Approved as OTC Pharmaceuticals candidate in the conference.
× : Not approved as OTC Pharmaceuticals candidate in the conference.
5. 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

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

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

*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)

<table>
<thead>
<tr>
<th>Item</th>
<th>Previous</th>
<th>Purpose and Contents of Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products' name</td>
<td>Replacement by the other characters from original name wasn’t allowed.</td>
<td>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)</td>
</tr>
<tr>
<td>Nickname</td>
<td>To be allowed in the range of permitted in general naming rule</td>
<td>Not to be allowed to use nickname (because there isn't any positive reason.)</td>
</tr>
<tr>
<td>Expression of feeling of use</td>
<td>To be allowed expression of feeling of some drugs use such as eye drops</td>
<td>Not to be allowed to emphasis on feeling of use in advertisement (it may cause misunderstanding of products)</td>
</tr>
<tr>
<td>Expression of not containing specific ingredients</td>
<td>To be allowed, if the product contains an ingredient which has similar effect to describe</td>
<td>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)</td>
</tr>
<tr>
<td>Advertisement for specific age and sex</td>
<td>To be allowed, if there are restrictions of age or sex for regarding the products</td>
<td>To be allowed unless it slander other companies and express emphasizes superiority (because it doesn’t cause disadvantage for consumers)</td>
</tr>
<tr>
<td>Sales history</td>
<td>Not to be allowed</td>
<td>To be allowed, as long as it doesn’t guarantee superiority over other companies' products</td>
</tr>
<tr>
<td>Expression of “not cause drowsiness”</td>
<td>- (No description)</td>
<td>To be allowed unless it slander other companies (it would be beneficial for consumer)</td>
</tr>
<tr>
<td>Period of “New Release”</td>
<td>6 months since launched</td>
<td>12 months since launched (considered product cycle)</td>
</tr>
<tr>
<td>Advertisement of discount</td>
<td>- (No description)</td>
<td>Not to be allowed excessive discount advertising by purchasing amount of products (it may cause unnecessary purchase)</td>
</tr>
</tbody>
</table>

(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
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)
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.

2. Restoration of insurance finance

- **Self-medication tax system (special exemption of medical cost)**
Thank you for your attention!
谢谢了垂闻!