

Vision for the Vitalization of OTC Industry



May 2009

Japan Self-Medication Industry

Introduction

Japan Self-Medication Industry (JSMI), which was established in 1985, has been acting with the common goal of enhancing the roles and functions of OTC medicines and the philosophy of contributing to maintenance and improvement of consumers' health by aiming at the sound development of Self-Medication industry..

More than 20 years have passed since the establishment of JSMI, and the environment surrounding OTC medicines in terms of social environment, consumer's consciousness of health, improvement of the quality of life, and so on has made substantial changes.

In order to respond to such changes and to further contribute to consumer's health, we considered it necessary to establish an environment for permeation of the Responsible Self-Medication by collaborating under the disinterested common vision among the member companies..

JSMI offers the following vision as our future goal, and starts new activities to realize it.

1. Vision (2009-2014)

In order to contribute to consumer's health, we will create a new OTC medicine market as well as revitalize the existing market by expanding the roles and improving the quality of the Responsible Self-Medication through responding to environmental changes such as aging society with declining birthrate and predicament of health insurance finance. We aim to develop the industry with production value of more than 1 trillion yen.

JSMI will create a new OTC medicine market as well as revitalize the existing market to contribute to consumer's health.

The new OTC medicine market will be created by communication and cooperation with consumers, retailers, wholesalers, and the government in Japan and overseas as well as by development of new products.

Perspective of product development

In order to meet the new needs of consumers, we will expand the functions and range of OTC medicines by developing products such as drugs for lifestyle-related diseases, lifestyle drugs and so on.

We will revitalize the existing OTC medicines market including traditional medicines by review of the approval standards, relaxation of the advertising regulation and addition of new efficacy of herbal medicines.

Perspective of communication

We will promote the Responsible Self-Medication by enlightening the role of OTC medicines including contribution to medical economics through communication with all organizations and consumers involved in OTC medicines and education at school.

We will improve the value of OTC medicines by clarifying the differences between OTC medicines and health foods, etc., through providing information of efficacy and safety and further ensuring quality by addressing GMP/GQP.

Perspective of distribution channels

Under the new retail system for OTC medicines, we will consolidate closer relationship with existing retailers and wholesalers, and build a new distribution channels to drive appropriate and fair trade in all channels.

We will promote proper channel management while ensuring safety.

Perspective of globalization

We will contribute to promotion of the Responsible Self-Medication in Asia Pacific region by establishing a regional association. And we will support Japanese OTC manufacturers to expand their international business activities.

Perspective of organization

In order to realize the vision, we will establish and operate a robust organization with high mobility.

2. Environmental analysis

Understanding of environment

(1) Demand for medical care cost containment

Because of an increase in the national medical expenditure, the government has implemented a medical care system reform consisting of measures such as promotion of separation of functions between dispensing and prescribing, increase in individual payment of medical care cost by patients, encouragement of generic drugs, and reform of the late-stage medical care system for the elderly (age 75 or over). However, the universal health insurance system which is unique to Japan is beginning to experience a downturn.

One of the solutions to the problem is the promotion of the Responsible Self-Medication including encouragement of Rx-to-OTC switch. It is expected that permeation of the Responsible Self-Medication might bring suppression of the increase in national medical expenditure because of its following advantages: 1) the number of both outpatients and inpatients will decrease; 2) aggravation of lifestyle-related diseases and other diseases can be prevented. Therefore, in August 2002, the Ministry of Health, Labour and Welfare (MHLW) issued “the Vision for the Pharmaceutical Industry”, in which they referred to the importance of Self-Medication. In November 2002, MHLW also made proposals including promotion of Rx-to-OTC switch in “the interim report of the Expert Consultation for Streamlining Procedures to Approve and Examine OTC Medicine”, and thereafter many of

these proposals have been realized. Furthermore, in “the New Vision of the Pharmaceutical Industry” issued in August 2007, MHLW pointed out the importance of effective utilization of OTC medicines in developing OTC medicine markets that, as a result of further development of Rx-to-OTC switch and OTC medicines with novel efficacy, such medicines will have indications superior to those of conventional OTC medicines and meet the public needs (e.g. prevention of metabolic syndrome, skin care effects). It is believed that the government will continue to promote Self-Medication, and therefore, expectations for OTC medicines are increasing.

(2) Revision of the retail system for OTC medicines

According to Revised Pharmaceutical Affairs Law to be enforced in June 2009, OTC medicines are categorized into 3 categories depending on the safety, and the Direct OTC and Rx-to-OTC switched products are categorized into the Category 1 OTC medicines, which are required an explanation of the profile of drugs and administration guidance by a pharmacist and a face-to-face selling. In contrast, it became possible for Registered Retail Person, in addition to pharmacists, to sell the Category 2 and Category 3 OTC medicines. As a result of these environmental improvements, it is expected that development of new beneficial therapeutic categories of OTC medicines and acceleration of Rx-to-OTC switch are achieved by further ensuring quality of OTC medicines including Rx-to-OTC switched drugs, etc., through more appropriate drug administration guidance. On the other hand, we need to address the ensuring of safety by providing appropriate information to the new channels, because convenience stores and supermarkets, which have not been permitted to sell OTC medicines so far, became able to sell OTC medicines under fulfilling the requirements.

(3) Diversifying needs and recognition of Self-Medication

Although the term “Self-Medication”, which indicates the use of easily accessible OTC medicines according to proper advice of specialists such as pharmacists, is recognized by consumers, OTC industry have faced difficulty to grow the production value of OTC medicines. This might be caused by 1) existing OTC medicines are not able to meet the needs of consumers because there are not sufficient kinds of OTC medicines on the market, 2) consumers, who have interests in health and medical care, purchase health food products like the food for specified health use (FOSHU) without having a clear understanding of the differences between OTC medicines and health food /supplements. In addition, consumers can now easily obtain various information on Self-Medication such as OTC medicines they need through mass media and internet.

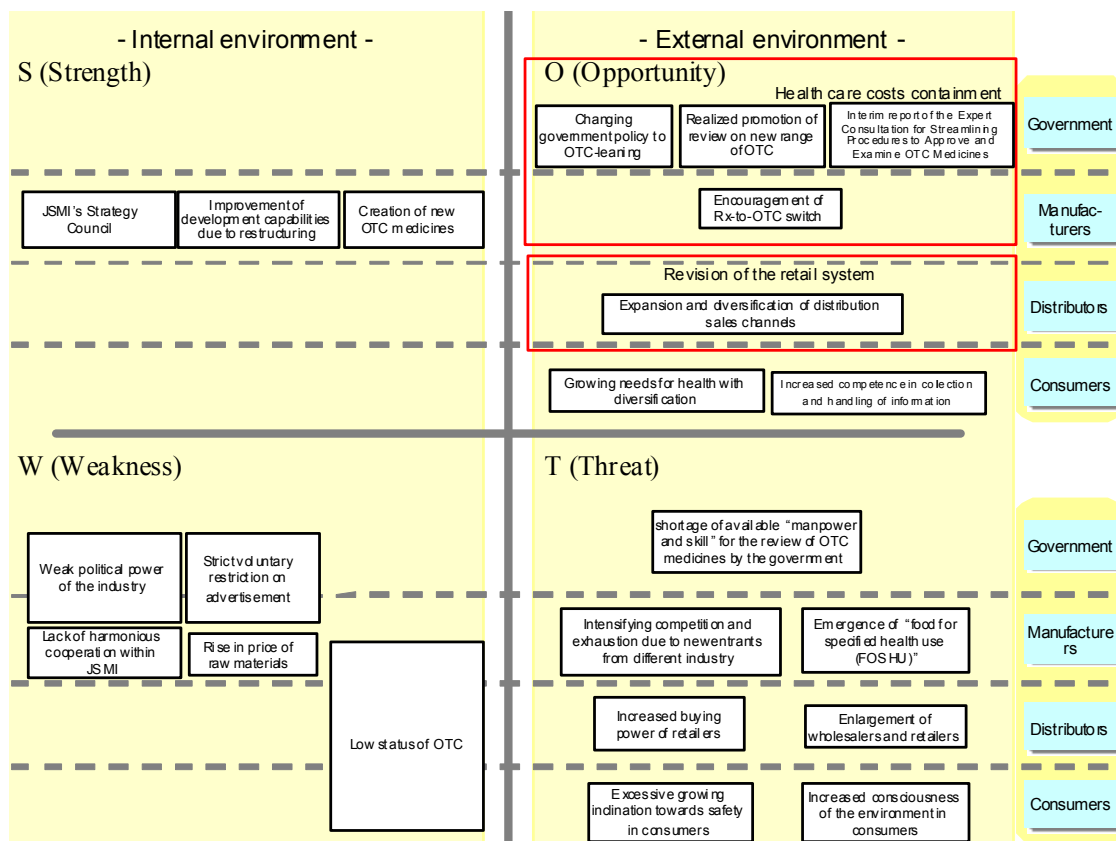
Under such circumstances, JSMI needs to fulfill the consumer’s needs to gain knowledge by appropriately providing correct information on efficacy and safety of OTC medicines,

and furthermore, to improve the position of OTC medicines through its activity.

SWOT analysis

We performed SWOT analysis on the factors having significant impact on JSMI, focusing on the above-mentioned 3 environmental factors, as shown in Figure 1, and determined the following strategic objectives:

Figure1



3. Strategic objectives

(1) Expansion of roles of OTC medicines

- *Expanding functions and range of OTC medicines*
- *Revitalization of the existing OTC medicine market*
- *Responding to globalization*

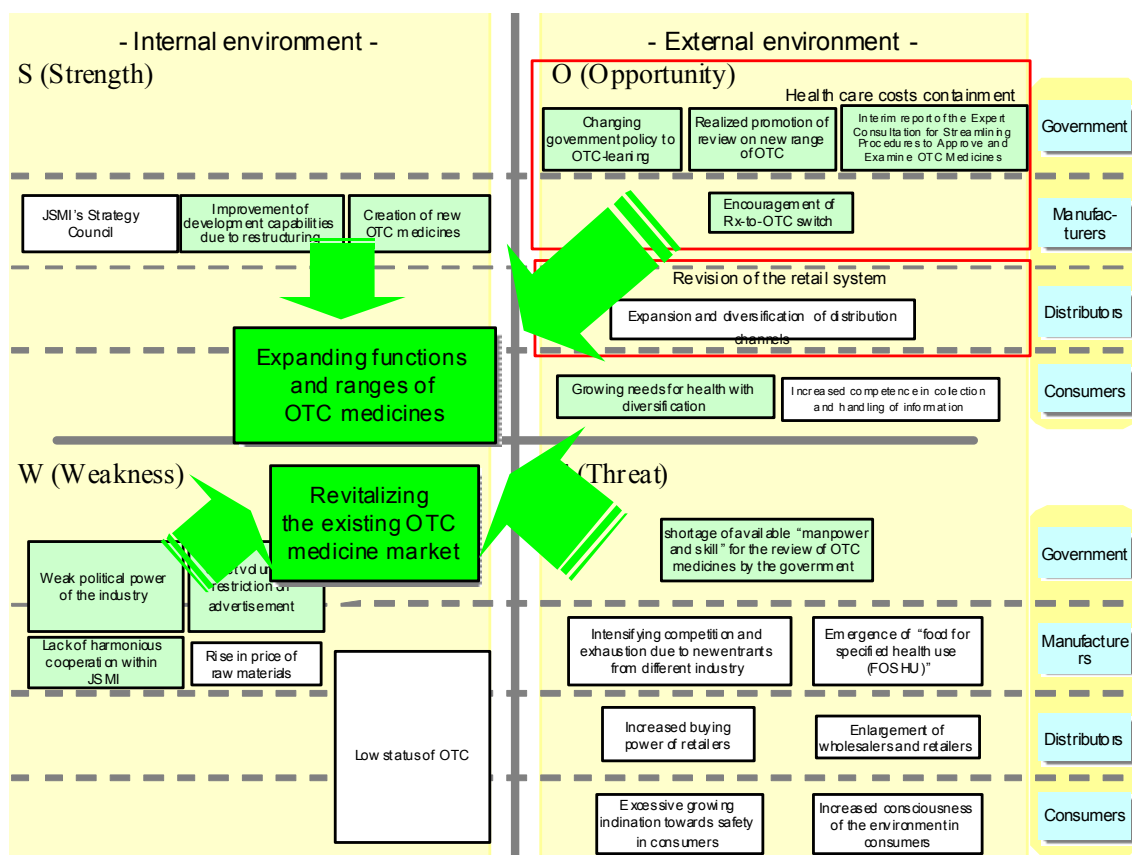
The companies which were formed as a result of the restructuring of OTC medicines industry in recent years are increasing their “capability of developing new products” by taking advantage of the enlarged company scale. Furthermore, environmental factors such as demands for “health care cost containment” and “sophisticated and diversified needs for healthcare” of consumers are expected to add impetus.

However, shortage of available “manpower and skill” for the review of OTC medicines by the government has been an obstacle for the examination of novel OTC medicines such as OTCs switched from Rx status. One of the solutions for this problem is an expansion of the approval standards for OTC medicines. This approach leads to simplify the examination tasks and to enable providing manpower for the examination of new OTC medicines such as Rx-to-OTC switch.

Advertising expressions for OTC medicines are strictly regulated by the Standards for Fair Advertising Practices of Drugs, Quasi-drugs, Cosmetics and Medical Devices as well as voluntary code in JSMI. On the other hand, such strict control causes an insufficient match to the needs of modern consumers to gain knowledge, which is one of the factors inhibiting activation of OTC medicine market. We aim to revitalize the market of existing OTC medicines by reducing undue regulations in accordance with the demands of the times. Such a review is considered to contribute to appropriate information provision to consumers.

These activities could lead to expand and strengthen the functions of OTC medicines. We also aim to build an environment for good quality Japanese pharmaceutical products to be available outside Japan.

Figure2



(2) Improvement of quality and reliability of OTC medicines

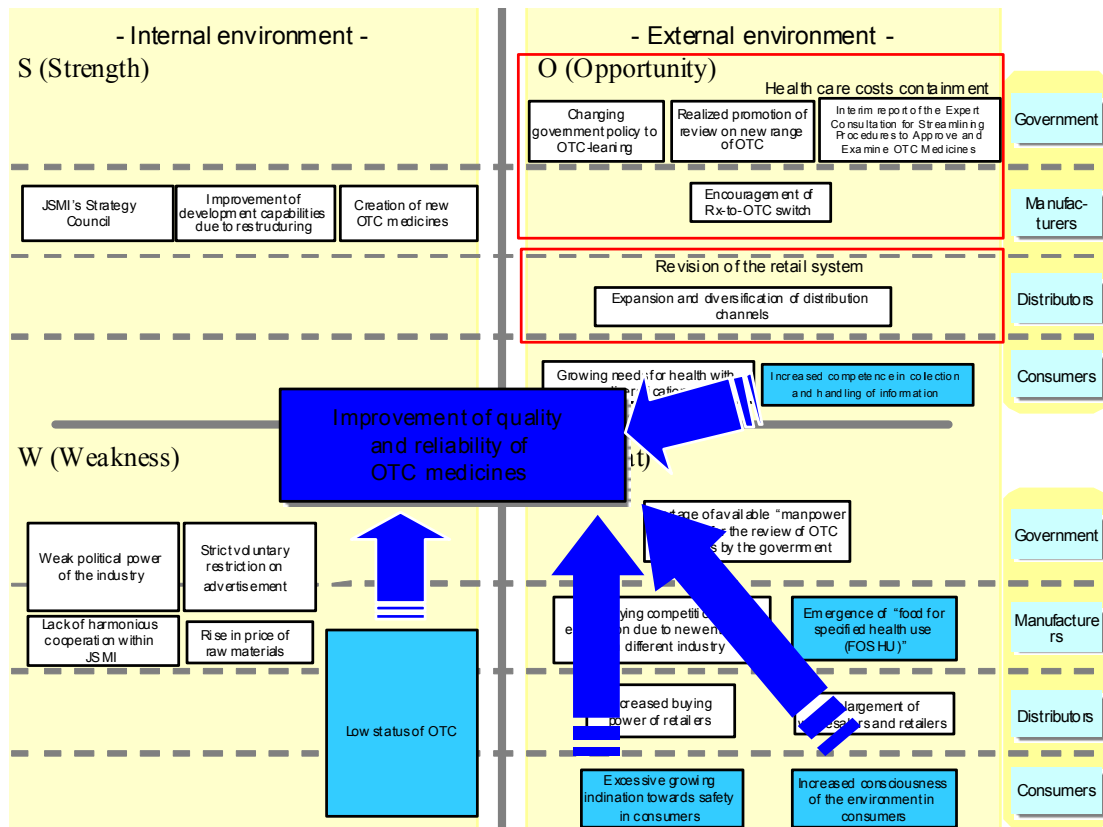
- *Striving for permeation of self-medication*
- *Enhancing value of OTC medicines*
- *Ensuring appropriate quality of OTC medicines*

OTC medicines are recognized to be positioned halfway between ethical drugs and health food typified by the food for specified health use (FOSHU), and to have lesser efficacy in comparison with ethical drugs. Although some inadequate expressions are found on the label and advertisement, recent health food claims various functions, which widely meets the consumers' needs. It seems that consumers think of them as a certain kind of substitute for OTC medicines, of which aspect of narrow territory and lower status in healthcare environment might be established. On the other hand, there is a "consumers' growing inclination towards safety", and their capability of collecting information for ensuring safety is expanding

OTC medicines are manufactured in compliance with the strict regulation such as GMP/GQP for ensuring high quality and have assured efficacy based on scientific evidence obtained from the clinical studies. We believe we are able to deepen consumers' understanding of the intrinsic value of OTC medicines, which surpass the FOSHU and

health food, by appropriately demonstrating the efficacy, quality, and safety. At the same time, we will continue to promote the Responsible Self-Medication not only through the mass media but also in the field of school education, to clarify the meanings of OTC medicines which differ from ethical drugs and to enhance the value of OTC medicines.

Figure3



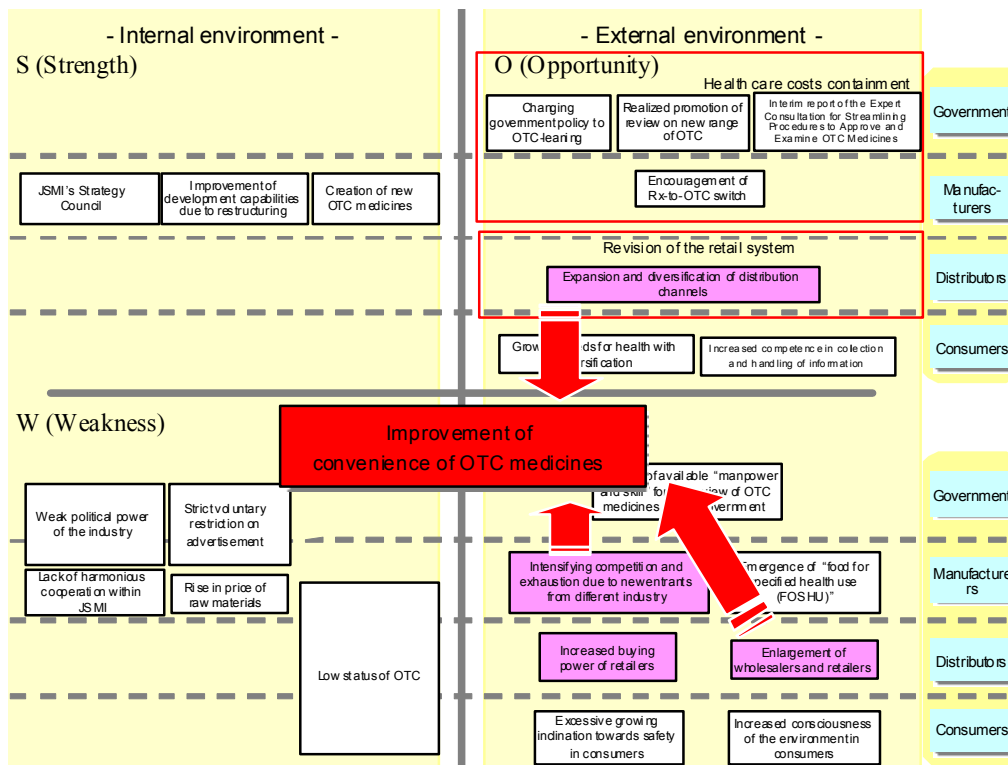
(3) Improvement of convenience of OTC medicines

- Responding to distribution channels established by the new retail system
- Ensuring safety
- Driving appropriate and fair trade

Enforcement of the new retail system for OTC medicines, which makes new entries to market, induces diversification of distribution channels of OTC medicines and convenience for consumers. In such diversified channels where only the Registered Retail Person, a registered retailer, is working instead of pharmacists in most cases, it is apprehend that only limited information and know-how on OTC medicines including their safety information could be shared. We will ensure safety by providing precise information to these new channels of retailers to prevent the increase in convenience of OTC medicines being an obstacle in ensuring safety.

On the other hand, in the market of OTC medicines, existing retailers have increased their buying power by processing restructuring and expansion more strongly than manufacturers and have strengthened their pressures of lowering supply price or such. It is worried that their pressure will exhaust OTC medicine manufacturers and negatively affect the quality and safety management of products. However, since warranty of quality and safety of pharmaceutical products is the top priority, we endeavour to maintain quality and safety while securing reasonable profits by driving appropriate and fair trade.

Figure4



The outline of the strategic objectives and Vision mentioned above is shown in Attachment 1 “Vision and strategy map of Japan Self-Medication Industry.”

4. Action plan

(1) Expansion of roles of OTC medicines

1) Expanding *functions and range of OTC medicines*

We consider that the following OTC medicines will be the targets of expanding the roles: 1) therapeutic and preventive drugs for lifestyle-related diseases, which are highly desired by consumers to improve hypertension, hyperglycemia, and hypercholesterolemia, 2) lifestyle drugs, which are not covered by medical insurance, such as appetite suppressants, drugs for erectile dysfunction, and oral contraceptives.

Because appropriate advice and encouragement to visit physicians given by pharmacists are necessary to treat the lifestyle-related diseases with OTC medicines, we aim to establish a collaboration framework among the physicians, pharmacists, and OTC medicine manufacturers through cooperation with Japan Medical Association (JMA) and Japan Pharmaceutical Association (JPA).

Building a favorable environment for convenient self-examinations for lifestyle-related diseases allows the self-medication/self-treatment for such diseases to be penetrated. We will start collaboration with other organizations to obtain approval of self-examination products for lifestyle-related diseases that are applied by blood sampling to measure blood glucose and cholesterol, and eventually aim to create such a favourable environment for both therapeutic drugs and self-examination products.

In order to promote Rx-to-OTC switch of drugs for lifestyle-related diseases and lifestyle drugs, we aim to establish the appropriate review system including relaxation of application requirements. In order to expand the marketing opportunities of OTC medicines, a multitude of applications for approval are necessary, however, insufficient man power and skill for the review in the government side has caused an obstacle.

In order to solve this problem, on the occasion of the regular meetings with the government, we will insist on the necessity of a reform of examination system in the government side, such as to focus its review on drugs for lifestyle-related diseases and lifestyle drugs through promoting simplification of other review tasks by expanding therapeutic categories of the approval standards for OTC medicines, which are classified into the application class eight (8), consisting of the largest number of applications.

We continue to support the task for Rx-to-OTC switch scheme through collaboration

with Japanese Association of Medical Sciences (JAMS) and Pharmaceutical Society of Japan (PSJ), and endeavour to switch the ingredients with immediate actions and few adverse drug reactions to the existing category of OTC medicines. Currently, it is practically essential that consent of the original manufacturer of the drug containing the candidate ingredients have to be obtained at the time of application for a novel switch. We will start negotiation with the government so that an application can be approved by the publicized documents and the results of clinical study conducted by the applicant without consent of the manufacturer.

2) Revitalizing the existing OTC medicine market

Expansion of the listed ingredients and dosage amount and review of the permitted indication/efficacy in the approval standards of OTC medicines must be effective for the revitalization of existing OTC medicines as well.

In order to fully convey the usefulness and appeal of OTC medicines, we will review the existing voluntary code of advertisement in JSMI so that advertisement can be better understood by the consumers. We also aim to expand the range of data on clinical studies that can be used for promotion and advertisement for satisfying the growing needs of consumers to gain knowledge, to the extent of documents attached at the time of application for reexamination and reevaluation, PMS data, and the results of clinical studies conducted after approval.

Because of the changes in regulations, indications of traditional medicines have been translated into general expressions which are mediocre and not appealing. We will try to properly express the original attractive efficacy of traditional medicines. Because traditional medicines contain many types of herbal component, we aim to build a database which is compiled with pharmacological actions and efficacy of each herb and to establish an environment in which practical discussion to obtain attractive efficacy can be conducted.

3) Responding to globalization

For enlightening the Responsible Self-Medication through Asia Pacific region and nurturing Japanese OTC medicines to the internationally worth level, , we, as the leader of the region, will formally establish the regional association, Asia Pacific Self-Medication Industry, APSMI with initiative by JSMI and aim to solve problems of pharmaceutical affairs which have been obstacles in the region.

In order to provide the members with information and benefits obtained from the activities of APSMI and WSMI, we will introduce actions such as publication of information papers.

(2) Improvement of quality and reliability of OTC medicines

1) *Striving for permeation of self-medication*

In order to increase the recognition rates of OTC medicines and Self-Medication to at least 50%, we will continue to make our efforts through publicity and periodical publication for public relation. For deepening public understanding of OTC medicines and Self-Medication, we will collaborate with Ministry of Education, Culture, Sports, Science and Technology, MEXT, educational institutions and JPA in terms of education on medicines in the field of the school education to permeate and improve the “Yaku-Iku”, education for promoting proper use of medicines.

We have been conducting a study on the effect on overall medical economics including medical insurance in case that antihypertensive drugs become OTC medicines, which is under examination. In order to evaluate the contribution of Self-Medication to society, we will expand the scope of this study to other therapeutic categories for further public relations activities.

2) Enhancing value of OTC medicines

As mentioned above, to fully convey the usefulness and appeal of OTC medicines, we will review the existing advertising regulations so that advertisement can be better understood by the consumers. We also aim to expand the range of data on clinical studies that can be used for promotion and advertisement to meet the growing needs of consumers to gain knowledge of OTC medicines, to the extent of documents attached at the time of application for reexamination and reevaluation, PMS data, and the results of clinical studies conducted after approval will be permitted.

3) Ensuring appropriate quality of OTC medicines

In order to gain the trust of consumers for OTC medicines, it is necessary to ensure the invariably high quality. Currently, the quality of OTC medicines at the time of purchase is warranted by complying with GMP/GQP. We will proceed with investigation to establish the voluntary standards by the industry to expand the range of quality warranty, so that traceability of raw materials and warranty of shelf life after opening.

However, we will not only aim to expand the range of quality warranty but also actively try to reduce the amount of carbon dioxide emitted at the time of manufacturing.

(3) Improvement of convenience of OTC medicines

1) Responding to distribution channels established by the new retail system

Even if channels and qualified persons for selling are expanded under the new retail system, pharmaceutical companies have the further responsibility to provide safety information, and therefore, we will provide safety information to all channels more actively. Currently, information on products is mainly provided by the Medical Representatives and wholesalers’ Medical Marketing Specialists. We will start to establish a system by which safety information not only on the products of member

companies but also on all OTC medicines will be provided uniformly via JSMI website because information provision from person to person seems to face the limit due to expansion of channels. In addition, in collaboration with the self-medication database center and by utilization of IT, we aim to expand and enrich the provision of product information such as package inserts and written instructions.

2) Ensuring safety

Safety is warranted by the quality and proper use of the product. Regarding package inserts which convey proper use and precautions for dosing instruction, we will complete a guide for preparing package inserts under the new retail system as a reference to preparing the package inserts by each company. We will also discuss the content of information provided to specialists such as pharmacists and the Registered Retail Person.

3) Driving appropriate and fair trade

We will review traditional business customs, aspire to actualize reasonable distribution with less burden on the environment such as returns, perform impartial and fair trade through any existing and new channels, and aim to consolidate the transparent industry which is understood and accepted by consumers.

(4) Enhancement and expansion of functions of JSMI

1) Strengthening organization of JSMI

In order to realize the Vision mentioned above, JSMI needs to convert itself from a community into a functional organization for achieving goals and to reinforce and enhance the organization.

To increase the member of the organizations which agrees to the Vision and works together will contribute greatly to realize the Vision. In order to do so, we offer the Vision of JSMI, review the requirements of admissions to JSMI, ask manufacturers related to OTC medicines which deal with items such as raw materials, formulation, and packages to participate, and accept the admission to be members of the association from mass communication and sales organization.

We will ask other organizations related to OTC medicines to cooperate for the establishment of a council, and we will manage administrative operation of such council.

2) Enriching the annual general assembly

As its membership and range are expanded, JSMI will encounter increased demands from members. Taking this into account, we will review the current framework of the general assembly and convert it into a big event where 1) reporting by subcommittees of

each committee and other events will also be held in addition to the resolution and report of the conventional general assembly, so that each member company can easily obtain information it wants, and 2) attractions will be included, such as the announcement of the self-medication grand prize in order to become attractive one that mass communication will focus on.

3) Reinforcing functions including committees' activities

We will clarify and rearrange the current roles and positioning of the JSMI's Strategy Council, Board of the Directors meeting, and each committee, and conduct overall review of the organizational management in order to establish an effective operation system in which each committee can perform activities in cooperation as a functional organization to achieve goals.



Activation Vision of OTC medicine industry (2009-2014)

Vision

In order to contribute to people's health, we respond to environmental changes such as aging society with declining birthrate and predicament of health insurance finance, and create new sound market for OTC medicine as well as revitalize the existing market by expansion of the roles and improvement of the quality of self-medication. We aim to develop the industry with production value of more than 1 trillion yen.

Strategic objectives

Contribution to people's health

Expansion of roles of OTC medicines

Improvement of quality and reliability of OTC medicines

Improvement of convenience of OTC medicines

Strategy map

Expanding functions and range of OTC medicines

Utilization of new Rx-to-OTC Switch
Lifestyle-related diseases
Lifestyle drugs

Revitalizing the existing OTC medicine market

Application of traditional medicines
Relaxation of advertising expressions
Expansion of the reference frame of approval
Review of standard indications

Responding to globalization

Support for expansion into overseas markets
Sharing of overseas information
Improvement of global presence

Striving for permeation of self-medication

Promotion of OTC medicines
School education
Awareness promotion to make a contribution to medical economics

Enhancing value of OTC medicines

Provision of efficacy and safety information

Ensuring appropriate quality

Complying with GMP/GQP requirements

Responding to distribution channels established by the new retail system

Close cooperation with existing retailers and wholesalers
Responding to new distribution channels

Ensuring safety

Provision of appropriate information

Driving appropriate and fair trade

Enhancement and expansion of functions of JSMI

Strengthening organization of JSMI
Review of membership requirement
Cooperation with related organizations

Reinforcing various functions including committees' activities
Review of organizational management
Establishment of APSMI project

Enriching the annual general assembly
Participation and information provision of JSMI as a whole
Co-hosting of events