INTERNATIONAL FORUM on Self-Medication was Held, Filled to Overflowing

On May 10, to celebrate its 20th anniversary, JSMI held an international forum on self-medication at Tokyo Kaikan, which was packed to its fullest capacity with some 310 participants from the competent authorities, academia, business sectors, mass media and the JSMI member manufacturers.

The forum consisted of two parts, under the theme "Self-Medication Policy around the World – What We Can Learn from the World", inviting four current and former regulators from home and abroad.

Part 1 was for the keynote speeches under the theme "Self-medication – Current situation and future perspective" and Part 2 for a panel discussion focused on further development of self-medication in each region.

JSMI Chairman Ibe, in his welcome address, said that many industrialized countries look at self-medication as the key element within their healthcare systems and that he sincerely wished the forum to provide a golden opportunity for JSMI to be able to know the global trend of self-medication, to promote self-medication in Japan and to eventually revitalize the market of nonprescription medicines.
Countering these social and economic tendencies which favor Rx-to-OTC switch is the heightened concern for safety, fueled by recent high profile reports of unanticipated adverse effects from drugs in the prescription market. In addition, the cost of FDA approval of an Rx to OTC switch must be balanced by the expected return on such an investment.

James Copping, Principal Administrator, Competitiveness in Pharmaceuticals Unit, DG Enterprise and Industry, European Commission, said as follows:

In recent years Europe has witnessed major changes in the legislative and policy framework governing self-medication products. The chief cause of these changes has been a general recognition that Europe would benefit from enhancing the competitiveness of the self-medication sector, not only economically but in terms of public health. There has been a growing demand by patients for a greater say in their own treatment decisions. Self-medication can contribute to meeting this demand while easing pressures on hard pressed medical services.

The focus of this debate has been the recent G10 Medicines initiative. In 2001 the Commission set up the small high level group (G10 Medicines) to examine ways to reverse the decline in the competitiveness of the European-based industry in line with our public health objectives. As a consequence of these twin objectives, the Group was chaired jointly by the then Commissioner for Enterprise, Mr. Liikanen, and the Commissioner for Health and Consumer Protection, Mr. Byrne.

The Group concluded that a competitive non-prescription sector was important "to meet public
to empower both healthcare professionals and the public, and to give them greater choice and wider access to medicines. The concept of the "expert patient" is being strongly developed. Modernising the NHS is about empowering patients, and an important part of this is to enable them, so far as possible, to manage their own health care. The UK Government is committed to making more medicines available over the counter – though patient safety is always the prime consideration in any decision to switch a medicine to OTC. There are now a wide range of medicines available OTC in the UK – including nicotine replacement therapy, emergency hormonal contraception and, most recently, statins.

UK Government policy is positioned firmly within the initiatives taken at European level, notably the G10 medicines initiative and the recent Review of EU Medicines legislation. Plans are currently under way in the UK both to continue to programme of switches of medicines to OTC, and to implement the EU legislation clinical trials have been undertaken. The UK sees a competitive and successful OTC market as beneficial to the national economy, to the pharmaceutical industry and to the public's health.

Tatsuo Kurokawa, Ph.D., Councillor for Pharmaceutical Affairs, Ministry of Health, Labour and Welfare said as follows:

The competent authorities place an emphasis on securing the best benefits of patients and populace. In the healthcare administration, safety has priority over anything else. In the environment surrounding the nonprescription medicines, drawing a distinction among the roles played by stakehold-
The panel discussion was carried out chaired by Akira Uehara, JSMI Vice Chairman, focusing on the following three theses:

1: The driving force for Rx-to-OTC switches

i) In the U.S. and Europe as well, further promotion of self-medication is ardently expected in the light of the rapidly graying society, medical care and medical insurance systems that sustain those aging populations, and furthermore, increased interest of consumers in their own responsibilities.

ii) Consumers, in particular, by changing their lifestyles with help of medicines designed for improvement of life, place a strong emphasis on prevention of life-style related diseases which accompany the aging. In this context, consumers expect Rx-to-OTC switches to play a key role.

2: Assurance of safety and enlightenment of consumers - Criteria for deciding Rx-to-OTC switches

i) Distribution systems long established in each
country should be valued when deliberation is given as to whether it should be mandatory or not to seek professional advice at times of purchases of medicines. The first priority should be “assurance of safety for consumers”.

ii) There are some factors to be taken into consideration in order to materialize assurance of safety.

A: Active ingredients which are truly valuable to consumers should be selected.

B: Both safety and efficacy of the products are essential. The pharmaceutical manufacturers should verify them using the state-of-the-art technologies of medical and pharmaceutical sciences. To utilize them, the means to provide the information shall be established and offered so that consumers can obtain, at any time they may wish, the information written in such terms as understandable by and agreeable to general consumers.

C: Consumers, as the purchasers of the medicines, shall be fully engaged in the management of their own health based on the correct understanding of the information on the medicines and in the use of OTC medicines. To support the consumers, the manufacturers of the pharmaceuticals should continue to make every effort to implement an enlightenment campaign on medicines, targeting at a wide spectrum of people including students of schools.

3: Dietary Supplements and Healthcare

The legal status of dietary supplements varies considerably from country to country. It is expected to see exchanges of information and opinions on herbal medicinal products and dietary supplements henceforth between Europe and Japan.

Yasunori Tsuruta, JSMI President gave a closing address as follows:

It is significant that the forum has enabled the audience to recognize the institutional differences between the countries and regions and, in particular, to understand the different ways of thinking.

In order to practice self-medication, it is prerequisite to supply the pharmaceutical products which meet the needs of each nation and society. In this context, the role our industry has to play is extremely important. Our industry is anxious to learn how self-medication has been practiced in the U.S. and Europe. Likewise, I would hope that other countries might be able to learn something from Japan. I am pleased to declare the closing of the forum by commending the forum was highly informative.
<table>
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<th>FOCAL POINTS of the Revised Pharmaceutical Affairs Law</th>
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<td>1: Sweeping reviews of the Approval and Licensing Procedures</td>
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<td>Introduction of Manufacturing Approval Procedures in line with an international consistency with a view to shifting from Manufacturing Approval to Manufacturing/Marketing Approval</td>
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The eye-catchers are the sweeping reviews of the approval and licensing procedures, namely, a shift from manufacturing approval to manufacturing/marketing approval, and the improvement of post marketing surveillance, namely, introduction of GVP and GQP.

With the implementation of manufacturing/marketing approval procedures, companies are encouraged to be fully prepared for the shift from "conventional product liabilities" to "both manufacturing and distribution responsibilities" in line with an international consistency.

Other than those amendments, revisions of the procedures regulating biologically derived pharmaceutical products and medical devices are one of the main pillars of the revised pharmaceutical affairs law.
THE GIST of Newly Introduced Measures based on the Revisions of the Pharmaceutical Affairs Law

- Designation of prescription (only) medicines
- Guidelines on the utilization of registry for drug substances (Drug Master-File)
- Survey on GMP compliance
- Procedures, to be initiated by medical institutions/physicians, to conduct clinical trials on drugs
- Procedures to file reports on adverse drug reactions directly from medical institutions
- Additional safety measures reflecting the characteristics of biologically derived pharmaceutical products

The above gist is considered either to be relevant to or to affect nonprescription medicines.

New JSMI President, Yasunori Tsuruta, Takes Office

At the JSMI 143rd Board of Directors Meeting held on January 14, the attendees unanimously elected Yasunori Tsuruta, former Councillor for Pharmaceutical Affairs, Ministry of Health, Labour and Welfare, to the presidency. Tsuruta released an inaugural address as follows:

It is my great honour that I have been elected to

President
Yasunori Tsuruta
the second JS MI President after Mr. Shinji Nitta, the first President and now Honorary Adviser. Being sensible of my heavy responsibilities, I will do my best to fulfill my duties and, in this context, may I cordially request all of you here to support me.

Taking up this occasion, I wish to commend the past chairmen and the first President for their contributions to the development of both the OTC industry and JS MI.

Today, the OTC industry in Japan finds itself positioned in the environment where the aging has been rapidly progressing at the speed unparalleled in the globe. Curtailment of medical expenses has resulted in sluggishness in the prescription medicines sector alike, which in turn happens to be with the nonprescription medicines on the tapering path. On the other hand, however, it is in the pharmaceutical area that new and advanced technologies can be expected to emerge and international harmonization can make great progress. There has not been any period in the past such as the past several years which witnessed the topics and issues on nonprescription medicines were so hotly discussed in the framework of regulatory affairs. I believe this phenomenon clearly indicates that the awareness of the general public towards their own health is quite high. In other words, this shows an optimistic aspect of potential growth of the business notwithstanding the lingering severe circumstances surrounding the nonprescription medicines sector. In this sense, I am glad to tell myself that my new assignment is really challenging and exciting.

Promotion of self-medication will, I believe, enhance recognition by the populace of the role played by the nonprescription medicines and social contributions made by them. Although I will not deny the importance of creating new nonprescription medicines through Rx-to-OTC switches, I want to attract your attention to the many products which have been used for a long period of time and valued by the consumers. I do want to pour my efforts into promoting and utilizing such products which might be called a national asset.

Now allow me to mention some tasks JS MI has to tackle right now: Facilitation of smooth enforcement of the revised Pharmaceutical Affairs Law from this April, compliance with the revisions of the retailing regulations on non-prescription medicines; Steady materialization of the Recommendations given in the "Interim Report on Role of Over-The-Counter 'OTC' Medicines in Self-Medication" compiled by "Expert Consultation for Streamlining Procedures to Approve and Examine OTC Medicines" issued in 2002; And full support for ensuring a success of the 15th WSMI General Assembly slated for June in Switzerland.

In the capacity of the JS MI President, I am determined to wrestle with various tasks and issues, fully supporting the Chairman Ibe. Needless to mention here, the activities of the JS MI member manufacturers are the pillars of the JS MI various activities, part of which is shouldered by the JS MI Secretariat represented by its President.

May I close my address by wishing that all the member companies continue to devote themselves in furtherance of responsible self-medication and to extend their support and collaboration to the Secretariat as much as they have done so far.
Development of New Pharmaceutical Products Containing Western Herbs

Strategic Alliance Conference for Business Promotion (SACBP), since its establishment in June 2004, has been discussing the issue, "Enlargement of functions of OTCs", focusing on development of new Rx-to-OTC switches, OTCs with new indications, OTCs in new therapeutic areas, and the like. SACBP has recently arrived at a conclusion that, "without submission of an actual application dossier for a product approval", creation of OTCs in a new genre would never be materialized. The herbs used in the foreign countries as OTCs would be classified as "CLASS 1" in Japan, if and when applied for an approval, for the reason that there have been no precedents. In addition, such an application would be required to submit massive substantiation. SACBP has further agreed to explore ways for obtaining approvals for OTCs in the new areas so far untouched in Japan. With the concurrence on the exploration granted by the 145th Board of Directors Meeting held on April 18, a notice "On Development of Pharmaceuticals using Western herbs" was already circulated among the member manufacturers.

The notice details the formation of "HERB PROJECT" (consisting of representative members from Pharmaceutical & Regulatory Affairs Committee, Products Safety Committee, Herbal Medicinal Products Committee, and International Affairs Committee) under SACBP, which will conduct surveys on the actual use of herbs as a single ingredient of OTCs in Germany, Italy, United Kingdom, France and USA (used as dietary supplements). The findings of the surveys will be compiled into a table, based on which the development will progress. Notably, what "HERB PROJECT" plans to tackle is an entirely new initiative to expedite early approvals or to expedite "making ground rules which will enable to obtain approvals for enlarged functions of OTCs".
Public Affairs Committee, as part of its campaign for enlightenment on self-medication, has recently edited two kinds of videotapes and distributed them to the parties concerned.

The first videotape is:

- "What is Self-Medication? : Your health management and nonprescription medicines" intended to be used for senior high school students

The contents in the videotape are designed to enable high school students understand the basic concept of self-medication and the correct use of nonprescription medicines so that students are motivated to practice self-medication. The videotape is intended to be utilized for health, physical education, health guidance, and ordinary curriculums at the schools. The Committee expects the videotape contributes considerably to enlightenment on self-medication together with those booklets titled "Self-Medication and Medicines" produced in last summer for use by senior high school teachers throughout the country.

The 20-minute videotape has the following contents:

- Health Management and Self-Medication
  An introduction to the concept of self-medication which properly uses nonprescription medicines based on one's own decision, utilizing one's information and knowledge to cope with the social changes relating the health management

- Nonprescription Medicines and Self-Medication
  To share basic knowledge such as the classification between prescription and nonprescription medicines, and adverse drug reactions; How to practice self-medication by properly using nonprescription medicines primarily based on one's own decision drawn from a variety of health information and, if circumstances require, on the proper advice of the healthcare professionals

- Correct Use of Medicines
  With a check list of YES or NO, to review actual experiences of the viewers so as to teach them how to correctly use medicines
• Reports on the actual purchases of medicines at pharmacies
To have senior high school students who have less experiences in purchasing medicines by themselves go to pharmacies to purchase medicines talking to pharmacists and submit the reports of their firsthand experiences at pharmacies

The Committee distributed the videotapes together with copies of the "Guidebook for Teachers" which includes a suggested curriculum plan and materials for teachers to use to 1,000 schools throughout the country at the beginning of March in the hope these enlightening aids can be used from the new school term.
The Committee plans to deliver the similar materials to additional 500 senior high schools also next year.

The second videotape is titled as follows;

• “How to correctly and wisely practice Self-Medication : Nonprescription medicines that maintain your health” intended to be used for the consumer
This is a revised version of the first one with a partial revision made such as a change from "Reports on the actual purchases of medicines at pharmacies" to "Reports on interviews with one's family pharmacy and pharmacist".

Also at the beginning of March, the Committee distributed them to 250 Consumer Centers and 150 regional pharmaceutical associations through Japan Pharmaceutical Association, so that they can be utilized at the assemblies for the consumers hosted by the regional pharmaceutical associations. A plan calls for providing the videotapes to health centers next year for enhancing the consciousness on self-medication among the consumers. The JSMI member manufacturers are encouraged to fully utilize those videotapes on such occasions as presentations on their products.