

# **APSMI NEWSLETTER**

## **July 2024**

### **GSCF/APSMI/TSMIA Joint Congress 2024**



*Congress Website is Scheduled to Open on 1<sup>st</sup> August*

<https://bangkok2024.tsmia.or.th/>

#### **Contents:**

##### **Event:**

- **GSCF/APSMI/TSMIA Joint Congress 2024**

##### **World Topics:**

- **WHO: Collaborative Registration Procedure (CRP) 11th Annual Meeting Materials Released**
- **Global: GSCF published RWE/RWD Playbook**
- **Europe: AESGP relaunched OTC Ingredient Dictionary**
- **UK: The General Pharmaceutical Council ( GPhC ) plans to change pharmacist-only medicines to consumer choice**
- **UK: PAGB lobbying new government to promote self-care policies**
- **Europe: STADA releases Health Report 2024**
- **US: FDA issues guidance on "OTC monograph submissions in electronic format"**
- **US: FDA issues guidance on "OTC monograph submissions in electronic format"**
- **Chinese Taipei: TSCIA co-hosted "Win in Pharmacy Workshop"**
- **China: The Japan Chamber of Commerce in China published White Paper 2024**
- **Japan: 49th ICH Report Meeting Held**
- **India: The 7th India - Japan Medical Products Regulatory Symposium**
- **Vietnam: Vietnam Government established the National Steering Committee for the development of Vietnam's pharmaceutical industry**



## ASIA-PACIFIC SELF-MEDICATION INDUSTRY

ITOHPIA IWAMOTOCHO 1-CHOME BLDG. 4<sup>TH</sup> FLOOR  
1-8-15, IWAMOTOCHO, CHIYODA-KU, TOKYO 101-0032, JAPAN

### Event

#### GSCF/APSMI/TSMIA Joint Congress 2024

Please register and book accommodations via the website.

However, the following persons should apply directly to TSMIA (at [tsmia.otc@gmail.com](mailto:tsmia.otc@gmail.com))

without registering via the website:

- a. Those eligible for Complimentary Registration
- b. Those who are invited to stay for free

Date: 13 – 15 November 2024

Venue: The Athenee Hotel, Bangkok

61 Wireless road (Witthayu)Lumpini, Pathumwan, Bangkok 10330 Thailand

<https://www.marriott.com/en-us/hotels/bkkla-the-athenee-hotel-a-luxury-collection-hotel-bangkok/overview/>

	Day 1	Day 2	Day 3
	13-Nov-24	14-Nov-24	15-Nov-24
AM		9:00 - 12:30 Conference	8:00 - 13:30 Conference
Lunch		Lunch	Lunch
PM	15:00 - 17:00 Digital Health Workshop	13:30 - 18:00 Conference	
Dinner	18:00 - Welcome dinner	18:30 - Gala Dinner	

- Board Meetings are to be held on 13 November 2024.

APSMI BM: 09:00 – 12:00

GSCF BM: 13:30 – 17:30

### World Topics

#### **WHO: Collaborative Registration Procedure (CRP) 11th Annual Meeting Materials**

##### **Released**

Presentation Materials of the 11th Annual Conference of the Collaborative Registration Procedure (CRP), held in Doha, Qatar on December 11-13, 2023, have been published online.

The annual conference on the Collaborative Registration Procedure (CRP) is held to support the rapid domestic registration of prequalified medicines, vaccines, in vitro diagnostics (IVDs), and products approved by "stringent regulatory authorities (SRAs)".

The 11th annual conference, held in a hybrid format, was attended by 475 people from government agencies and 13 industry associations and companies from 57 countries, including Japan.

11th Annual Conference Information & Presentation Materials:

<https://indico.un.org/event/1008139/>



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### **Global: GSCF published RWE/RWD Playbook**

In July 2024, Global Self Care Foundation (GSCF) published a Playbook on the use of RWE/RWD in the consumer health field.

GSCF will hold a webinar on the Playbook on 12<sup>th</sup> September 2024 as follows:

Date and time: 13:00-14:00, 12 September 2024 (CET)

URL(TEAMS):

[https://teams.microsoft.com//meetup-join/19%3ameeting\\_YzRkYTJmNDMtY2RiNi00ODQ4LTg5MTktOGE4ZjkYzM1Mjcx%40thread.v2/0?context=%7b%22Tid%22%3a%22456b82b4-666a-4779-96db-7221edc5d79b%22%2c%22Oid%22%3a%2281343c50-6928-474c-8a7e-87ae8d327cd6%22%7d](https://teams.microsoft.com//meetup-join/19%3ameeting_YzRkYTJmNDMtY2RiNi00ODQ4LTg5MTktOGE4ZjkYzM1Mjcx%40thread.v2/0?context=%7b%22Tid%22%3a%22456b82b4-666a-4779-96db-7221edc5d79b%22%2c%22Oid%22%3a%2281343c50-6928-474c-8a7e-87ae8d327cd6%22%7d)

The playbook is available at the following share point:

[https://apsmi01-my.sharepoint.com/:f/g/personal/k\\_masuda\\_apsmi01\\_onmicrosoft\\_com/EvGcEaDQ-OJlpDh-Xy8semMBj1mAW\\_KsTzKFwi8WKhCXjg?e=A59Caa](https://apsmi01-my.sharepoint.com/:f/g/personal/k_masuda_apsmi01_onmicrosoft_com/EvGcEaDQ-OJlpDh-Xy8semMBj1mAW_KsTzKFwi8WKhCXjg?e=A59Caa)

### **Europe: AESGP relaunched OTC Ingredient Dictionary**

The Association of the European Self-Care Industry (AESGP) has resumed the operation of its temporarily suspended OTC Ingredient Dictionary.

The new dictionary covers 269 ingredients and allows users to search the registration status in 30 European countries.

OTC Ingredient Dictionary: <https://otc.aesgp.eu/> \*No ID or password is required.

The video and materials from the information session held online on 2 July are available below.

On-demand video (English): <https://vimeo.com/974109384/4cbcf713a2>

Information session materials (English):

[https://mcusercontent.com/cb67e176a005eff58acf6efbf/files/8ff93085-f533-1bef-9052-2944e9301948/2024\\_07\\_01\\_OTC\\_Directory\\_Info\\_Session.pdf](https://mcusercontent.com/cb67e176a005eff58acf6efbf/files/8ff93085-f533-1bef-9052-2944e9301948/2024_07_01_OTC_Directory_Info_Session.pdf)

### **UK: The General Pharmaceutical Council ( GPhC ) plans to change pharmacist-only medicines to consumer choice**

On 20 June 2024, the UK regulatory authority, the General Pharmaceutical Council ( GPhC ), published a "Statement on self-selection of pharmacy medicines", announcing that it would



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be changing its policy to allow consumers to make their own selection of pharmacy medicines ("P" medicines) which are prescribed for sale under pharmacist supervision.

The GPhC statement is available at the following URL:

<https://www.pharmacyregulation.org/about-us/news-and-updates/statement-self-selection-pharmacy-medicines>

### **UK: PAGB lobbying new government to promote self-care policies**

The Consumer Healthcare Industry Group in UK (PAGB) is lobbying the new UK government to promote self-care policies and has published the results of its annual Self-Care Census to mark International Self-Care Day on 24 July.

● **July 15:** Submitted a letter to the new administration requesting support for self-care policies

● **July 19:** PAGB sets six priorities for the first 100 days of the administration

- ① Primary care services provided by community pharmacists, with referrals to secondary care where necessary
- ② Help users find certification information and manage self-treatable conditions
- ③ Helping people access trusted self-care advice
- ④ Self-care for minor illnesses and the role of pharmacists as knowledgeable healthcare professionals should be covered by the end of secondary education.
- ⑤ Leveraging the collaborative research already undertaken by DHSC, MHRA and industry (led by PAGB) to publish an update on expanding patient access to OTC medicines for indications and categories identified as suitable for reclassification;
- ⑥ Representing the OTC sector on the Life Sciences Council through the Consumer Healthcare Association PAGB

These letter and reports are available at PAGB website:

#### **PAGB News Release:**

<https://www.pagb.co.uk/news/>

### **Europe: STADA releases Health Report 2024**

In July 2024, STADA released the Health Report 2024, which summarized the results of a consumer opinion survey in Europe (17 pages in total).

The survey was conducted on 46,033 people from 23 European countries.

The report is available at the following URL:

[https://www.stada.com/media/9097/stada\\_health-report\\_en\\_final.pdf](https://www.stada.com/media/9097/stada_health-report_en_final.pdf)



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### **US: FDA issues guidance on "OTC monograph submissions in electronic format"**

On 22 July 2024, the US FDA issued guidance for industry on electronic submission of monograph OTC drugs .

This guidance explains how to use the CDER NextGen Portal , an electronic submission portal, and how to use the OTC Monographs@FDA portal , which allows the general public to view OTC monographs and allows applicants to provide information .

CDER will hold an information session on electronic drug applications, including OTC drugs, on 12 September.

This guidance is available at:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-over-counter-monograph-submissions-electronic-format>

Information session registration site:

<https://www.fda.gov/drugs/news-events-human-drugs/electronic-drug-registration-and-listing-edrls-using-cder-direct-2024-09122024>

### **Chinese Taipei: TSCIA co-hosted "Win in Pharmacy Workshop"**

Taiwan Self Care Industry Association (TSCIA) co-host a "Win in Pharmacy" Workshop on July 19 which the key players from OTC industry and pharmacy chain stores have a brilliant conversation to identify the opportunities to support the consumers for better self care!

This workshop aims to explore the changes in the current pharmacy business model, and provide participants with in-depth discussions and sharing of industry status and trends.

Post pandemic, consumers become more proactive in managing their own health. While pharmacies are the first-line health care to support the consumers need. The conversations highlight both OTC industry and pharmacies need more innovations in products and service via utilizing digital and capability building in people.

We expect to create the value to the society through the end-to-end collaboration between OTC industry and pharmacy.



**China: The Japan Chamber of Commerce in China published White Paper 2024**

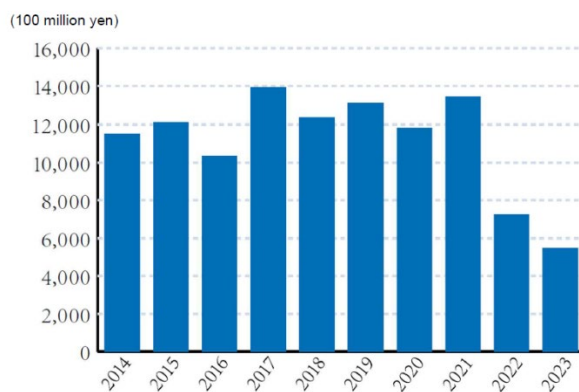
On July 10, 2024, the Japan Chamber of Commerce in China held a press conference for the "China Economy and Japanese Companies 2024 White Paper" at the Chang Fu Gong Hotel, Beijing, with approximately 40 members of Japanese, Chinese, and international media in attendance.

As in previous years, Japanese and Chinese versions have been created, with a total of 234 pages, with odd-numbered pages in Chinese and even-numbered pages in Japanese.

Requests in the pharmaceutical field are listed on pages 212 and 214.

In addition, this year's Executive Summary is available in English, which includes a look at the annual trends in Japanese investment in China, showing that investment has fallen sharply since peaking in 2021.

Figure 1: Japan's Investment in China



Note: Figures for 2023 are preliminary.

Source: Ministry of Finance

This white paper is available at:

<https://www.cjcci.org/detail/576/576/4679.html>



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### **Japan: 49th ICH Report Meeting Held**

On 26 July 2024, a webinar was held to provide an immediate report on the contents of the ICH Meeting held in Fukuoka in June 2024, and information on the revision status of each guideline was provided.

Among these revised guidelines, the stability guidelines Q1/Q5C in particular are scheduled to be completely revised, and OTC drugs will also be included in the scope of the revision.

The revision schedule is scheduled to reach Step 1 (public comment period) in November 2024 and Step 4 (guideline finalization) in November 2025.

Presentation materials are available below (in Japanese).

<https://www.jpma.or.jp/information/ich/sokuji/index.html>

### **India: The 7th India - Japan Medical Products Regulatory Symposium**

The 7th India - Japan Medical Products Regulatory Symposium was held in New Delhi, India on July 10, 2024. The symposium program and all presentation materials are available on the PMDA website.

PMDA Website:

<https://www.pmda.go.jp/int-activities/symposia/0147.html>

### **Vietnam: Vietnam Government established the National Steering Committee for the development of Vietnam's pharmaceutical industry**

On July 23, 2024, the Vietnam Government announced the establishment of **the National Steering Committee for the development of Vietnam's pharmaceutical industry (Prime Minister's Decision No. 705/QD- TTg dated July 23, 2024 )**.

The Steering Committee, an assistant to the Prime Minister, is responsible for the implementation of the "**Establishment of a National Steering Committee for the Development of Vietnam's Pharmaceutical Industry to 2030, with a Vision for 2045**" (dated October 9, 2023 ). The role of the ministry is to support research, guidance and coordination to solve key interdisciplinary issues in implementing the "**Plan for the Development of Domestic Pharmaceutical and Medical Materials Industry to 2030 with a View to 2045**" ( approved under Prime Minister 's Decision No. 1165 /QD-TTg dated 17 March 2021 ) and the "Plan for the Development of Domestic Pharmaceutical and Medical Materials Industry to 2030 with a View to 2045" ( Prime Minister's Decision No. 376/QD- TTg dated 17 March 2021 ) .

Deputy Prime Minister Le Thanh Long has been appointed chairman, the Minister of Health



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will serve as vice-chairman and the Deputy Minister of Health (Pharmaceutical Affairs) will serve as a standing committee member.

The period of operation of the Steering Committee and the Steering Committee Support Team : from the publication date of this decision (23 July 2027) until 31 December 2024 .

Related regulations and information are available at the following:

### ●Regulations:

- ◆ **Decision of the Prime Minister No. 705/QD- TTg : Establishment of the National Steering Committee for the Development of Vietnam's Pharmaceutical Industry to 2030, Vision to 2045**

Government WEBSITE: <https://chinhphu.vn/?pageid=27160&docid=210741>

- ◆ **Decision No. 1165/QD- TTg of the Prime Minister : National strategy for the development of Vietnam's pharmaceutical industry with a period up to 2030 and a vision up to 2045**

Government WEBSITE: <https://vanban.chinhphu.vn/?pageid=27160&docid=208759>

- ◆ **Decision No. 376/QD- TTg of the Prime Minister : Plan for the development of domestic pharmaceutical and medical materials industry up to 2030 with a view to 2045**

GOVERNMENT WEBSITE:

<https://vanban.chinhphu.vn/default.aspx?pageid=27160&docid=202813>

### ●Related information: Vietnam.VN (Vietnam Industry and Trade News):

- ◇ June 27, 2024 article: **Prioritize the development of pharmaceutical and chemical industries that create high added value**

<https://www.vietnam.vn/ja/uu-tien-phat-trien-nganh-cong-nghiep-hoa-duoc-la-nganh-co-kha-nang-tao-gia-tri-gia-tang-cao/>

- ◇ April 16, 2024 Article: **Most of Vietnam's common medicines can be produced domestically, but 90% of raw materials must be imported**

<https://www.vietnam.vn/ja/da-so-thuoc-thong-thuong-viet-nam-tu-san-xuat-duoc-nhung-90-nguyen-lieu-phai-nhap-khau/>