

# ***APSMI NEWSLETTER***

## ***November 2023***

### **Contents:**

#### **World Topics:**

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- **World: ICH Assembly Meeting, Prague, Czech Republic, October/November 2023**
  - **World: Landmark listing of first three countries as WHO-Listed regulatory Authorities**
  - **World: OECD published “Health at a Glance 2023”**
  - **Latin America: São Paulo Declaration on Self-Care for UHC**
  - **US: FDA Grants Marketing Authorization of First Test for Chlamydia and Gonorrhea with at-home Sample Collection**
  - **US: Voluntary recall of 7 brands and 27 items of OTC eye drops manufactured by Kilitch Healthcare India Ltd.**
  - **Vietnam: Draft amending and supplementing of Pharmaceutical affairs law**
  - **India: CDSCO has ordered 76 of 237 pharmaceutical companies it has inspected to stop manufacturing for poor standards**



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## World Topics

### **World: ICH Assembly Meeting, Prague, Czech Republic, October/November 2023**

The Assembly of the International Council for Harmonisation (ICH) met in-person on 31 October & 1 November 2023, in Prague, Czech Republic in parallel of meetings of 16 Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Management Committee.

The next ICH meeting will be held in Fukuoka from 1 to 5 June 2024.

Press release of the meeting is available at the following URL:

<https://www.ich.org/news/press-release-ich-assembly-meeting-prague-czech-republic-octobernovember-2023>

### **World: Landmark listing of first three countries as WHO-Listed regulatory Authorities**

On 31 October 31 2023, The Health Sciences Authority (HSA), Singapore; the Ministry of Food and Drug Safety (MFDS), Republic of Korea; and the Swiss Agency for Therapeutic Products (Swissmedic), Switzerland are the first three countries to be listed as WHO-Listed Authorities.

Detail information is available at the following URL:

<https://www.who.int/news/item/31-10-2023-landmark-listing-of-first-three-countries-as-who-listed-regulatory-authorities>

### **World: OECD published “Health at a Glance 2023”**

On 7 November 2023, OECD published “Health at a Glance 2023”.

Health at a Glance provides a comprehensive set of indicators on population health and health system performance across OECD members and key emerging economies. These cover health status, risk factors for health, access to and quality of healthcare, and health system resources. Analysis draws from the latest comparable official national statistics and other sources. Alongside indicator-by-indicator analysis, an overview chapter summarises the comparative performance of countries and major trends. This edition also has a special focus on digital health, which measures the digital readiness of OECD countries’ health systems, and outlines what countries need to do accelerate the digital health transformation.

The report is available at the following URL:

<https://www.oecd.org/health/health-at-a-glance/>

### **Latin America: São Paulo Declaration on Self-Care for UHC**

On 9 November 2023, the Global Self-Care Federation (GSCF) and the United for Self-Care Coalition are proud to announce a significant step towards advancing global health equity and access to healthcare services by endorsing the new [Sao Paulo Declaration on Self-Care for Universal Health Coverage \(UHC\)](#).

At the 1st Latin American Self-Care Regional Congress in Sao Paulo, this landmark declaration reflects the commitment of Regional Policymakers, Ministries of Health within the Latin American Region, and the United for Self-Care Coalition Members, to improving the well-being of people worldwide through advancing self-care as an essential component of UHC.

The main areas of action include commitments to:

- ◆ Promote self-care for Primary Health Care and Universal Health Coverage
- ◆ Support self-care education and awareness
- ◆ Leverage technology and digital solutions
- ◆ Strengthen collaboration and partnerships
- ◆ Ensure equity and inclusivity
- ◆ Advocate for better self-governance
- ◆ Monitor progress and accountability





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The original text of the São Paulo Declaration (English) is available below.

<https://www.selfcarefederation.org/news-events/sao-paulo-declaration-self-care-universal-health-coverage>

**US: FDA Grants Marketing Authorization of First Test for Chlamydia and Gonorrhea with at-home Sample Collection**

On November 15, 2023, the U.S. Food and Drug Administration granted marketing authorization to LetsGetChecked for the Simple 2 Test. This is the first diagnostic test for chlamydia and gonorrhea with at-home sample collection to be granted marketing authorization. Prior to today's authorization, the only cleared tests for either condition were used with samples collected at the point of care, such as a doctor's office. The Simple 2 Test is available over-the-counter (OTC) and is intended for use in adult patients ages 18 years and older. It is the first FDA-authorized test with at-home sample collection for any sexually-transmitted disease other than HIV.

US FDA News Release:

[https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-test-chlamydia-and-gonorrhea-home-sample-collection?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-test-chlamydia-and-gonorrhea-home-sample-collection?utm_medium=email&utm_source=govdelivery)

**US: Voluntary recall of 7 brands and 27 items of OTC eye drops manufactured by Kilitch Healthcare India Ltd.**

On 15 November 2023, the U.S. Food and Drug Administration announced a voluntary recall of 7 brands and 27 items of OTC eye drops manufactured by Kilitch Healthcare India Ltd. On 16 November 2023, U.S. FDA issued a warning to consumers to refrain from purchasing the product due to the risk of infection.



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U.S. FDA Voluntary Recall Notice:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kilitch-healthcare-india-limited-issues-voluntary-nationwide-recall-various-eye-drops-potential#recall-announcement>

U.S. FDA purchase restraint warning statement:

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-eye-drops-several-major-brands-due-risk-eye#eyedrops>

### **Vietnam: Draft amending and supplementing of Pharmaceutical affairs law**

The Ministry of Health is drafting a Law amending and supplementing of the Pharmaceutical affairs law. On 15 November 2023, The Government Web Portal introduced the full text of the draft of amended law and report of requests from domestic and foreign agencies, organizations and individuals to government.

Original documents are available at the following URLs (in Vietnamese).

- THE LAW: Amending and supplementing some articles of the Pharmaceutical Affairs Law  
<https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fdatafiles.chinhphu.vn%2Fcpp%2Ffiles%2Fduthaovbpl%2Fdu-thao-luat-sua-doi-bo-sung-mot-so-dieu-cua-luat-duoc.docx&wdOrigin=BROWSELINK>
- REPORT: Regarding the development of the Law amending and supplementing a number of articles of the Pharmacy Law  
<https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fdatafiles.chinhphu.vn%2Fcpp%2Ffiles%2Fduthaovbpl%2Fdu-thao-to-trinh-chinh-phu-du-an-luat-duoc.docx&wdOrigin=BROWSELINK>

### **India: CDSCO has ordered 76 of 237 pharmaceutical companies it has inspected to stop manufacturing for poor standards**

On 23 November, The Central Drugs Standard Control Organization (CDSCO) has ordered 76 of 237 pharmaceutical companies it has inspected to stop manufacturing for poor standards.

Detail information is available at the following URLs:

**Wired:**

<https://thewire.in/government/cdsco-halt-production-pharma-firms-poor-standards>



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**Economic Times:** (Original News Source. ID&PW required)

<https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/drug-regulator-halts-production-at-76-units-over-poor-standards/articleshow/105425061.cms>