



Dear Colleagues,

The CEPSA team is pleased to share with you our second quarterly newsletter.

As part of our commitment to fostering a vibrant and interactive Community of Practice (CoP), we regularly compile and circulate updates on recent developments in PV, CEPSA activities, and, most importantly, your contributions, initiatives, and publications. We therefore warmly encourage you to share your updates, achievements, and requests for support with us at [cepsa@uwc.ac.za](mailto:cepsa@uwc.ac.za) so that we can feature them in upcoming editions.

Please feel free to circulate this newsletter within your professional networks. We would also like to remind you that the CoP is open and inclusive; your colleagues and peers are welcome to join. Registration can be requested by emailing [cepsa@uwc.ac.za](mailto:cepsa@uwc.ac.za).

We hope you enjoy this edition.

Warm regards,

**The CEPSA Team**

*“The CoP is open and inclusive; your colleagues and peers are welcome to join. Registration can be requested by emailing [cepsa@uwc.ac.za](mailto:cepsa@uwc.ac.za)”*

*“A Warm Welcome to the New Members of Centre of Excellence for Pharmacovigilance in Southern Africa (CEPSA) Community of Practice”*

### What is CEPSA’s Community of Practice (CoP)?

The CoP was established following the successful inaugural edition of CEPSA’s flagship Pharmacovigilance (PV) Training, held in November 2025 in Cape Town, and organised in close collaboration with the Africa Centres for Disease Control and Prevention (Africa CDC). The CoP is a network of excellence between and by PV experts in Africa. Beyond facilitating communication, exchange, and cross-fertilisation among members and their wider networks, the CoP constitutes the foundational pillar for CEPSA’s activities, which include new PV training editions, research activities, and support in the field of risk communication and policy-making.

Being a member of the CoP, you play a key role as an ambassador for the Centre of Excellence.

## Newsletter Highlights

### CIOMS Cumulative Glossary, with a focus on Pharmacovigilance (Version 2.4)

The Council for International Organizations of Medical Sciences (CIOMS) has recently published the CIOMS Cumulative Glossary, with a focus on Pharmacovigilance (Version 2.4).

“The CIOMS Cumulative Glossary is an organized collection of the terms and definitions included in published CIOMS Working Group reports, with a focus on pharmacovigilance. It includes links to the reports and, where applicable, provides references to the sources from which the definitions were adopted or modified.

Version 2.4 covers the terms included in eighteen different CIOMS reports published between 1992 and 2025. It does not cover CIOMS reports on the subjects of research ethics, pharmacogenetics, clinical pharmacology, publications on the development and use of standardised MedDRA® queries (SMQs), or publications resulting from CIOMS Roundtable Discussions (1967-1997)” (text extracted from the CIOMS webpage).

The Glossary is publicly available here: [CIOMS Cumulative Glossary](#)

### Safe in Pregnancy and Children – Living Systematic Review

Safe in Pregnancy and Children ([safeinpregnancy.org](http://safeinpregnancy.org)) is a website that provides scientific, evidence-based information about the safety of vaccines during pregnancy and early childhood. It gathers and analyzes research studies from around the world to help people better understand how vaccines affect pregnant individuals and children. The platform focuses on diseases such as COVID-19, mpox, chikungunya, and Lassa fever, and presents its findings through clear summaries, charts, and data analyses. It uses “living systematic reviews,” which means the information is continuously updated as new research becomes available. The website is designed to support healthcare professionals, researchers, and policymakers in making informed decisions. It also aims to improve preparedness for future health threats by including emerging diseases.

More information can be found here: <https://www.safeinpregnancy.org/>

## Newsletter Highlights

### AMA Secretariat Convenes First Virtual Meeting of Heads of NRAs and RECs Coordinators across the continent – 8 January 2026

“The African Medicines Agency (AMA) successfully convened its first virtual meeting with Heads of National Regulatory Authorities (NRAs) and Coordinators from Regional Economic Communities (RECs) from across the continent, bringing together 79 participants to shape the future of medical products regulation in Africa.

AMA Director-General, H.E. Dr. Delese Mimi Darko, highlighted the pivotal role of NRAs as the implementing arm of AMA. Discussions focused on key priorities including:

- Universal ratification of the AMA Treaty
- Involvement of NRAs and RECs in the development of AMA’s multi-year strategic plan
- Tiered capacity-strengthening programme for NRAs
- Establishment of AMA Technical Committees and Advisory Bodies
- Deployment of Africa-wide Vigilance System

- Establishment of an AMA SME & Innovation office to, among other things, facilitate local manufacture of medical products in Africa



This virtual meeting sets the stage for the first in-person AMA Heads of NRAs and RECs Coordinators Forum, scheduled to take place from 29th to 30th January 2026 in Kigali, Rwanda.

The Heads of NRAs Forum is a critical platform to refine AMA’s strategic plan and advance regulatory harmonisation across Africa.” (text extracted from the AMA webpage)

The link to this publication is available here: [AMA-Heads of NRA First Virtual Meeting](#)

## Newsletter Highlights

### EMA's recommendation to withdraw marketing authorisations for levamisole containing medicines and the results of a short CEPSA survey

The European Medicines Agency (EMA)'s safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), has recommended that medicines containing levamisole be withdrawn from the European Union (EU) market. This follows an EU-wide safety review which concluded that the benefits of these medicines no longer outweigh their risks for the treatment of parasitic worm infections due to the risk of leukoencephalopathy, a rare but serious side effect of levamisole that affects the brain's white matter.

The information reviewed showed that symptoms of leukoencephalopathy may occur after a single dose of levamisole and may develop within one day to several months after treatment. The review did not identify any measures to reduce the risk or any group of people who may be at higher risk of developing leukoencephalopathy with levamisole use. Overall, considering that levamisole medicines are used to treat mild parasitic worm infections and that levamisole-induced leukoencephalopathy is a serious condition with an unpredictable

onset, the benefit–risk balance of these medicines was considered negative. More information is available in EMA's [public health communication](#).

One of the CEPSA's key objectives is to support and conduct research in the field of PV in collaboration with National PV Centres. In this context, the Centre invited the CoP members to participate in a short survey aiming at collecting information on the access to, utilisation, and safety of levamisole-containing medicines in Africa. Seven CoP members originating from 6 African countries kindly completed the short questionnaire. Aggregated data indicated that levamisole-containing drugs are not indicated as an anthelmintic treatment in these countries; in some countries, they may be used for other indications and in veterinary medicine.

In conclusion, even though this short survey suggests that levamisole-containing medicines are not widely used as an anthelmintic in African countries that completed the questionnaire, regulators should proactively monitor its safety for any remaining use and inform prescribers of the risk of leukoencephalopathy, and the benefit–risk balance. CEPSA would like to warmly thank the CoP members who spent some time to gather the necessary information and completed the survey.

## Scientific Publications

This section highlights recent publications by, or of interest to, CoP members. The selection is not based on a systematic review. Members are encouraged to apply their own critical appraisal when consulting these publications.

### **A Comprehensive Review of the Revolutionary Potential of Blockchain in Safe, Secure, and Sustainable Pharmaceutical Operations.**

Faiyazuddin M, Moharir K, Gholap AD, Christodoss PR, Choonara YE, Mnqiwu K, Sundaram G, Tahir M.

Pharm Res. 2026 Mar 26. doi: 10.1007/s11095-026-04041-3. Epub ahead of print. PMID: 41888483.

<https://pubmed.ncbi.nlm.nih.gov/41888483/>

### **Pharmacovigilance capacity and readiness of vaccine manufacturers in low- and middle-income countries: a maturity-based assessment of the pharmacovigilancesystem.**

de Oliveira PMN, Bosman R, Lucchesi MBB, Ogar C, Pedro RS, Hartmann K

Vaccine. 2026 Mar 18;79:128481. doi: 10.1016/j.vaccine.2026.128481. Epub ahead of print. PMID: 41855649.

<https://pubmed.ncbi.nlm.nih.gov/41855649/>

### **Determinants and outcomes of adverse drug reactions among people living with HIV on antiretroviral therapy in Nigeria.**

Etuk VP, Adeoye IA, Salawu MM, Fawole OI. BMC Infect Dis. 2026 Mar 13. doi: 10.1186/s12879-026-12975-7. Epub

ahead of print. PMID: 41820848.

<https://pubmed.ncbi.nlm.nih.gov/41820848/>

### **Trends and Patterns of Adverse Drug Reaction Reporting in Sierra Leone: A Retrospective Analysis of VigiFlow Data (2008-2022).**

Jalloh I, Abiri OT, James PB, Vagiri R, Padayachee N.

Pharmacoepidemiol Drug Saf. 2026 Mar;35(3):e70344. doi: 10.1002/pds.70344. PMID: 41807284; PMCID: PMC12975695.

<https://pubmed.ncbi.nlm.nih.gov/41807284/>

## Scientific Publications

### Enhanced passive safety surveillance during the first use of the meningococcal vaccine A/C/W/Y/X conjugate for outbreak response in Niger and Nigeria.

Menang O, Gambo M, Keoulon KC, Babale SM, Elemuwa U, Who MD, Hamzat O, Agbenu.

Vaccine. 2026 Mar 5;79:128390. doi: 10.1016/j.vaccine.2026.128390. Epub ahead of print. PMID: 41791242.

<https://pubmed.ncbi.nlm.nih.gov/41791242/>

### Pharmacovigilance Through Fresh Eyes: The International Society of Pharmacovigilance Student Community's Role in Shaping the Future of Pharmacovigilance.

Saleh H, Amidu IM, Ziaudeen Z, Walker RJ, Younus M.

Drug Saf. 2026 Mar;49(3):259-262. doi: 10.1007/s40264-026-01651-z. Epub 2026 Feb 12. PMID: 41678038.

<https://pubmed.ncbi.nlm.nih.gov/41678038/>

### An international scoping review of epidemiologic studies on severe cutaneous adverse reactions.

Lee J, Ha HJ, Ko M, Kim IW, Kim H, Kim K, Kang HR, Oh JM.

World Allergy Organ J. 2025 Dec 18;19(1):101145. doi:

10.1016/j.waojou.2025.101145. PMID: 41531648; PMCID: PMC12794054.

<https://pubmed.ncbi.nlm.nih.gov/41531648/>

### Pharmacovigilance and herbal medicines safety: a cross-sectional study of healthcare professionals' knowledge, attitudes and practices in selected regions of Tanzania, 2021.

Mssusa AK, Kagashe G, Maregesi S, Holst L.

BMC Complement Med Ther. 2025 Dec 29;26(1):37. doi: 10.1186/s12906-025-05226-w. PMID: 41462198; PMCID: PMC12860113.

<https://pubmed.ncbi.nlm.nih.gov/41462198/>

## Scientific Publications

**The prevalence of adverse drug reactions to antiretroviral therapy and associated factors among pediatric patients living with HIV in sub-Saharan African countries: a systematic review and meta-analysis.**

Omotoso BR, Olashore AA, Sempa JB, Alaofin OS, Dheda M, Tabane NE, Khutsafalo KK, Mofokeng TR.

BMC Infect Dis. 2025 Dec 29;25(1):1782. doi: 10.1186/s12879-025-12107-7. PMID: 41462137; PMCID: PMC12750582.

<https://pubmed.ncbi.nlm.nih.gov/41462137/>

**Knowledge, attitude, and practice of pharmacovigilance among healthcare professionals at a tertiary level hospital, Sudan: a cross sectional study.**

Hamid M, Osman M.

BMC Health Serv Res. 2025 Dec 6;26(1):89. doi: 10.1186/s12913-025-13364-7. PMID: 41351049; PMCID: PMC12822209.

<https://pubmed.ncbi.nlm.nih.gov/41351049/>

**Adverse drug reactions associated with doxorubicin and epirubicin: A descriptive analysis from Vigibase.**

Matesun DA, Mensah KB, Yamoah P, Bangalee V, Padayachee N.

J Oncol Pharm Pract. 2026 Mar;32(2):252-262. doi: 10.1177/10781552221113578. Epub 2022 Jul 13. PMID: 35833221; PMCID: PMC13018245.

<https://pubmed.ncbi.nlm.nih.gov/35833221/>

**The interlinked crisis: pharmaceutical pollution as a driver of antimicrobial resistance in East Africa: an urgent call for ecopharmacovigilance and one health approach.**

Mekasha YT, Hasen G, Berihun AM, Feleke MG, Kumarachari RK, Girma M, Tegegne AA, Mekonnen AW, Kinde MZ, Mengistu BA, Berrie K, Dessalegn B, Ozawa S, Padayachee N, Belew S, Suleman S.

One Health Outlook. 2026 Feb18;8(1):17. doi: 10.1186/s42522-026-00202-x. PMID: 41709293; PMCID: PMC12983500.

<https://pubmed.ncbi.nlm.nih.gov/41709293/>

## Scientific Publications

### **Zimbabwe adverse events following immunisation surveillance system: A descriptive study with COVID-19 vaccine safety updates**

Nyambayo PPM, Manyevere R, Chirinda L, Marekera SF, Nyamandi T, Chaitezvi RP, Rukwata RT, Mehta U, GoldB MS.

Southern African Journal of Infectious Diseases | Vol 41, No 1 | a785 | DOI: <https://doi.org/10.4102/sajid.v41i1.785>

## Forthcoming Events

### ISoP Africa Chapter Meeting, May 18-20, 2026, Windhoek, Namibia

The ISoP Africa chapter meeting, will gather over 300 pharmacovigilance experts, regulators, and industry professionals to discuss “Opportunities and key challenges for enhancing patient safety in Africa” (text extracted from the ISoP Africa webpage).

#### **Patient Safety First: Strengthening Continental Pharmacovigilance Collaboration through the African Medicines Agency**



**Please note that CEPSA Team members will attend and present during this event. We hope to meet you there!**

More information can be found here:  
<https://isopafrika.com/>

### ISPE 5th Annual African Regional Interest Group Meeting, April 20-22, 2026, Accra, Ghana

The International Society for Pharmacoepidemiology (ISPE) African Regional Interest Group (AfRIG) is a member of ISPE and established in May 2018. The ISPE African Regional Interest group’s mission is to develop, sustain and advance Pharmacoepidemiology research in the African region, through intra- and intercontinental scientific collaborative work. It includes professionals dedicated and/or interested in pharmacoepidemiology (text extracted from the ISPE webpage).

**Please note that CEPSA Team members will attend and present during this event. We hope to meet you there!**

More information can be found here:  
<https://www.pharmacoepi.org/meetings/african-conference/>



## Forthcoming Events

### ISoP 2026 Global Meeting, September 22-25, 2026, San José, Costa Rica

This year the International Society of Pharmacovigilance (ISoP) Global Meeting will be held in Costa Rica under the theme:

**“Ecosystems of Trust: Pharmacovigilance for a Healthier World”**



**25th GLOBAL MEETING**  
San José, Costa Rica 2026

This milestone meeting will bring together global experts, regulators, industry leaders, academics, healthcare professionals, and patients to advance medicines safety worldwide (text extracted from the ISoP webpage).

The abstract submission deadline is 20 April 2026!

More information can be found here:  
<https://www.isop2026costarica.org/>

### 18th World Congress on Public Health, September 6-9, 2026, Cape Town, South Africa

Organized by the World Federation of Public Health Associations (WFPHA) and the Public Health Association of South Africa (PHASA), this prestigious event will unite public health professionals, policymakers, and advocates worldwide to address the most pressing global health challenges.

The Congress's theme, **“Health Without Borders: Equity, Inclusion, and Sustainability,”** reflects the urgent need for collective action in a world shaped by war, political instability, epidemics, and systemic injustices. These principles are not just themes, they are the equitable future for all a foundation of a healthier, more (text extracted from the WFPHA webpage).

**Please note that CEPSA Team members will attend and present during this event. We hope to meet you there!**

More information can be found here:  
<https://www.wfpha.org/world-congress-on-public-health/>

## Forthcoming Events

### CIOMS - Artificial Intelligence in Pharmacovigilance – 3rd webinar

The webinar will be held on the 20th of April 2026 during 2 pm – 3.30 pm CEST (5 am – 6.30 am PDT / 8 am – 9.30 am EDT / 9 pm – 10.30 pm JST), and speakers include experts from the CIOMS Working Group.

In December 2025, the Council for International Organizations of Medical Sciences (CIOMS) published its consensus report on Artificial Intelligence in Pharmacovigilance. This webinar introduces and explains the main concepts of the report.

Artificial intelligence in pharmacovigilance addresses a rapidly emerging cross-disciplinary field that is at the intersection of pharmacovigilance, computer science, mathematics, regulation, law, medicine, human rights, psychology and social science. Consequently, just as with medicinal products, it is important to establish the approved indications, posology, side effects, and warnings and precautions for use of artificial intelligence in pharmacovigilance. The latter must be clearly defined and understood by many

people from different backgrounds to propel research and practical implementation in an effective, safe and responsible manner. The diverse pool includes professionals, researchers, and decision makers working in pharmacovigilance in biopharmaceutical industry, regulatory authorities, and academia. It also includes software vendors that develop artificial intelligence solutions for pharmacovigilance, including signal management and all aspects of Individual Case Safety Report processing. This report provides the requisite terminology and conceptual understanding to actively engage in this space, either by participating in the applied scientific research and public discourse, or by performing evaluations and making decisions at your organisation. (text extracted from the CIOMS webpage).

More information about the event can be found here: [CIOMS AI in PV 3rd Webinar](#)

# Contact & Information

