CEPSA NEWSLETTER #1
December 2025

Dear Colleagues,

We are delighted to welcome you to CEPSA's Community of Practice (CoP)!

As you know, 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 forthcoming activities, which include new PV training editions, research activities, and support in the field of risk communication and policy-making.

"We wish to create a vibrant and interactive community"

Share your updates and requests for support at cepsa@uwc.ac.za

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

"A Warm Welcome to the Centre of Excellence for Pharmacovigilance in Southern Africa (CEPSA) Community of Practice"

As we wish to create a vibrant and interactive community, the CEPSA Team will share regular newsletters including updates on recently published information on PV, CEPSA activities, and, most importantly, on your activities and publications. Through the CoP, we also would like to foster peer-support; hence, we invite you to proactively share your updates and requests for support at cepsa@uwc.ac.za and we will make sure it will be part of the next newsletter.

We are pleased to share with you CEPSA's very first newsletter and wish you an enjoyable read.

The CEPSA Team

Newsletter Highlights

CEPSA's Inaugural Pharmacovigilance Training, Cape Town, South Africa, November 2025

In November this year, we proudly launched our very first PV workshop, marking an exciting milestone for the Centre of Excellence for Pharmacovigilance in Southern Africa (CEPSA). The event was co-hosted in Cape Town by the University of the Western Cape and the Institute of Tropical Medicine Antwerp, in a very welcome partnership with the Africa Centres for Disease Control and Prevention (Africa CDC) and the Team Europe Initiative on AU-EU Health Partnership, which includes support for manufacturing and access to vaccines, medicines and health technologies in Africa (MAV+).

At CEPSA, we are committed to transforming the PV landscape in Southern Africa, and beyond. Our mission is to strengthen every aspect of PV for medicines, including vaccines, across their entire lifecycle, with advanced training and capacity building at the core of our work. Through this flagship training programme, we aim to empower a new generation of PV leaders, innovators, and advocates, both within the region and internationally, while supporting the development of a stronger regulatory ecosystem around local production hubs.

What makes CEPSA's PV training programme truly innovative is its immersive, hands-on design. Delivered entirely in person, it creates a dynamic environment for collaboration, networking, and shared learning. Participants engage directly with real-world PV challenges, following a practical problem-solving journey that takes them from signal detection to effective risk communication.

During this successful fist training edition, we welcomed our first cohort of 21 participants from 18 African countries! It has been a unique opportunity to connect, learn, and share as we help lay the foundation for a vibrant, long-term PV community of practice.

Newsletter Highlights

CIOMS report on Artificial Intelligence in Pharmacovigilance

The Council for International Organizations of Medical Sciences (CIOMS) has recently published a report on Artificial Intelligence in Pharmacovigilance.

“This report 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 their respective organisations” (text extracted from the CIOMS webpage).

The report is publicly available here: Artificial Intelligence in Pharmacovigilance

CIOMS Benefit-risk balance for medicinal products

The Council for International Organizations of Medical Sciences (CIOMS) has recently published a report on Benefit-risk balance for medicinal products.

“This report provides insights into the methods used to evaluate the benefit-risk (BR) balance of a medicinal product. A favourable BR profile must be established for all medicinal products prior to marketing. This balance must be reassessed periodically in the post-marketing setting when new information regarding the benefits and risks, or the landscape of their application, becomes available.

This report builds on the foundations of the CIOMS Working Group IV report published in 1998, and entitled: Benefit-Risk Balance for Marketed Drugs: Evaluating Safety Signals; and expands to BR management throughout a product’s lifecycle using structured

Newsletter Highlights

approaches and updated methodologies. This report reflects the consensus opinion of the CIOMS Working Group XII members, including experts in BR assessment drawn from academia, industry, and regulatory organisations. It was finalised after considering comments received during a public consultation.

The report is intended for medicinal product developers, regulatory authorities, and key stakeholders including academic and government researchers, healthcare professionals, and patients/consumers – all those interested in how the balance between the benefits and risks associated with a medicinal product is established and managed" (text extracted from the CIOMS webpage).

The report is publicly available here: Benefit-risk balance for medicinal products

WHO book "The global smart pharmacovigilance strategy"

The World Health Organization has recently published a book on "The global smart pharmacovigilance strategy".

This book offers a practical framework to help countries strengthen medicine and vaccine safety systems. It promotes risk-based prioritization, reliance, and integration into regulatory systems, with real-world examples and tools for implementation and impact measurement (text extracted from the WHO webpage). More information can be found here: The global smart pharmacovigilance strategy

Uppsala Reports: "Pharmacovigilance as a key tool in the One Health approach to AMR"

The Uppsala Monitoring Centre has recently issued an article on PV as a key tool in the One Health approach to AMR. The article is the second in a series authored by Marmar Nekoro and James Mount from the Department of medicinal products in veterinary use at the Swedish Medical Products Agency, to address the different elements of the One Health approach. This article introduces the interconnection between One Health and antimicrobial resistance (AMR), emphasising the actions needed to promote responsible use, improve infection control, and increase global cooperation. It also highlights the role of pharmacovigilance in AMR monitoring (text extracted from the Uppsala Reports webpage). The article is publicly available here: Uppsala report

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.

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. doi:10.1186/s12913-025-13364-7. Epub ahead of print. PMID: 41351049

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

A Mixed-Methods Pilot Study to Explore the Feasibility and Acceptability of SMS Reminders to Improve Adverse Drug Reaction Reporting among Adults on ART in Tanzania.

Masika LV, Emmanuel N, Mirai T, Nyanungu G, Shirima M, Sumari-de Boer M, Maro R, Mtesha B, Ngowi K.

J Int Assoc Provid AIDS Care. 2025 Jan-Dec;24:23259582251381868.doi:10.1177/23259582251381868. Epub 2025 Sep 26. PMID: 41004416; PMCID: PMC12475335.

https://pubmed.ncbi.nlm.nih.gov/41004416/

Clinical Trial Safety Surveillance in Africa: Experts' Perspectives on Current Practices and Opportunities.

Ejekam CS, Nyarko KA, Abiri OT, Beno YN, Adechina Adehan RM.

Vaccines (Basel). 2025 Nov 5;13(11):1139. doi: 10.3390/vaccines13111139. PMID: 41295512; PMCID: PMC12656440.

https://pubmed.ncbi.nlm.nih.gov/41295512/

Strengthening Signal Detection in Pharmacovigilance by Using International Nonproprietary Name (INN) Stems.

Balocco R, Aronson JK, Malan SF, Figueras A.

Drug Saf. 2025 Oct 25. doi: 10.1007/s40264-025-01620-y. Epub ahead of print. PMID: 41138033.

https://pubmed.ncbi.nlm.nih.gov/41138033/

Scientific Publications

Barriers and enablers of adverse drug event reporting in South Africa: a cross-sectional survey of medicine users.

Ncube N, Lubbe MS, Steyn H, Motaze NV.

BMC Public Health. 2025 Sep 25;25(1):3132. doi: 10.1186/s12889-025-24409-1. PMID: 40999334; PMCID: PMC12465802.

https://pubmed.ncbi.nlm.nih.gov/40999334/

Perception of healthcare administrators on the impediments of optimizing adverse events following immunization e-Reporting in Nigeria.

Erekosima GF, Isiaka SD, Oni F, Garba AR, Bassey O, Asaolu SO, Samuel OW, Ozioko G, Ayodeji OA, Agomuo EC, Okoye IO, Sampson S, Iyayi P, Daniel V.

PLoS One. 2025 Aug 28;20(8):e0331093. doi: 10.1371/journal.pone.0331093. PMID: 40875746; PMCID: PMC12393695.

https://pubmed.ncbi.nlm.nih.gov/40875746/

Advancing Pharmacovigilance Practice in Africa: Moving from Data Collection to Data-Driven Decision Making-Report from the 5th ISoP Africa Chapter Meeting.

Ndagije HB, Ampaire S, Sabblah GT, Ogar C, Pandit JM, Kotecha N, Russom M, Nambasa VP, Ambale C, Aywak D, Bassi PU, Mathenge W, Meyer JC, Khaemba C, Kwikiriza E, Mayengo J, Atuhaire J, Nahamya D, Aimer O, Caro-Rojas A.

Drug Saf. 2025 Aug 10. doi: 10.1007/s40264-025-01598-7. Epub ahead of print. PMID: 40783895.

https://pubmed.ncbi.nlm.nih.gov/40783895/

Strengthening Vaccine Safety Systems, Research, and Regional Collaboration in Africa: A Call to Action.

Tagbo BN, Ejekam CS, Oppong-Amoako W, Yameogo TM, Mitiku A, Esangbedo DO, Khuzwayo N, Mahlangu G, Badar SM, Agbenu EA, Adechina RM, Nyarko KA.

Vaccines (Basel). 2025 Jun 19;13(6):661. doi: 10.3390/vaccines13060661. PMID: 40573992; PMCID: PMC12197761.

https://pubmed.ncbi.nlm.nih.gov/40573992/

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Scientific Publications

Strengthening National Regulatory Authorities in Africa: A Critical Step Towards Enhancing Local Manufacturing of Vaccines and Health Products.

Duga A, Dereje N, Fallah MP, Angasa T, Bayih AG, Agbenu E, Ngongo N, Tajudeen R, Kaseya J.

Vaccines (Basel). 2025 Jun 16;13(6):646.doi:10.3390/vaccines13060646. PMID:40573977; PMCID: PMC12197664.

https://pubmed.ncbi.nlm.nih.gov/40573977/

Building functional and sustainable pharmacovigilance systems: an analysis of pharmacovigilance development across high-, middle- and low-income countries.

Menang O, van Eeuwijk P, Maigetter K, de Soyres-Kuemmerle A, Agbenu E, Burri C.

Ther Adv Drug Saf. 2025 Jun 10;16:20420986251342941.doi:10.1177/20420986251342941. PMID: 40557277; PMCID: PMC12185949.

https://pubmed.ncbi.nlm.nih.gov/40557277/

Prioritizing interventions to address healthcare worker barriers to reporting adverse events following immunization in Ghana.

Laryea S, Blau E, Dodoo A, Addo E, Owusu-Boakye B, Amponsa-Achiano K, Mohammed NT, Asamoa-Amoakohene A, Gidudu J.

Vaccine. 2025 Jul 11;60:127324. doi: 10.1016/j.vaccine.2025.127324. Epub 2025 May 30. PMID: 40449279; PMCID: PMC12230940.

https://pubmed.ncbi.nlm.nih.gov/40449279/

Diethylene glycol: Unnoticed threat in the landscape of fixed-dose combination medications.

Duga AL, Fallah MP, Figueras A.

J Public Health Afr. 2025 Apr 24;16(1):1271.doi:10.4102/jphia.v16i1.1271. PMID: 40356729; PMCID: PMC12067596.

https://pubmed.ncbi.nlm.nih.gov/40356729/

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Scientific Publications

Background incidence rates from electronic healthcare databases for vaccine safety monitoring: review of challenges from the COVID-19 vaccination campaign and proposal for best practices

Gandhi-Banga S, Serradell L, Layton D, Dreyfus J, Praet N, Garofalo DC, Bauchau V, Kelly SP, Li L.

Front Drug Saf Regul. 2025 Dec 1;5:1651090.doi:10.3389/fdsfr.2025.1651090. PMID: 41404127; PMCID:PMC12702953.

https://pubmed.ncbi.nlm.nih.gov/41404127/

Herbal medicines adulteration with erectile dysfunction pharmaceuticals in sub-Saharan Africa: call to strengthen regulatory measures.

Ouoba K, Dori D, Ashie A, Soulama I, Semdé R.

Front Med (Lausanne). 2025 Nov 5;12:1694833.doi:10.3389/fmed.2025.1694833.PMID:41267866; PMCID: PMC12626933.

https://pubmed.ncbi.nlm.nih.gov/41267866/

Understanding causes of incomplete reports of adverse drug reactions associated with dolutegravir-based HIV treatment in uganda: a qualitative study.

Zakumumpa H, Ndagije HB, Atuhaire J, Mayengo J, Odipiyo F, Ronald K.

BMC Infect Dis. 2025 Nov 3;25(1):1475. doi: 10.1186/s12879-025-11592-0. PMID: 41184753; PMCID: PMC12581420.

https://pubmed.ncbi.nlm.nih.gov/41184753/

Monitoring for Adverse Events Following Immunisation with COVID-19 Vaccines During the SARS-CoV-2 Pandemic: An Evaluation of the South African Surveillance System.

Sankar C, Evans S, Meyer JC, Gunter HM, Sekiti V, McCarthy K. Signal

Drug Saf. 2025 Aug;48(8):909-922. doi: 10.1007/s40264-025-01547-4. Epub 2025 Apr 16. PMID: 40238055; PMCID: PMC12259799.

https://pubmed.ncbi.nlm.nih.gov/40238055/

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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

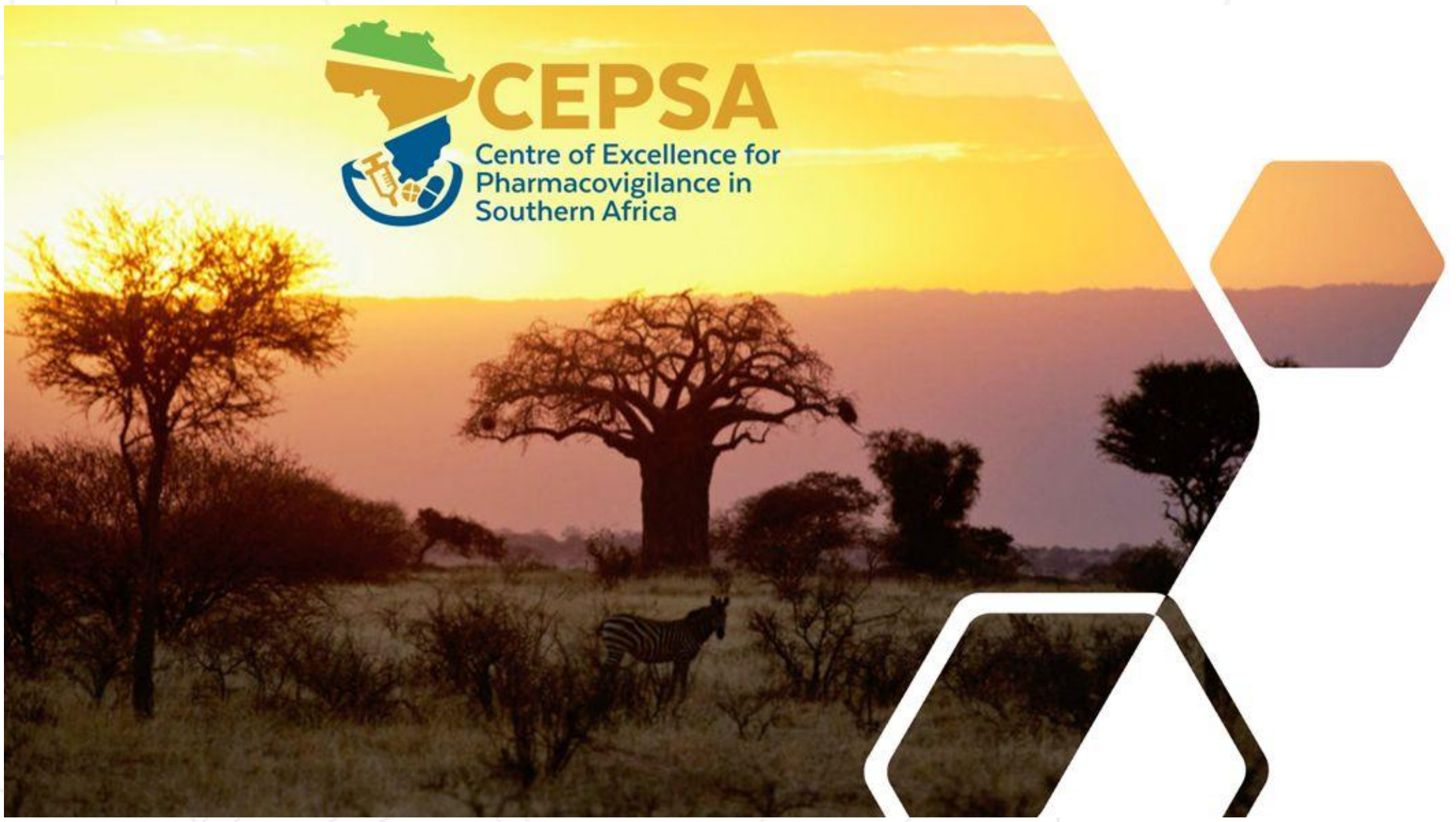
More information can be found here: https://isopafrica.com/

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).

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

Contact & Information



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