



Pharmacovigilance Advisory Board Panel 2023

Global



Ms. Willemijn van der Spuij
Executive Director Europe,
Patient Safety
Bristol Myers Squibb

North Africa



Dr. Ahmed Hegazy
Managing Director
PVigilant Health

West Africa



Ms. Comfort Ogar
Secretary Africa Chapter
International Society of
Pharmacovigilance
(ISoP).

Southern Africa



Dr. Judy Coates
Sr Mgr Regulatory Affairs
Aspen Pharma

East Africa



Dr. Jayesh Pandit
Pharmacovigilance Country Head-
Middle Africa, Bayer East Africa
& Immediate Past Chairperson
KAPI Pharmacovigilance and
Medical Affairs Committee

Day 1: 1 November 2023

08:00 - 09:00 CAT

PLATFORM OPENING

Times in Central African Time Zone (GMT+2)

09:00 - 09:15 CAT

WELCOME ADDRESS



Dr. Mona Al Moussli
Co Owner and Managing Director
PRA Consultancy

09:15 - 09:45 CAT

PV Updates & Drug Safety Strategy EDA

Moderator



Dr. Ahmed Hegazy
Managing Director
PVigilant Health

**Egyptian GVP
Guidelines and Updates**



Dr. Maha Mohammed Ahmed
Deputy General Manager of
General Administration,
Pharmaceutical Vigilance, EDA

PRESENTATIONS FOLLOWED BY
Q&A and PANEL DISCUSSION

09:45 - 11:00 CAT

PV Updates & Drug Safety Franco Africa

Moderator



Ms. Hela Ben Soltana
PV Manager Middle East Africa
Bausch & Lomb.

Algeria



Dr. Fraoui Nesrine
PharmD, in charge of Vigilance
Dept Technical monitoring,
inspections & vigilance
APPN

Sécurité des médicaments au Sénégal.



Dr. Aliou NDIAYE
ARP Sénégal

Mali



Dr. Diakalia Traore
Médecin chez Mali INSP -
Institut national du service public



PANEL DISCUSSION: COUNTERFEIT STRATEGY AND DRUG SAFETY



11:00 - 11:30 CAT Coffee Break and Network

11:30 - 12:45 CAT Pharmacovigilance Harmonization

**Stepping stones to PV Harmonisation
SPaRCS Project**



Dr Hazel Bradley BPharm, MPH, PhD
Senior Lecturer
School of Public Health
University of the Western Cape

**SPaRCS Team:
PV lessons learnt and next steps towards harmonized PV**



Mr. Libert Chirinda
Chief Regulatory Officer
Pharmacovigilance and
Clinical Trials Division
MCAZ



Dr. Mukesh Dheda
Director
Pharmacovigilance Centre for
Public Health Programmes
National Department of Health
South Africa



Ms. Frieda M. Shigwedha
Medicines Information and Safety Pharmacist -
Therapeutic Information and
Pharmacovigilance Center (TIPC)
NMRC

Moderator



Dr. Rania Aly
Patient Safety Lead
Roche

**ECOWAS PV Harmonisation Strategy
and the platform for its support**



Dr. Sahr Emmanuel Gbomor
Chairman Information Management Systems
Technical Working Group:
Medicines Regulation Harmonization
Initiative of the West African Health Organization
WAHO

ECOWAS Panel and Q&A



Ms. Abena Asamoah-Amoakohene
Safety Monitoring Department
Food and Drugs Authority (FDA)
Ghana

12:45 - 14:00 CAT West Africa PV updates

Moderator



Ms. Comfort Ogar
Secretary Africa Chapter
International Society of
Pharmacovigilance (ISoP)

Ghana



Mr. George Tsey Sabblah
Head, Safety Monitoring Dept.
Food and Drugs Authority (FDA)
Ghana

Nigeria



Pharm Uchenna Elemuwa
Director
Pharmacovigilance Directorate,
NAFDAC Nigeria

Cape Verde



Eduardo Tavares
President and Chairman
ERIS

Sierra Leone



Dr. Sahr Emmanuel Gbomor
Head of Department Complementary
and alternative medicines Department
'Pharmacy Board of Sierra Leone

14:00 - 14:30 CAT Lunch



**PHARMACOVIGILANCE
AFRiSUMMIT**
FOR A HEALTHIER
FUTURE FOR AFRICA



1 & 2 November 2023

14:30 - 16:00 CAT

Economic evaluation of the impact of PV systems and tools

Moderator



Dr. Jayesh Pandit
Pharmacovigilance Country Head-
Middle Africa, Bayer East Africa
& Immediate Past Chairperson
KAPI Pharmacovigilance and
Medical Affairs Committee

**Economic impact of
Pharmacovigilance**



Dr Reem El Essa
Coordination & Development
Superintendent
Ministry of Health Kuwait

**Cost Benefit Analysis of
Pharmacovigilance**



Bassem Toeama MD, Ph.D.
CEO and Founder
MD Pharma Consulting Group

**Modalities for funding and financial
sustainability of National
Pharmacovigilance Centres in Africa**



Prof Ambrose Isah
Professor
University of Benin,
Nigeria

16:00 - 16:45 CAT

Covergence of Pharmacovigilance in Africa

Moderator



Dr. Catherine Mbwiri,
Regulatory Affairs Lead – East Africa,
Africa Sub regional LPVRP
Glenmark Pharmaceuticals Limited



Jean-Christophe DELUMEAU, MD, PhD, FISoP,
Board Director,
Institute of Pharmacovigilance.

16:45 - 18:00 CAT

Maturity Levels GBT Global bench marking Tool

Moderator



Ms. Willemijn van der Spui
Executive Director Europe,
Patient Safety at Bristol Myers Squibb

Maturity levels in Africa's PV



Dr Andrea Keyter
Technical Officer
Regulatory System Strengthening Team
World Health Organization (WHO)

SAHPRA in Process



Ms. Mafora Matlala
Pharmacovigilance Unit Head
South Africa

**EDA overcoming the
challenges in obtaining
maturity Level 3**



Dr. Maha Mohammed Ahmed
Deputy General Manager of
General Administration,
Pharmaceutical Vigilance, EDA

**Maturity within PV Industry
& HCP Perspective**



Dr. Ahmed Hegazy
Managing Director
PVigilant Health

Panel Discussion - Authority and Industry - Healthcare professionals and patient perspective

18:00 CAT

End of Day 1



Day 2: 2 November 2023

08:00 - 09:00 CAT

PLATFORM OPENING

Times in Central African Time Zone
GMT+2

09:00 - 09:30 CAT

Welcome back to day 2 and an Introduction to EcoPV



Dr. Jayesh Pandit
Pharmacovigilance Country Head-
Middle Africa, Bayer East Africa
& Immediate Past Chairperson
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Medical Affairs Committee

09:30 - 11:15 CAT

Vigilance Innovation Accomplishment of the Southern African Countries

Moderator



Dr. Judy Coates
Sr Mgr Regulatory Affairs
Aspen Pharma

South Africa



SAHPRA
Ms. Mafora Matlala
Head of Pharmacovigilance Unit
South Africa

Zimbabwe



MCAZ
Ms. Priscilla Nyambayo
Head PV & Clinical Trials
Zimbabwe

Namibia



NMRC
Ms. Nadine Mouton
Medicines Information and Safety Pharmacist
Namibia
Therapeutic Information and
Pharmacovigilance Centre (TIPC)

Botswana



BoMRA
Mr. Lebogang Koitsiwe
Manager Pharmacovigilance
Botswana

Zambia



ZAMRA
Ms. Mwewa M Siame
Principal Surveillance Officer
CT/PV/DI
Zambia

11:15 - 11:30 CAT

Coffee Break



11:30 - 12:15 CAT

Data Management and Ai in PV

Moderator



Ms. Willemijn van der Spuij
Executive Director Europe,
Patient Safety
Bristol Myers Squibb

Application of Ai in
Pharmacovigilance



Dr. Raghavendra Pai
PV Director
Ipsen

Status quo in Africa



Sarisha Naicker
Pharmacovigilance Manager
Adcock Ingrem

12:15 - 13:30 CAT

Inspections to ensure Quality Pharmacovigilance

Moderator



Dr. Ahmed Hegazy
Managing Director
PVigilant Health

Risk based approach for
PV Inspections & Common
Findings in Egypt



Dr. Walaa Ebrahim Saber
Manager Pre-Marketing Vigilance
Regulatory Affairs Administration
Gnl Administration for PV
Egyptian Drug Authority (EDA)

PV Inspection:
The Ghana Experience



Ms. Adela Ashie
Head of the Vigilance Unit,
Safety Monitoring Department
Food and Drugs Authority Ghana

Practical Inspection
Workshop - Break Out



Dr. Nahed Yaish
General Manager
SOP Consultancy

Workshop Feedback and Discussion

13:30 - 14:30 CAT

Lunch

14:30 - 15:30 CAT

Emerging East Africa

Rwanda

What are the Inspection findings -
learnings and how is it helping
to shape the PV in Tanzania.



Dr. Jayesh Pandit
Pharmacovigilance Country Head-
Middle Africa, Bayer East Africa
& Immediate Past Chairperson
KAPI Pharmacovigilance and
Medical Affairs Committee



Phn. Lazare NTIRENGANYA
Division Manager
Pharmacovigilance &
Safety monitoring
Rwanda FDA



Dr. Elirehema Mfinanga
National Focal Person for
Pharmacovigilance
Tanzania Medicines and
Medical Devices Authority (TMDA)



15:30 - 16:00 CAT Coffee Break

16:00 - 17:15 CAT "New generation" Vaccine Surveillance

Moderator



Ms. Comfort Ogar
Secretary Africa Chapter
International Society of
Pharmacovigilance
(ISO-P).

Benefit Risk Assessment
for Vaccines; Key Functions of
Open-Source Digital Platform



Dale Nordenberg
Digital Transformation lead
Safety Platform for Emergency Vaccines
(SPEAC) program

Leveraging the rollout of
COVID-19 vaccines to strengthen
PV systems in Africa



Ms. Laura Martin, PhD
Vaccines Program Director,
Global Health Technical Programs
United States Pharmacopeial Convention
(USP)

Panelist



Dr. Bassem Toema MD, Ph.D.
CEO and Founder
MD Pharma Consulting Group

17:15 - 17:30 CAT Wrap up and Close of Summit



Ms. Willemin van der Spui
Executive Director Europe,
Patient Safety
Bristol Myers Squibb



Dr. Ahmed Hegazy
Managing Director
PVigilant Health



Ms. Comfort Ogar
Secretary Africa Chapter
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