



# ISO P and the African Society of Pharmacovigilance

The African Chapter of the  
International Society of Pharmacovigilance  
(ASoP)



Symposium  
& Training

## Pharmacovigilance in Africa beyond Spontaneous Reports

Nairobi, Kenya 6-7-8 May, 2019

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This Symposium and Training event, the first of this kind organised in Africa, will be addressing the specific needs and interests of people working in the field of pharmacovigilance either in regulatory agencies, pharmaceutical companies, in academia, hospitals or community settings.

Despite efforts for improving the spontaneous reporting of adverse events in Africa, the reporting behaviour remains sub-optimal to the extent of urging to develop new approaches for collecting safety data e.g. by involving consumers and patients directly. On the other hand, risk minimisation methods that suit African health care systems need to be developed and implemented. In such a context, and moreover in the perspective of the upcoming constitution of the African Medicinal Agency, this mid-year Symposium & Training Course is aimed to be a milestone for sharing ideas on how to improve the different components of safety regulatory systems and practices.

This ISO P Symposium & Training Course is intended for an audience including representatives from National Regulatory Authorities, Universities, Hospitals and industry professionals. At the term of this event the participants are expected to have an overall understanding of pharmacovigilance systems, practices and issues in Africa and beyond, and be capable of promoting practices according to international standards.

The faculty contributing to this course consists of international and national experts in pharmacovigilance, representing government, academia, and industry.

Monday May 6<sup>th</sup> | Day 1 | Symposium: Serving Africa's needs in Pharmacovigilance

08:00 - 09:00	60'	Registration.
09:00 - 09:30	30'	Introducing the perspective of the 2019 ISO P/ASoP Symposium & Training, by the chairpersons of the event.
<b>AM Session: Place of Africa in Global Pharmacovigilance</b>   Session chairs: Hilda Ampadu, WHO collaborating centre for advocacy and Training in pharmacovigilance, Ghana.		
09:30 - 10:15	45'	Current trends in global pharmacovigilance Presenter: Sten Olsson, President of ISO P, Sweden.
10:15 - 11:00	45'	Pharmacovigilance in Africa: current status and trends Presenter: Hilda Ampadu.
11:00 - 11:30	30'	Coffee break & Networking.
11:30 - 12:15	45'	What is Africa missing in pharmacovigilance? Presenter: Prof. Ambrose Isah, University of Benin, Nigeria.
12:15 -13:00	45'	Key drivers of the change in pharmacovigilance in Africa. Presenter: Dr. Christabel Khaemba, Pharmacy and Poisons Board, Kenya.
13:00 -14:00	60'	Lunch break and networking.

**PM Session: Building the African Medicines Agency (AMA)** | Session chair: Margareth Ndomondo-Sigonda, New partnership for Africa's development (African Union-NEPAD), Tanzania and South Africa.

14:00 - 14:45	45'	African Medicines Regulatory Harmonisation: NEPAD/AMRH/AMA Presenter: Margareth Ndomondo-Sigonda.
14:45 - 15:30	45'	Creating a GVP for Africa: principles and milestones   Presenter: Paul Tanui, New Partnership for Africa's Development (NEPAD), South Africa.
15:30 - 16:00	30'	Coffee break & Networking.
16:00 -17:00	60'	Supporting creating the African Medicines Agency (AMA): <b>Panel discussion</b> with the Presenters of the morning and afternoon sessions.
17:00		End of Day 1.

Tuesday May 7<sup>th</sup> | Day 2 | Course 1: Africa's changing safety-regulatory landscape

08:45 - 09:00	15'	Introducing <b>Africa's changing safety-regulatory landscape</b> . <i>Session chair: Thuli Makhene, IPASA and Bayer, South Africa.</i>
09:00 - 09:40	40'	Post-approval safety regulatory systems in Africa including inspections. <i>Presenter: Helen Byomire, National Drug Authority, Uganda.</i>
09:40 - 10:20	40'	Implementing Qualified Persons for Pharmacovigilance (QPPV) in Africa. <i>Presenter: George Sabblah, Ghana FDA.</i>
10:20 - 10:40		<i>Coffee break &amp; Networking.</i>
10:40 - 11:20	40'	Solutions for improving the collection of Individual cases safety reports (ICSRs) <i>Presenter: Victoria Nambasa, National Drug Authority, Uganda.</i>
11:20 -12:00	40'	Focusing pharmacovigilance resources on activities the most value-adding for the safety of patients: License holders' point of view. <i>Presenters: Thuli Mahkene, Jabeen Ahmad, and J.C. Delumeau</i>
12:00 -13:00	60'	Focusing resources on activities the most value-adding for the safety of African patients: <b>Panel discussion</b> with the Presenters of the session.
13:00 -13:50		<i>Lunch break and networking.</i>

Tuesday May 7<sup>th</sup> | Day 2 | Course 2: Access to medicines to meet Africa's needs

13:50 - 14:00	10'	Introducing the session <b>Access to medicines to meet Africa's needs</b> . <i>Session chair: Sten Olsson.</i>
14:00 - 14:40	40'	Vaccines for Africa: Current issues and perspective for the future. New mechanisms for vaccines. <i>Presenter: Houda Langar, Director and Regional Advisor for Vaccines, WHO-EMRO, Cairo, Egypt.</i>
14:40 - 15:20	40'	Performing clinical trials in Africa: Pre-approval safety regulatory systems, achievements, challenges and trends. <i>Presenter: Edward Abwao, Pharmacy and Poisons Board, Kenya.</i>
15:20 - 15:40	20'	<i>Coffee break &amp; networking.</i>
15:40 - 16:20	40'	Advances in Safety Technology for Africa. <i>Presenter: Deirdre McCarthy, IQVIA, USA.</i>
16:20 - 17:00	40'	3S, Proforma, and PAVIA: Three initiatives aimed at making new medicines available in a safer way in Africa   <i>Presenter: Sten Olsson.</i>
17:00 - 18:00	60'	ASoP Assembly.
18:00		<i>End of Day 2.</i>

Wednesday May 8<sup>th</sup> | Day 3 | Course 3: Pragmatic Active Methodologies for Africa

08:45 - 09:00	15'	Introducing the session <b>Methodologies for Africa.</b> <i>Session chair: Tanzania Food and Drugs Authority (TFDA)</i>
09:00 - 09:40	40'	Pharmacovigilance methods to address Africa's unique challenges. <i>Presenter: George Sabblah, Ghana FDA.</i>
09:40 - 10:20	40'	Safety communication in Africa: Challenges and opportunities: NRA and MAH perspectives.   <i>Presenters: Christabel Khaemba, PPB Kenya and Jayesh Pandit, KAPI and Bayer Kenya.</i>
10:20 - 11:00	40'	Measuring the burden of drug related harm in Africa. <i>Presenter: Mulugeta Russom, National Pharmacovigilance Centre of Eritrea.</i>
11:00 - 11:20	20'	<i>Coffee break &amp; Networking.</i>
11:20 - 12:20	60'	The new version of VigiLyse, the tool to search and analyse VigiBase <i>Presenter: Helena Sköld, Uppsala Monitoring Centre.</i>
12:20 -13:00	40'	Eritrea's achievements in signal detection. <i>Presenter: Merhawi Debesai, National Pharmacovigilance Centre of Eritrea.</i>
13:00 - 13:50	50'	<i>Lunch break and networking.</i>

Wednesday May 8<sup>th</sup> | Day 3 | Course 4: Benefit vs Risk and Risk minimisation

13:50 - 14:00	10'	Introducing <b>Benefit vs Risk and Risk minimisation.</b> <i>Session chair: Jean-Christophe Delumeau, ISO P EC member, Bayer South East Asia, Singapore.</i>
14:00 - 14:40	40'	Safety specifications and Benefit vs Risk evaluation <i>Presenters: Jean-Christophe Delumeau and Jayesh Pandit.</i>
14:40 - 15:30	50'	Risk management planning and risk minimisation methods <i>Presenters: Jean-Christophe Delumeau and Christabel Khaemba.</i>
15:30 - 15:50	20'	<i>Coffee break &amp; Networking.</i>
15:50 – 16:50	60'	<b>Hand-on group Exercise:</b> Implementing a risk minimisation decision in the context of African Health Care Systems. Facilitators: <i>Christabel Khaemba, Jayesh Pandit and Jean-Christophe Delumeau.</i>
16:50 – 17:00	10'	Concluding remarks of the meeting.
17:00		<i>End of the training course.</i>