SAAPI
South African Association of Pharmacists in Industry

Pharmacovigilance (PV) Symposium

Presenters:

To be confirmed
SAHPRA, Pharmacovigilance

Andrea Julsing Keyter
Senior Manager: Medical Devices and Radiation Control

Prof. Marc Blockman
Director, WHO Collaborating Centre for Medicines Information (MIC)

Symposium Overview:
In South Africa, there are few service providers who offer training courses in pharmacovigilance. Courses available are aimed at introducing basic pharmacovigilance concepts to employees who are just entering the area of pharmacovigilance or to other industry colleagues who would like a better understanding of what pharmacovigilance is. There is no adequate advanced PV training available to PV specialists who have been in industry for more than 3 years. Most PV specialists gain their knowledge through on-the-job training. This PV training is limited to how the specific organisation functions e.g. there are differences in terms of PV processes between innovator and generic companies as well as differences between international companies and South African companies.

Symposium Objectives:

1. Create an annual platform to discuss advancements and changes to PV regulations and their impact to industry for individuals and organizations involved and participating in Pharmacovigilance in the pharmaceutical, academic and general health sector in SA.
2. Knowledge/best practice sharing between the PV Specialists so that PV Specialists are gaining knowledge of how PV functions in an organisation different to their own.
3. Engage with SAHPRA regarding local PV requirement clarity or challenges and for SAHPRA and industry to gain an understanding to each organisation functions to advance PV in South Africa.
4. Increase PV awareness
5. Remain abreast of industry developments and regular changes
6. Create a networking opportunity among PV stakeholders.

Who should attend?
Pharmacovigilance Managers, officers or persons responsible for Pharmacovigilance activities within an organisation who typically have at least 3 years of solid PV working experience.

Symposium Format:
Online on Microsoft Teams

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AGENDA

Topic	Discussion Points	Speakers
Update on RSA PV Regulations and Developments	• VigiBase • VigiAccess • Timelines for medication errors to be reported to SAHPRA • Pharma oversight of ADRs received for their products reported directly to SAHPRA by HCPs • DHCPL • Annual PSUR – New addition • Dissemination of SAHPRA PV Unit recommendation/request letters to Applicants– New addition	**To be confirmed** SAHPRA, Pharmacovigilance
Medical Devices	• Overall PV requirements for devices • Case reporting format • Number of cases received thus far relating to devices in South Africa • Is there a mutual recognition agreement with South Africa and other Health Authorities regarding exchange of device ADRs? • Plans to have an electronic case reporting system? • Any other relevant point the presenter feels should be discussed	**Andrea Julsing Keyter** Senior Manager : Medical Devices And Radiation Control, SAHPRA
Signal Detection, DHCPL, RMPs	• Signals from other HAs • Increased frequency of RMPs • Approach for generic companies • SAHPRA monitoring of action item close out • Sharing of responsibilities • Holding doctors accountable for certain activities in the RMP • Feasible action items	**Prof. Marc Blockman** Director, WHO Collaborating Centre for Medicines Information (MIC)