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The Standalone Pharmacovigilance Policy: a tool for engagement and collaboration of stakeholders in the Pharmacovigilance System in Resource Limited Settings.

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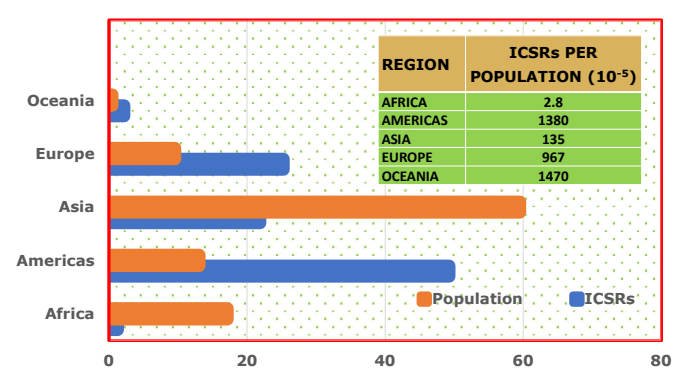
Introduction

- The establishment of the WHO Program of International Drug Monitoring commenced with countries in Europe and America in 1968 and it was about 25 years that the first African countries were admitted
- . The less developed countries, Africa constituting a substantial number, with their minimal resources have in the last two to three decades established Pharmacovigilance (PV) systems
- Many of which remain weak, with poor visibility and contending with many challenges; reporting rates of Individual Case Safety Reports (ICSRs) remain low and the trajectory unimpressive (Figure 1)
- Policies, Laws and Regulations regarding Medicine Safety (Pharmacovigilance) where they exist, are usually terse statements embedded in other pharmaceutical documents.
- In order to further strengthen PV in these settings, there is need to develop a Policy document (standalone) to serve as a non-intimidating engaging tool for obtaining commitment from stakeholders and serving as a guide to action in the PV scenario.



REGION	ICSRs PER POPULATION (10^{-5})
AFRICA	2.8
AMERICAS	1380
ASIA	135
EUROPE	967
OCEANIA	1470

Fig 1. Percentage of Total World Population and ICSRs per Region

***Source*: ICSRs in WHO UMC Database (Vigibase)**
Population: https://www.worldometers.info/world-population/population-by-region

Method

- A clear understanding of the PV system, structure and processes is an essential initial step to be addressed by a Lead Team.
- Advocacy focused on Policy development as well as a provision for Standalone in its use
- Identification and invitation of Stakeholders required for the engagement exercise.
- The process of development requires the involvement of government and other major operators in the health and pharmaceutical systems (MOH, NMRA, MAHs) as well as the public-consumer.
- The Policy Framework and Provisions should be duly addressed taking into considerations the various elements ensuring good PV practices and a consensus reached.
- The zero draft is developed by the Lead Team and subjected to multiple reviews amongst stakeholders.
- Following clarifications and inputs from policy organs of government the necessary endorsements, approval is obtained from the Executive arm of government.

Objective

- To discuss the development of a Standalone PV Policy document not limited to Ministries of Health (MOHs), National Medicines Regulatory Authorities (NMRAs), Market Authorization Holders (MAHs) and even Health Care Professionals (HCPs) as a tool for advocacy to address the overlooked engagement and collaboration of multiple stakeholders.

Result

- The application of the above in Nigeria and Eswatini resulted in the development of National PV Policy documents. The implementation framework accompanying the documents and a recently developed guidance document will facilitate implementation

Nigerian PV Policy

Eswatini PV Policy

Conclusion

- The Concept of the Standalone PV Policy when properly applied following appropriate stakeholder engagement is likely to ensure inclusiveness, increased awareness and strengthened PV in resource limited settings without undermining other statutory laws and regulations. It will also serve as a tool for advocacy and future engagement with all stakeholders
- The use will also allow for unhindered discourse and understanding of Pharmacovigilance by both health and non health professionals

Acknowledgement

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- The participation of all Stakeholders and their contribution is noted with due gratitude

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