



# Pharmacovigilance funding landscape in Africa – a survey

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## Introduction

- The establishment and growth of Pharmacovigilance in Resource Limited African countries has been slow since the inception of the WHO Programme for International Drug Monitoring (PIDM) in 1968.
- African countries were late entrants into the PIDM with the admission of Morocco and South Africa in 1992.
- Most of the countries are yet to achieve the maturity required to carry out activities to ensure optimal medicine safety, more so taking into consideration the peculiarities of medicines deployed in the setting.
- One of the main factors highlighted as hindering this growth is the inadequacy of funding.
- In order to further strengthen PV in these settings, there is need to identify the various factors undermining sustainable financing.

## Objective

- To assess the prevailing Pharmacovigilance funding landscape in African Countries
- To identify factors hindering and measures likely to improve sustainable funding.

## Method

- A standardized questionnaire was developed in English with French and Portuguese translations and effectively distributed to 35 African countries during the period July 2020 to October 2021.
- The information sought related to features and operation of the Pharmacovigilance system, sources of and factors impacting on PV funding.
- Suggestions were solicited in free text format on hindrances and measures to improve sustainable PV financing.
- The information was requested from the Head of the National Pharmacovigilance Centre (NPC) or a designated Officer.
- The data collected were handled qualitatively, analysed and presented descriptively.
- Values were expressed as range, median (and mean) as appropriate.
- A thematic synthesis was carried out to aggregate the free text responses. No inferential statistical comparison between countries was done.

## Result

- The questionnaire was completed by NPCs in 24 African countries - response rate of 68.6% (17.6% in the low to low-middle income category).
- The background information of the participating countries is shown in Table 1
- PV activities were funded mainly by Governments and donor agencies.
- The mode of support was by cash grants, technical and other logistics channeled mainly through the NMRA and Public Health Programmes. Nine of the countries had a clear budget line and 85.7% had their funding linked to the NMRA.
- Factors identified as hindering PV funding included - lack of awareness of the importance of PV and poor prioritization in the national scheme, unfavourable legal environment, non-generation of revenue, poor budgetary allocation, non-release and diversion of funds etc. Measures suggested to improve PV financing include adequate prioritization and political goodwill, improved legal environment with increased annual budgetary allocation, revenue generating activities, non-diversion of funds etc.

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## Regions of Africa



Table 1 Background Information

Parameter	Value (%)
Number of Countries	24
World Bank GNI per capita (US\$)	
- Low Income ( $\leq 1056$ )	4 (25.0)
- Low Middle Income (1056 - 4045)	15 (62.5)
- Upper Middle Income (4046 - 12,555)	2 (8.3)
- High Income ( $\geq 12,555$ )	1 (4.2)
No. of countries with NMRA (%)	22 (91.7)
No. of countries with NPO PV Unit	20 (87.5)
Membership of PIDM	20 (87.5)
Staff disposition (Median values)	
- Total (NMRA + NPO)	51
- NPO Staff	5
- NMRA/NPO ratio	11

Table 2. Budgetary and other fiscal issues

Parameter	No. of Countries N (%)	Median Value (Range)
Direct Government Funding	12/21 (57.1)	NA
Proportion of total budget contributed by govt the previous year?	11/21 (52.3)	(0.11 - 100)
Clear Budget Line	9/21 (42.9)	NA
Adequacy of amount budgeted for PV activities	4/21 (19.0)	NA
Proportion of govt total budget for PV released previous year (%)	9/11 (81.8)	15.4%
PV funding linked to NMRA's	18/21 (85.7)	0.06 - 100%
Dedicated NMRA budget for PV	15/20 (75.0%)	NA
Proportion of NMRA budget dedicated to PV	13/21 (61.9%)	4.4%
		(0.115 - 30.9)

## Conclusion

- In all, funding of Pharmacovigilance in Africa is inadequate, arbitrary with no legislative provisions and tied to the NMRA with significant donor funding channelled through the NMRA and PHP. There is need for PV financing to be backed by statute which will ensure sustainable funding and also put into operation suggested measures to improve funding