FUNDING AND FINANCIAL SUSTAINABILITY OF PHARMACOVIGILANCE

Suggested Model for funding Pharmacovigilance in Resource Limited African Countries

PhArmacoVigilance Africa (PAVIA)

Funding and Financial Sustainability of Pharmacovigilance

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Table of Contents

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Abbreviations

EDCTP: European-Developing Countries Clinical Trials Platform

EMA: European Medicines Agency

LMICs: Low- and Medium-Income Countries

MEB: Medical Evaluation Board

MHRA: Medicines and Healthcare products Regulatory Agency

MOH: Ministry of Health

NDA: National Drug Authority

NMRA: National Medicines Regulatory Agencies

NPC: National Pharmacovigilance Centre

PAVIA: Pharmacovigilance in Africa

PIDM: Programme of International Drug Monitoring

PHP: Public Health Programmes

PV: Pharmacovigilance

PDUF: Prescription Drug Users Fee Act

VAT: Value Added Tax

WHO: World Health Organisation

Executive Summary

Introduction

The establishment and growth of Pharmacovigilance (PV) over the last fifty years has contributed to the identification and minimisation of risks attributed to medicines in no small measure. The impact has been most appreciated in more advanced countries. However, the growth trajectory would have been more impressive but for some hindering factors negatively influencing its growth. This is most significant in the resource limited settings where the establishment of National Pharmacovigilance Centres (NPC) and their membership of the WHO Programme of International Drug Monitoring (PIDM) are more recent.

The need for a functional system to monitor the adverse effects of medical products and vaccines in Africa has become more urgent when the peculiarities of medicines used to treat the new and emerging diseases in the continent and indeed globally are considered. Recent examples include HIV/AIDS, Ebola, COVID-19 amongst others. The differential response by Africans as compared to other populations is worthy of note and remediable measures to minimise these effects can only be put in place if there is a systematic monitoring of the outcomes following use.

A major factor hindering the growth of the monitoring schemes has been the lack of resources to finance PV activities in these countries coupled with the lack of personnel and essential infrastructure. Where and when funds are made available there are usually ad hoc and most times donor driven There is utmost need to put in place a more sustainable financing model which

would address the funding of PV activities in the African setting. Thus, this paper addresses the various ramifications to attaining this fiscal state for PV.

Objective

The objective of this paper is to provide an overview on the considerations and approach to establishing a financial mechanism to ensure sustainable funding of PV in Africa thus ensuring medicine safety in resource limited Africa.

Conceptual Framework and Processes

Financial sustainability in this regard, will entail a long term, continuous, adequate, stable, vested interest – free funding. The funding mechanisms determining its sustainability should ensure the availability of funds for its stipulated functions. Notable challenges of funding PV were taken into considerations and the essential elements in the operating model should include but not limited to the ethics and independence to be built into its operations, credibility of the source of funding, transparency as well as accountability in financial operations. The inclusiveness to ensure that all PV organs are incorporated holistically in the model so as to ensure its sustainability is of utmost importance,

There are critical issues to consider in PV financing since they are determinants in the development of a functional financing model. The process of developing this framework entailed a review of PV financing in some developed economies, a landscape study of funding of PV in some African countries, an in-depth understanding of the PV system and the organisational structure and nexus between the regulatory agencies and NPCs.

These include the following: Pharmacovigilance System /NMRA Structure, sources of fund, budgeting and allocation of funds, disbursement and expenditure profile, the activities of the NMRAs and the NPCs and the overarching enabling legal provisions.

The prevalent integrated NPC/NMRA structure in the African setup as against the independent NPC/NMRA, is a major determinant as to the model of PV financing to be established. The multiple sources of funding include public financing – directly from government and its agencies, approved fees from commercialised services and donor financing amongst others. There are many potential sources yet to be explored. These include the insurance schemes, PV tax on pharmaceutical sales, other taxes direct for PV or Earmarking of the revenue for PV such as Consumption Tax (alcohol and other beverages, tobacco, sugars etc.) Value Added Tax and Lottery.

The financial model to ensure a sustainable funding for PV in Africa will depend on a legal provision governing most of the outfits, their activities, pooling of resources and subsequent disbursement and expenditure. Areas like the nexus between the NPC and NMRAs should be guided by definite laws and regulations in their fiscal operation. This should also guide the pooling of resources with due prioritisation of PV in the national scheme. The exploration of potential revenue sources coupled with that expected from government would to a large extent ensure the availability and sustainability of funds.

Conclusion

In all, the harnessing of the multiple sources of funds both statutory and the potential sources yet to be explored would make a sizeable revenue pool for PV. The provision of an overarching legal framework would ensure the availability and sustainability of funds for PV. Furthermore, due prioritisation of PV in the healthcare system, financial prudence, fiscal transparency and accountability will ensure financial sustainability for PV in the resource limited settings.

1.0 Introduction

The onerous responsibility of ensuring the safety of medicinal products and vaccines has become urgent and of utmost importance following the significant potential morbidity and mortality with the intake of these products. The duties are delegated to establishments with experts which operate within the context of the National Medicines Regulatory Agency (NMRA) or independently. Over the years, these set of activities have come under the umbrella of Pharmacovigilance and the establishments addressing the activities and processes of this system have been designated as National Pharmacovigilance Centres (NPCs) or units. Many of these establishments are members of the WHO Programme for International Drug Monitoring (PIDM) which was established in 1968 [2].

African countries were late entrants into the PIDM, starting in 1992 with South Africa and Morocco. The gradual entry of the African countries occurred over a period of three decades and now stand at forty four[3].

The performance of African countries remains under par when assessed by various measures including the objective indices of number of reports forwarded to the UMC Uppsala database. Until recently the number of reports from the entire African countries in the database averaged 1% with an unimpressive trajectory, though with some marginal increase following the monitoring of the COVID 19 vaccines[4].

In Africa, the concept of pharmacovigilance and the establishment of NPCs started much later. The first two African countries to join the PIDM were Morocco and South African in 1992. Although forty-four African countries are now members

of the PIDM, NPCs in African countries are hindered by financial and logistics factors and are thus unable to monitor the safety of medicinal products optimally in their countries.[5, 6]. Considering the competition by various sectors of the economy in the resources limited settings (RLS) it could be inferred that the low prioritisation of PV activities is an important factor. The resource challenges in most African countries with a low GNI per capita[7] is beset by a huge debt profile, spiralling inflation and unfavourable foreign exchange status of local currency. The psyche of government usually relates to provision of medicines in the healthcare system which is considered beneficial with no consideration for potential harmful effects and the need to monitor them. In effect, the financing of pharmacovigilance is poorly prioritised. The various other factors that contribute to the poor funding of pharmacovigilance activities and measures to obviate them in African RLS have not been studied in a focused manner. Again, how all these impact on the funding of pharmacovigilance in the very competitive scheme of national resource allocation and how to remedy them is still speculative.

In realisation of this situation, dedicated efforts have been directed to strengthen PV in the African setting [8], with a sustainable funding mechanism in view. This paper evaluates the PV system, potential sources of funding and proposes a framework that is likely to guide the establishment of a sustainable financial system.

2.0 Conceptual Framework

2.1 PV Funding and Financial Sustainability

Definitionally, financial sustainability entails a long term, continuous, adequate, stable, vested interest – free funding. The funding mechanisms determining its sustainability should ensure the availability of funds for its stipulated functions

In order to espouse the approach to developing a sustainable financing framework for Pharmacovigilance in the health care system amidst competing demands and interests, a proper understanding of the milieu and overarching important considerations likely to impact on the process and eventual outcome is imperative. This also require clarity regarding the essential elements of a financing model, potential challenges, and the critical points to address as highlighted below.

2.2 Some notable challenges of Financing Pharmacovigilance

The notable challenges in PV Financing include though not limited to the following:

- Undermining of funding of pharmacovigilance activities in healthcare /pharmaceutical systems.
- Low prioritisation of PV funding in the fiscal scheme of country's pharmaceutical care
- Conflict of interest of major stakeholders undermining the setting up of a robust mechanism to ensure appropriate funding.
- Lack of budgetary provisions and legal structures to support funding.

It is imperative that the importance of PV be realised in the polity and placed on an appropriate pedestal so as to ensure adequate and sustainable funding.

2.3 Essential Elements of a Financing Model

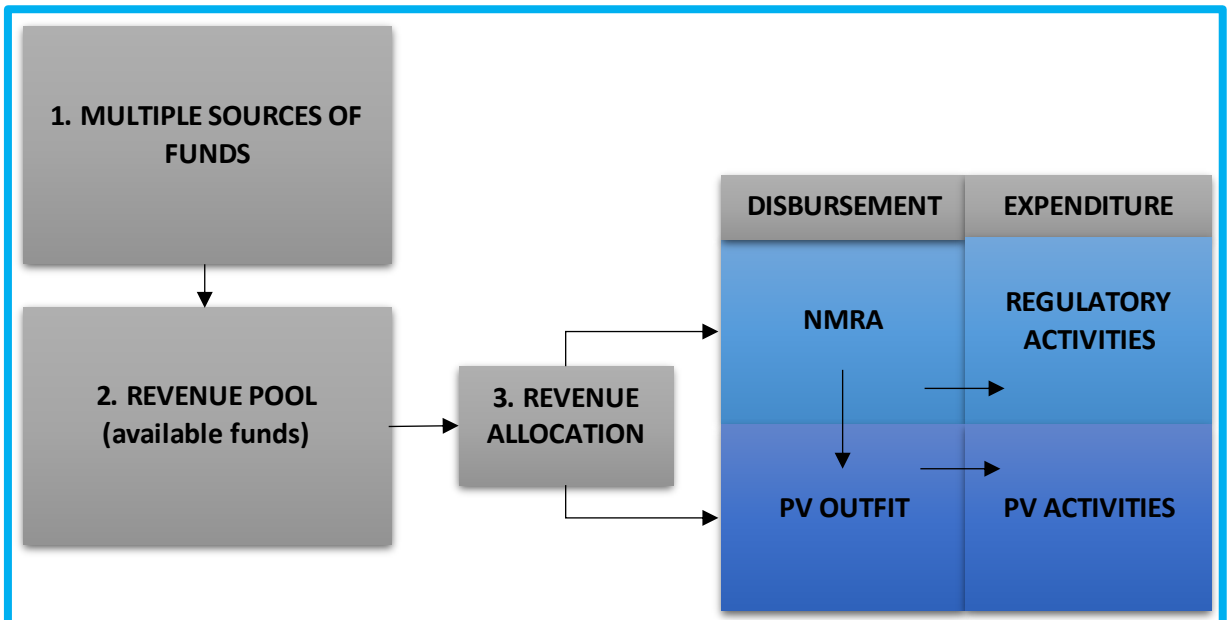
In view of the nature of pharmacovigilance, the ethics required in its operations and the set objectives to be realised, optimal considerations should be given to the funding mechanisms and the financial dynamics. The essential elements of any financing model should include and not limited to the following:

- Insulation of PV establishments from influences/interests likely to undermine its function.
- Credibility of the source of funding.
- Transparency and accountability in financial operations.
- Availability of adequate funding devoid of bureaucratic hindrances.
- Sustainability of funding to ensure continuity of PV programmes.
- Funding should be holistic in scope so as to cover the PV outfits at all levels: Facility, Local Govt, State or Provincial, National, Regional/Continental as well as those at International/Global levels.
- Public Health Programmes must be given due consideration.

3.0 Critical points for consideration in PV financing

There are critical issues to consider in PV financing since they are determinants in the development of a functional financing model. These include the following (**Figure *1***):

- Pharmacovigilance System /NMRA Structure
- Sources of Fund and Financial Pool
- Budgeting and Allocation of Funds - Scope
- Disbursement and Expenditure Profile
- NMRA and Regulatory Activities
- PV Facility and PV Specific Activities
- Enabling Legal Provisions



Sources of Fund (1); Revenue Pool (2); Revenue Allocation (3); NMRA//PV outfit nexus (4); Disbursement and Expenditure on activities (5); Overarching Legal framework (1 – 5)

Figure 1. Critical points for consideration in PV Financing

3.1 Pharmacovigilance System /NMRA Structure

An in-depth understanding of the Pharmacovigilance System, its operations and its nexus with the National Medicine Regulatory Agencies is of utmost importance for a proper characterisation of PV financing. The multiplicity of organisational structure of PV establishment vis a vis the National Medicines Regulatory Agencies (NMRA) implies the need for a financial model which will address the nexus between the two outfits. The prevalent organisational structures include the following:

- The Pharmacovigilance Outfit is fully integrated within the NMRA as a unit, department or a directorate. The operational name is the 'National Pharmacovigilance Centre' (NPC)
- The Pharmacovigilance Outfit is semi-autonomous (as a parastatal or directorate) with administrative issues handled independently but fiscal issues tied to the NMRA.
- The Pharmacovigilance Outfit is totally autonomous, independent regarding administrative and fiscal issues though interacting on matters of medicine safety

The most common organisational structure in African countries is that in which the PV outfit is integrated into the NMRA's administrative and fiscal operations (**Figure *2***). The PV outfits in Morocco and Tunisia are independent from their NMRAs regarding their administrative and fiscal operations (**Figure *2***). The relevance of these structure will be discussed below.

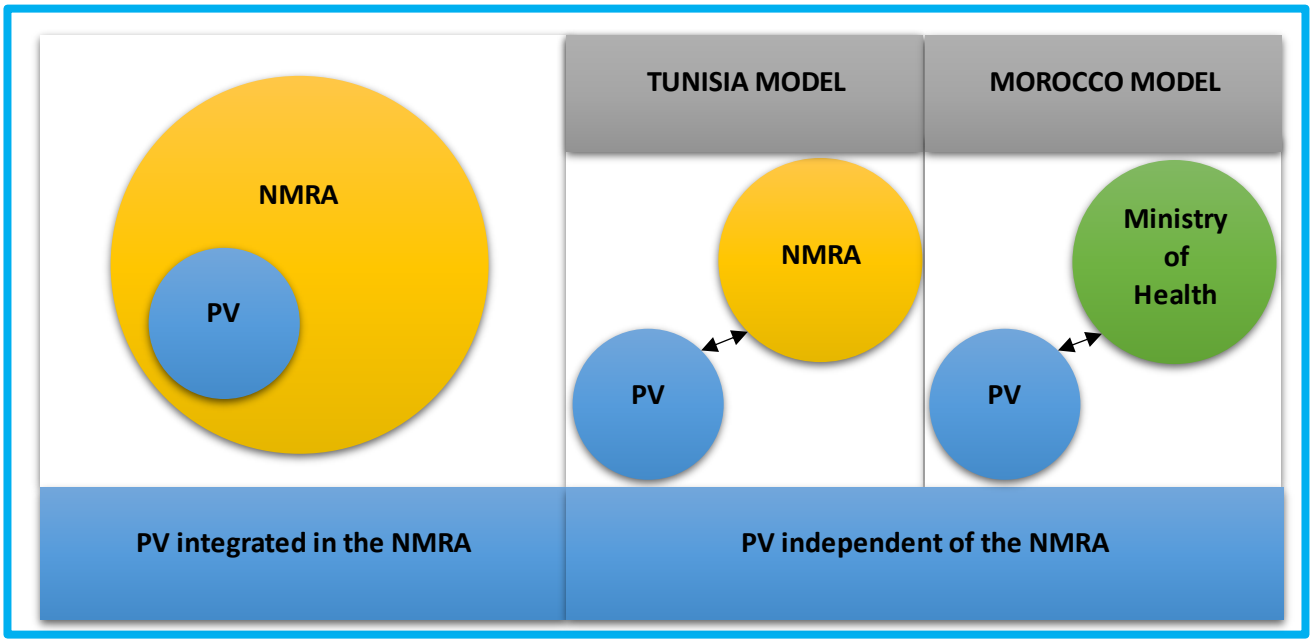


Figure 2. Organisational Structure of Regulatory Agencies in relation to the Pharmacovigilance Outfit with variant organisational structures for PV outfits independent of the NMRA.

3.2 Sources of Fund and Financial Pool

There are several potential sources of funds for pharmacovigilance. Indeed, financial sustainability may require focusing on several funding sources. To a large extent the source(s) should provide an uninterrupted flow of funds to the revenue pool and essentially the pool should be maintained at a critical level, robust to absorb shocks and not easily decapitated by minor programmatic challenges. Some potential sources are mentioned below (**Box *A***). The extent to which the extant funding mechanisms is able to access these sources is of paramount importance. The revenue pool available for PV is further impacted by a number of other factors as well as the organisational structure which determines the principal recipient of the available fund.

The details of these sources and on how to access them vary from country to country. There are some local measures such as the revenue law and the treasury single account which may impact negatively on the funds available for PV activities (***Figure 3***). Some of the potential sources are yet to be explored and where and when explored are suboptimal in their reach. This includes the various revenue generating commercial services. The various health insurance schemes are yet to be implemented and early attempts remain infantile with poor coverage of the population. The Ghanaian experience is a case in point, where the capitation payment model used in a pilot implementation of the national health insurance scheme failed due in part to political reasons and perception of the population[9]. The promotion of health insurance schemes to increase its penetration in the country polity with due recognition of the

need to contribute to PV activities will definitely be a veritable source[10].

Box A. SOME SOURCES OF FUNDS	
Public Financing • Government statutory budgetary allocation • National Tax • Other statutory allocations Fees from commercialized services • User Fees • Registration and Licensing • Prescription Fees etc. Community Financing Pharma Consortium PV tax on pharmaceutical sales Earmarking • Consumption Tax • Value Added Tax • Health Insurance • Lottery	Donor Financing • World Health Organisation (WHO) • United Nations International Children's Fund (UNICEF) • The United States Agency for International Development (USAID) • Management Sciences for Health (MSH), • The United States Pharmacopoeia (USP) • European and Developing Countries Clinical Trials Partnership (EDCTP) • New Partnership for Africa's Development (NEPAD) • Global Fund (GF) • Bill and Melinda Gates Foundation (BMGF) • Clinton Health Access Initiative (CHAI)

There is also need for Government to put in place earmarking policies as one of the mechanisms for generating revenue for PV. Earmarking is a promising source of revenue mobilisation if properly applied, for instance to consumption tax of alcohol, tobacco and other food products such as sugary beverages that impact negatively on health ('sin' tax)[11]. The earmarking measures have been used for other purposes in several countries including South America, Philippines, Egypt, Ghana, South Africa. This can be applied to PV with appropriate advocacy to government to enable development of politically acceptable policies. Other consumption tax e.g., Value added tax (VAT) has been useful sources. The Task Force on Fiscal Policy on Health[12] highlighted that raising the price of tobacco, alcohol and sugary beverages by increasing excise taxes not only reduces morbidity and mortality but also generates additional tax revenues. Lotteries have also been a useful source.

The role of different categories of donors in the development and sustenance of PV has been substantial over the years. The ad hoc and perennial nature of this source does not guarantee financial sustainability and does not allow for proper budgeting. However, sizeable donations may increase the revenue pool and considering the focus of these donations they may be useful in achieving objectives of many public health situations.

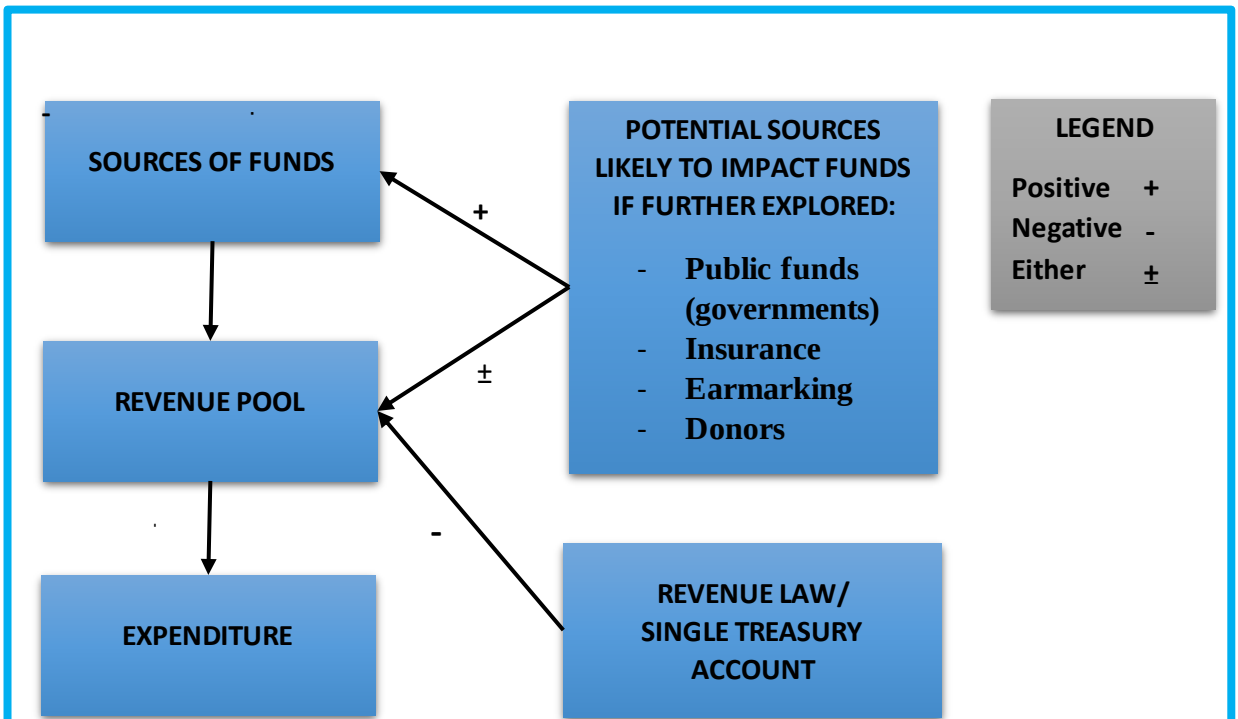


Figure 3. Factors impacting on the size of the Revenue Pool

3.2.1 Pharma Consortium and PV tax on pharmaceutical sales

The setting up of a pharmaceutical consortium dedicated for pharmacovigilance activities is a potentially useful source of funds. However, this is usually difficult to achieve at national levels considering the chain of command. The Head Office of the Pharma are located in foreign countries and are unlikely to adapt such policies. Of interest is the support from big pharma during the COVID pandemic. The most likely approach to achieve success at the national level is the PV tax on pharmaceutical sales. This could be established after due consultation in accordance with statues. However, the possible backlash of an increase in drug prices (mark-up) must be dealt with.

3.3 Budgeting and Expenditure of funds

Realistic budgeting is an important element in ensuring judicious fiscal planning. One of the factors highlighted in the African PV financial landscape survey was the poor budgeting. There was a poor understanding and arbitrariness of the budgeting process. There is need to relate pharmacovigilance activities[13] (**BOX *B***) to financial expenditure so as to develop a realistic budget which can be reflected in a dedicated budget line in the national fiscal plan. The expenditure profile in PV result from wages, operational costs and development of infrastructure which vary to a large extent depending on the programmes and growth of the outfit. The expenditure including purchasing arrangements must be well planned having in view available resources (***Figure 1***)

The WHO PV Tool Kit[14] is a useful resource to achieve this. Again, there should be compliance with extant provisions of the national Laws and provisions to ensure transparency and accountability. Attention to detail must be applied in the development of budgets by attributing realistic cost to the intended activities and items for purchase to achieve its objectives.

BOX B. SOME FUNCTIONS OF THE PV SYSTEM[13]

1. Adverse Drug Reaction /Event Reporting (Post- Marketing etc)
2. Medication Errors, SFs, DD, Lack of effectiveness, misuse/abuse of medicines etc
3. Management of ICSRs and its Database
4. Coding of Adverse Events and Drug Names
5. Expedited and Aggregate Reporting incl. PSURs and PBRER
6. Signals and Signaling in the context of Risk Management
7. Causality assessment, Signal detection and management (Confirmatory activities etc)
8. Clinical Trials - Data Monitoring, DSMB etc.
9. Pharmacovigilance System Master File
10. Pharmacovigilance Inspections and Audit
11. Corporate and Drug Safety SOPs, Working Documents, Guidelines and Manuals
12. Stakeholder Advocacy and Engagement
13. Communications

3.4 Allocation of Funds (Scope) and Disbursement

The mechanisms for allocation and distribution of funds depend on the levels in view. This paper deals with national and subnational levels which include Zonal and/or Regional Centres, Primary Care and Hospitals – Cottage and Tertiary and Public Health Programmes

Government should ensure a sustainable funding by expenditure earmarking to PV as a subsector of the health system guaranteeing allocation of funds from the Ministry of Health or relevant agencies. This will increase the financial pool available for PV activities

The allocation of resources is to a large extent determined by the organisational structure. As mentioned above, when the primary recipient is the NMRA with the integrated PV outfit, the allocation of funds to the later has been arbitrary. Most times the priorities of the agencies are set far and above those of PV. It may not relate to budgetary provisions. It is therefore necessary to define a clear formula for the funds to be allotted predicated on the PV budget. The absence of a clearly defined formula is a frequent cause of friction and underfunding of PV.

In the instance, when the PV outfit is the primary recipient of the pooled revenue, the main concern is the judicious use of funds vis a vis a realistic budget. The funds allocated to other sublevels should depend on the responsibilities they bear and the expected deliverables.

3.5 Legal Framework

One of the main findings in the African PV funding landscape study was the absence of a legal framework in most of the countries. One exception was Zimbabwe which has a legal

provision for the NMRA which also oversees PV in the integrated system operating in the country [15]. However, there is no formula to ensure clarity in the allocation/distribution of resources from the NMRA to the PV outfit

The legal framework in an overarching manner should address all steps identified in the chain of critical points likely to influence the PV finances (**Figure *1***). The fiscal policies of the government should be inclusive of issues related to Medicine Safety. The US PDUF Act is an example of a source of funding backed by legislation.

The WHO study reported a decrease from 100% to 60% donor funding between 1995 and 1997 in Uganda as a result of changes in the NMRA funding policy with increase in the proportion from government and industry[16]. The study of Ndomondo-Sigoonda et al[17], in 2020 confirmed this earlier finding of the WHO study stating that the Uganda National Drug Authority (NDA) is currently 98.25% funded through fees for service with minimal contribution from donors.

Areas to be addressed include statutory allocation of funds from government, provision granting financial autonomy to the PV outfits thus enabling retention of their fees for service provided i.e exemption from revenue law/single treasury account. Legal provisions to enable Earmarking in identified areas including health insurance should also be considered. In effect, definite policies, laws and regulations must be put in place to ensure a favourable environment for PV using provisions of the legislative and executive arms of government.

4.0 Methods/Process

The process of developing a model for sustainable financing of pharmacovigilance activities in resource limited African countries required extensive consultation and understanding of the prevailing pharmacovigilance system and the financial dynamics. This series of evaluation was carried out during the period 2019 to 2022 in the context of the overall PAVIA project by Work Package 2 and significant contribution from Work Package 1 PAVIA (Pharmacovigilance in Africa) an EDCTP (European-Developing Countries Clinical Trials Platform) - sponsored project intend to strengthen PV in the African setting [8].

The various steps entailed the following:

- A review of funding of PV in some well-developed economies

  A purposed literature search was conducted mainly targeting PV financing models from the developed and well-resourced countries with a view to understanding the PV financing models and systems in these countries. Information about these models was collected from journals and other on-line information through basic Google searches. The search was further extended to include multi lateral/bilateral funding agencies such as the World Bank, Global fund, EDCTP and Bill and Melinda Gates Foundation (among others).

- A landscape questionnaire survey[15] of the funding modalities for pharmacovigilance in African countries provided a situational analysis and notably provided information regarding the organisational structure of the

regulatory agencies and the nexus with the national pharmacovigilance outfits, sources of revenue and the constraints in ensuring sustainable funding.

- Consultative meetings, webinars, interviews with experts on sustainable funding for pharmacovigilance was solicited as reflected in the Acknowledgement Section.

The information thus obtained enabled the development of potential frameworks for PV financing models.

5.0 Findings

5.1 Literature search on funding of PV in some well-developed economies

The establishment of the Programme for International Drug Monitoring (PIDM) by the WHO required a substantial grant from the USA government facilitated by a Presidential executive order and later the Swedish government following transfer to Uppsala Sweden in 1978[18]. The Uppsala Monitoring Centre (UMC) as it is called eventually became self funding as a Foundation and financially independent relying on internally generated revenue mainly from sales of its dictionaries)[19].

The funding of activities to ensure the safety of medicinal products and vaccine has been supported by the governments of the various countries usually through their various agencies and competent authorities. In the USA, the FDA benefitted from the Prescription Drug Users Fee Act (PDUF)[20] which was an executive-legislative overture to financially empower the FDA to enhance its efficiency in the handling of processes for licensure since 1992. This was specifically extended to enhance activities relating to ensuring the safety of medicines in a subsequent legislative provision in PDUF IV Act 2007[21]. In the European Union, the European Medicines Agency (EMA) coordinates the European Union pharmacovigilance system and operates processes and services to support pharmacovigilance. Around 86% of the agency's budget derives from fees and charges and 14% from the European contribution for public health issues and less than 1% from other sources[22]. Iin the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the national competent authority and main

regulatory body regarding medicines and pharmacovigilance and is an executive agency of the Department of Health, which is responsible for matters of legislation and finance. In Germany, the national competent authorities are financially dependent on the Federal Ministry of Health[23]. The French Ministry for Health and Social Security is responsible for the legal framework, finances, and the overall supervision of the French pharmacovigilance system. The regional centres rely on financing from the state budget and political priorities set by the Health Ministry. Thus, regional budgets are rather limited, and pharmacovigilance does not appear to be high on the political agenda.

The governments of some countries in Europe such as Portugal due to economic crisis in Southern Europe with lean budgets which impacted on their pharmacovigilance systems is now slowly recovering from the deep financial and personnel cuts in recent years[23]. Lareb in the Netherlands is an independent foundation and is funded by the Medical Evaluation Board (MEB) and the Ministry of Health[24]. In Japan, the substantial source of PV funding is from User fees and other contributions with much less from government[25].

5.2 Findings from the landscape study of pharmacovigilance funding in African countries

In a preliminary PV landscape study of 24 African countries[15], the findings were remarkable and notably included the following:

- The funding from Government for PV though significant is amorphous with budgetary allocations only partially, if released.
- The funding mechanisms of PV is inextricably linked to the NMRAs
- Limited Statutory Provisions (legal framework) for PV financing
- Significant Donor Funding (Multilateral and Bilateral Agencies)
- Prominence of Public Health Programmes (PHPs)
- Budgetary items regarding PV activities are not clear
- No clear formula for release of PV related funds by NMRAs to NPCs
- Absence of permission to accrue, retain and use revenue for PV activities
- Involvement of PV personnel in other activities outside PV
- Unclear disclosure of funds received from donor bodies

The various factors hindering and those likely to improve and ensure sustainable PV funding are stated in an earlier publication[15].

6.0 Considerations for Proposed Model(s)

In essence, considering the factors outlined above the framework for any model for PV financing in Africa will be based on the prevalent organisational structure for Pharmacovigilance establishment and a likely futuristic option as highlighted above, thus:

- NMRA with integrated PV outfit
- Independent PV Outfit operating outside the administrative ambits of the NMRA though interacting on issues of Medicine Safety (and variants thereof)

6.1.1 NMRA with integrated PV outfit

This is the operating framework for Medicine regulation and pharmacovigilance in most African countries. The degree of integration may vary from country to country but for a majority of countries the governance is intertwined.

Figure 4 illustrates this integrated NMRA-PV Model. The recipient of the revenue from the sources shown is usually the NMRA. The allocation from the pool to the PV establishment or for PV activities is determined by the Regulatory Agencies according to its set priorities.

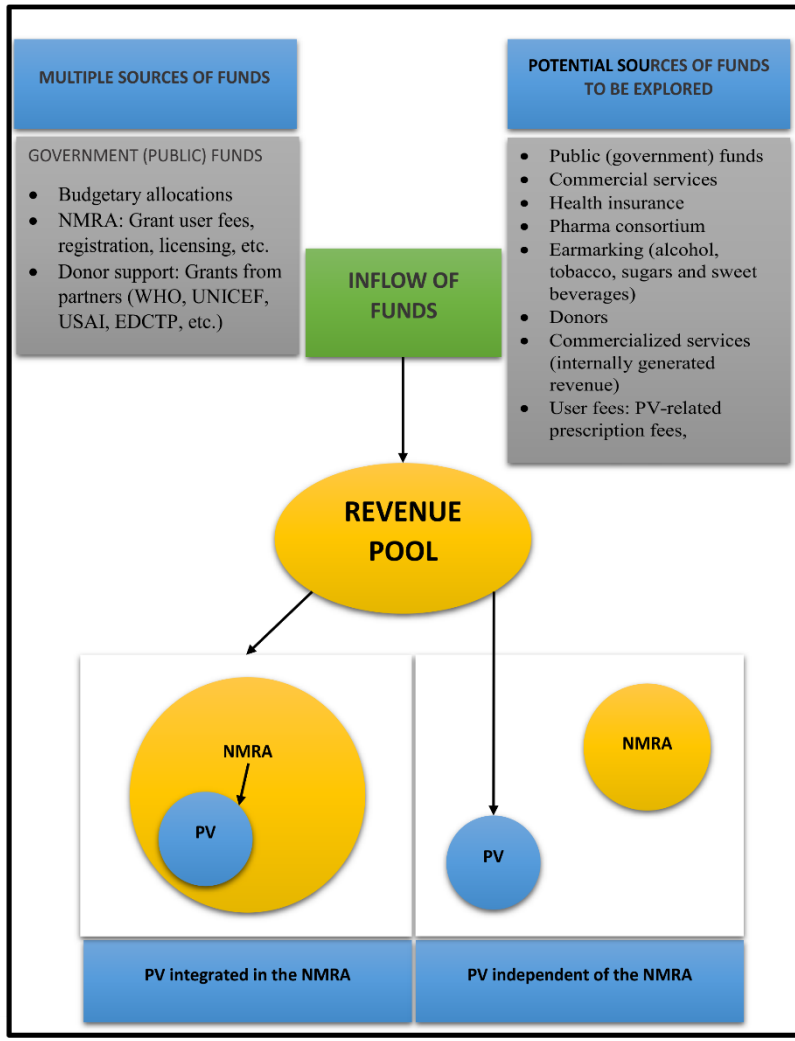


Figure 4. The proposed model for financing pharmacovigilance: Integrated NMRA-PV and Independent PV organisational models

To ensure PV is not marginalised with this prevalent framework the following considerations should be addressed:

- A clear proportion of the revenue should be allotted to the PV establishment for PV activities
- Some formula for sharing of revenue should be clearly stated and backed by statute.
- Funds including donations primarily dedicated for PV activities should not be diverted by the NMRA

6.1.2 PV independent of the NMRA

PV outfits with administrative structure independent of the NMRA are not common. Lareb in the Netherlands represents an example outside Africa. In Africa, the PV outfits in Morocco and Tunisia are independent from the NMRA. While the Moroccan PV Centre is linked to the NMRA that of Tunisia relates with the Ministry of Health which carries out the regulatory functions. With this framework, the PV Outfits are the principal recipient of resources. Internal mechanisms have to be put in place to manage the resources in a prudent and transparent manner

There may be variants of these two organisational structures which form the framework for the model options (**Figure *2***).

The main focus for either framework is revenue pooling mechanisms which determine the available funds for PV activities. As mentioned above, there are several potential sources of funds.

These may fall into two main categories; Statutory Funding backed by a legal framework and the Perennial Ad hoc funding.

While the former is likely to be sustainable, the later is not. The various measures including intense advocacy to position PV in the National polity so as to secure this funding should not be underestimated. The Low- and Medium-Income Countries (LMICs) priorities set by governments are at times uninformed, misplaced and definite revenue generating measures are absent and when present infantile and tied to political squabbles. Areas such as Health Insurance, are futuristic due to the poor coverage, reluctance of stakeholders to provide support and unwillingness of the legislature to put in place the legal framework[9].

It is essential that the main objective is the sustainability of financing for which ever framework is operational. It is pertinent to ensure an adequate revenue flow and maintain an appropriate revenue – expenditure balance. The robust nature of this model is such that it should be able to absorb shocks from the peculiar demands of the pharmacovigilance system such as seen in crisis situations. This is more so for the Low- and Medium-Income Countries (LMICs) with erratic economies where perturbations in the overall economy can crash the PV establishment.

7.0 Conclusion

In essence the availability and sustainability of funding for pharmacovigilance activities is paramount if the requisite monitoring to ensure the safety of medicines is to be done. The advocacy to the stakeholders on the need to adequately fund the pharmacovigilance activities bearing in mind the sacrosanct nature of its operation and deliverables should not be undermined. There exist multiple sources of potential revenue which should be fully explored and due regard should be given to the organisational structure notably the nexus between the regulatory agencies and the pharmacovigilance outfits. The sustainability of the model hinges to a large extent on the legal framework; statutory provision of funds, unbundling of the system from bureaucratic and fiscal hindrances so as to provide a seeming autonomy of a robust financial operation. Again, the sustainability of any financial model will depend on fiscal discipline with prudent expenditure subject to a transparent accounting procedure.

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