Guide for Effective Implementation of a Pharmacovigilance Policy

in Resource Limited Settings

PhArmacoVigilance Africa (PAVIA)

PAVIA

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Abbreviations

AMA	African Medicine Agency
AMRH	African Medicine Regulatory Harmonisation
EAC	East African Community
ECOWAS	Economic Community of West African States
EDCTP	European and Developing Countries Clinical Trials Partnership
FBO	Faith Based Organisation
MAH	Market Authorization Holders
NEPAD	New Partnership for Africa's Development
NGO	Non- Governmental Organisation
PAVIA	PhArmacoVigilance Africa
PHP	Public Health Programme
PV	Pharmacovigilance
QPPV	Qualified Persons for Pharmacovigilance
RECs	Regional Economic Communities
SADC	Southern African Development Community
SOP	Standard Operating Procedures

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How to use this Guidance Manual

The development of a policy document is an exacting process which requires building of consensus by the stakeholders. An elaborate engagement and plans should be made prior to, during, and after the launch of the document, to enable a successful implementation.

This practical document provides the critical steps and actions that should be put in place in a proactive and well coordinated manner in order to effectively implement a national pharmacovigilance policy. This will involve the various stakeholders in a process driven by the pharmacovigilance unit/department. The engagement will be interactive and of a continuous nature. Resets in the approach may be necessary, without unduly changing the policy objectives and provisions.

It is pertinent for the key operators to familiarize themselves with the provisions of the policy document and use this guide initially to assist the take-off process and, thereafter, as an *aide de memoire*. The elements regarding the implementation strategies, such as the targets and timelines, should be kept in view.

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1.0 Preamble

Policies essentially provide a guide to action and orientation of attitude, with clear commitments to a defined goal. They define the stakeholders who (in this particular case) are actors in the theatre of medicine safety (pharmacovigilance). They define their roles and responsibilities to ensure a concerted performance towards achieving successful outcomes. The policy document, if appropriately introduced, is a good advocacy and sensitisation tool.

The policy provisions are determined through a highly participatory and consensual manner in order to make it easily implementable. However, due to various lapses, mainly administrative and bureaucratic hurdles, the calculated provisions may not be implemented as planned. It is not surprising then that at times a policy document may be placed on the shelves and in the drawers of the executive offices following launch. The copies allotted to facilities may not find their way out of the warehouses or are not even retrieved from the printers. In other cases, the electronic versions may not be published on the relevant websites.

This manual provides some guidance on how to mitigate these challenges and actualize the objectives by proper and focused implementation of the policy provisions.

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2.0 Pre – Launch Activities

2.1 Stakeholders Engagement

All the key stakeholders need to be identified and must be kept engaged in all the processes during the launch and throughout the implementation of the policy. They should implicitly accept ownership and serve, not only as custodians, but also as ambassadors and promoters of the policy provisions.

Some of the stakeholders, having been involved in the development of the policy document, are aware of the provisions therein. The degree of engagement will vary for the different categories of stakeholders; however, the inclusivity of all stakeholders, despite their perceived relevance, must not be overlooked. There is need for periodic meetings at a reasonable frequency, to maintain the tempo of pharmacovigilance (PV) consciousness and activities.

2.1.1 The Stakeholders

The identification of key stakeholders should be related to the goal and objectives of the policy. It is also of particular interest that the role of the general public as stakeholders should not be underrated. In Pharmacovigilance, the stakeholders include, but are not limited to, the following:

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Policy and Decision Makers: Collaborators and Implementing Institutions

Government (all arms)

- Executive: Presidency and Head of Government
- Legislature: Senate President, House Speaker and Members of the National Legislature
- Government Officials: Ministers and Directors – Finance, Education, Commerce and Industry
- The Judiciary
- Policy Makers and Health Managers
- Ministry of Health (Departments and Agencies),
- Regional/International Organizations such as AMA, AMRH, EAC, ECOWAS, NEPAD and SADC
- African Regional Economic Communities (RECs) as applicable
- Development Partners, NGOs and FBOs
- Healthcare Executives and Managers (Public and Private sectors)
- International and Local Pharmaceutical Industry (with the Marketing Authorization Holders)
- Health Insurance Executives
- Legal Practitioners
- National Medicines Regulatory Authority (NMRA)
- National Drug Safety Advisory Committees
- Public Health Programs

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Academia

Universities

- Heads of Department
- Deans
- Provost
- Vice Chancellor
- University Senate/Council

Professional Regulatory Bodies:

Education

- National Universities Commission

Health

- Medical and Dental Council
- Pharmacy Council
- Nurses and Midwifery Council
- Medical Laboratory Sciences Council

Undergraduate and Postgraduate Students

- Medicine, Dentistry, Pharmacy, Nursing, Laboratory Sciences, Social Sciences, etc.

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Clinical and other Healthcare Providers
• Hospital Executives and Operatives – Medical Consultants • Doctors (including Traditional/Alternate Medicine Practitioners • Pharmacists and Patent Medicine Dealers • Nurses and Midwives • NGOs, FBOs, etc. **Professional (Clinical) Associations/Societies** • Medical • Dentistry • Pharmacy • Nursing/Midwifery • Laboratory Sciences **Public** • Patient and Consumer Organizations • Patient Advocacy Groups • Public and Consumer **Media Executives and Operatives** • Print and Electronic • Mainstream and Social

2.2 Statutory Endorsement

All statutory approvals/endorsement must be obtained. This is to ensure that the document has the required legal backing and political goodwill of government in its entirety. It is of utmost importance that there are no contradictions in regard to laws and regulations. The approvals from the appropriate organisations must have been obtained with signatures of designated officers.

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3.0 Institutionalization of the Pharmacovigilance Policy

3.1 The Formal Launch of the Document

The policy document should be formally launched to ensure visibility in the public space. This is the first step towards institutionalizing this consensual document. This will further facilitate 'visibility' and create an image for Pharmacovigilance in the country healthcare system and polity.

The relevant department should ensure that enough copies are available for distribution and an e copy is available on the internet. The distribution plan should be discussed pre-launch and checks should be put in place to prevent maldistribution or undue storage in warehouses.

An essential element in the development of a policy document is a clear understanding of the intended goals of the policy, stakeholders likely to be affected by its provision, the inclusivity required of these persons, their active participation in the process, and the consensus that should be reached in its formulation.

3.2 Advocacy and Communication Strategy (The Media)

The operational PV unit/department, in collaboration with the relevant department in the ministry of health, must constructively engage the media. The roles and responsibilities of the media, as per policy, should be clarified.

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The media should be engaged to achieve the appropriate publicity and educate the public, including, but not limited to, the stakeholder segment that was actively involved during the development of the policy. The positive attributes of the policy, as well as possible limitations or likely misconceptions, must be discussed in a frank and transparent manner.

Again, the media should be further oriented on the various provisions of the policy, especially those perceived as sensitive. They should be saddled with the duty of ensuring the visibility of the document and the merits of its successful implementation. Any areas likely to be misconceived should be handled in a professional non-contentious manner, seeking clarification when necessary.

The media will remain an important partner in public education throughout the life of the policy and plays an important role during subsequent revisions.

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4.0 Addressing the Roles and Responsibilities of Stakeholders

4.1 The Pharmacovigilance (PV) Unit

4.1.1 Human Resource Capacity

The initial or first step of the PV unit in implementing its mandate is the identification and profiling of its staff and characterisation of PV structures. The PV unit/department should, in a timely manner, identify its personnel disposition and document the inventory of the super-infrastructure available, determining its immediate and long-term needs in executing its functions. The disposition of staff, their level of competence and career plans should be noted and plans for capacity building should be set in motion to ensure the acquisition of required skills. Again, to ensure that staff morale remains high and staff are well motivated with a clear career trajectory, the internal and external educational or professional training and career plans should be discussed. The endorsement of these plans should be done realistically and timely, in consultation with the appropriate levels of approving authorities. This is to ensure staff retention and less mobility out of the PV unit. The Standard Operating Procedures (SOP) should be developed to facilitate and ensure clarity in carrying out routine PV operations.

The PV unit/department should quickly engage key stakeholders in order to put the provisions of the Policy into operation. It is pertinent to implement the assigned roles and responsibilities without delay. The activities of the Regulatory Agency, the MAH, the PHPs and the herbal practitioners should be discussed with the personnel in these areas to see how the goals of the PV unit could better align with these key stakeholders.

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4.2 Engagement and Reinforcement of other Stakeholders

4.2.1 The Ministry of Health and the Regulatory Agency

The interaction between the PV unit/department, the ministry of health, and the Regulatory Agency should be well coordinated. The pharmaceutical regulations, which are a useful tool for further engagement of the industry/Marketing Authorization Holders (MAH), should be accessible and accordingly applied when available. In case there are not available, they should be developed because these are enabling or facilitating tools. The PV department should be able to initiate and assist the Regulatory Authority in developing statues that impact medicine safety when necessary.

Again, a timely discussion of the administrative procedures and the statutory budget allocation is important to guarantee PV activities are running efficiently and effectively (see 5.0 Funding). In this regard, the PV department should be familiar and conform with routing paths outlined in the organization chart as well as the extant rules of engagement with internal and especially external organisations or development partners.

4.2.2 Executives of Hospitals/Public Health Programmes and Donor Agencies

The hospital executives and those in charge of PHPs should ensure that PV provisions are incorporated in the routine operations of their facilities and programmes. There is need to educate their staff on the PV systems, its operations, notably the reporting responsibilities and the handling of the reports at their level and forwarding them to the zonal and national PV centres. Guidelines on PV with documented

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information in form of manuals, monographs, and other literature should be made available for use by personnel and for consultations in the Medicines Information Unit.

4.2.3 The Pharmaceutical Industry/ Marketing Authorisation Holders (MAH)

The engagement of the pharmaceutical industries, in collaboration with the Regulatory Agency, should be timely. The appointment of a Qualified Person for Pharmacovigilance (QPPV), by the MAH, is of utmost importance. This should be implemented urgently, so as to streamline PV activities in the industry. The operationalisation of the roles and responsibilities stipulated in the PV document is important. It is also important to keep focus on the requisite pharmacovigilance inspections, submissions of aggregate reports as stipulated in the policy and pharmaceutical regulations, and in compliance with statute.

4.2.4 Herbal and Traditional Remedies

It is well known that many people throughout Sub-Saharan Africa consult traditional healers and take herbal remedies. There are safety concerns regarding these products. Practitioners in this field are unwilling to fully factor into National Programmes. It is pertinent to engage these stakeholders at the launch, and in a continuous manner. It is necessary to create a framework with proactive advocacy to ensure their participation.

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5.0 Funding

The operational funding mechanisms should be activated in a timely manner. This will include the following:

Statutory Budget: An important initial step is for the PV Unit/Department to ensure its sustainability by working in concert with the Ministries of Health, Finance, Budget and Planning (or ministries performing similar functions) as well as with the Regulatory Agencies to secure a budget line in the national budget for pharmacovigilance. This may require approval at higher levels of authority such as the legislature and executive arm of government. It is pertinent that budgetary allocation is direct to avoid any fiscal hindrances, undue bureaucracy, or limitations in cash flow that would disrupt the unit's activities.

Other sources that should be explored may include internally generated revenue such as approved fees allowed by government, grants, donations, etc.

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6.0 Research

The early documentation of activities and collection of data usually provides reference/baseline data for subsequent research. The pharmacovigilance centre should be aware of regional and global issues/studies and factor them into their larger plan.

The centre should also identify local issues relevant to medicine safety as well as raise hypotheses related to findings from the local data. These should then be further studied and explored through well-designed research.

The frequently asked questions and feedback from stakeholders provide further data for research, the outcome of which will facilitate various aspects of its operations.

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7.0 Maintenance of Momentum/ Monitoring and Evaluation

Following the launch, the tempo of activities should be sustained by continuous interaction with stakeholders. There should be workshops and seminars (with the new normal virtual platforms) for various sectors and stakeholders on different aspects of medicine safety.

Capacity building must be sustained and sustainability further guaranteed by addressing the aspects relating to staff welfare. Educational activities should be geared towards providing more information and knowledge on medicine safety.

The regular monitoring and evaluation of pharmacovigilance activities should be carried out with the use of standard PV indicators. The timeline for this should be as specified by the indicator set. This should be related to the targets and timelines set while outlining the strategies for implementation.

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8.0 Revision of the Policy Document

Pharmacovigilance is a dynamic discipline influenced by many factors. To maintain its relevance, the extant policies should be adapted to the various changes occurring locally and globally. The revision of the document should be adapted accordingly. The statutory revision timetable should note the overall goal and objectives.

The revision of the policy is a multi-stakeholder process and the perception of the various stakeholders of their roles and responsibilities should be appropriately scrutinized in tandem with the overall goal and objectives.

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9.0 Conclusion

In essence, this guide for effective implementation of the pharmacovigilance policy is geared to ensuring the timely and appropriate execution of the provisions so stated relating this to the strategies for implementation. When properly put to use, it will help both to ensure an adequate launching of the document as well as avoid the disturbing practice of docility after the launch of the PV document.

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