AFRICA PHARMACOVIGILANCE MEETING 2012

Ensuring Quality and Safety of Medicines in Sub-Saharan Africa

NAIROBI, KENYA
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Pharmacovigilance is neither a luxury nor a distraction; it is a necessity

— Conclusions of a High-Level Panel on Access and Patient Safety at the Africa Pharmacovigilance Meeting 2012 held at the Intercontinental Hotel, Nairobi.

The Ministry of Health, Kenya, the Pharmacy and Poisons Board, and the USAID-funded Management Sciences for Health (MSH) implemented Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program co-organized the **Africa Pharmacovigilance Meeting 2012 — Ensuring Quality and Safety of Medicines in Sub-Saharan Africa.** The meeting which was held April 18-20 at the Intercontinental Hotel, Nairobi, Kenya brought together over 100 attendees from 32 countries including Thailand, Philippines, and Vietnam, and pharmacovigilance partners from the African Regulatory Authorities, WHO, Bill & Melinda Gates Foundation, European Medicines Agency, Centers for Disease Control and prevention, U.S. Food and Drug Administration (FDA), USAID, and other key stakeholders**.**

The highlights of the meeting included the launch of the recent publication entitled: *Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance* and a panel discussion on Access and Safety. Margareth Ndomondo-Sigonda (NEPAD Ageny) chaired the panel; other members of the panel included Dr. Paul Orhii (NAFDAC, Nigeria)**,** Dr. Shanthi Pal (WHO, Geneva)**,** Dr. Alex Dodoo (WHO collaborating Center, Accra, Ghana)**,** Mr. Anthony Boni (USAID, Washington), Dr. Stephen Duparc (MMV), and Dr Jayesh Pandit (representing Dr. K.C. Koskei from the Pharmacy and Poisons Board). Provided below is the background, discussion, and recommendations from the panelists.

1. BACKGROUND:

The negative implications of adverse drug events from poor product quality, adverse drug reactions (ADRs), and medication errors contribute significantly to morbidity and mortality globally. Economic impacts of adverse events that are not frequently reported include the impact of adverse events on patient adherence to treatment, drug resistance, and treatment outcomes. Besides the economic impact, cases of adverse events affect the credibility of the health system leading to a loss of confidence in the health system.

Although most cases go undetected particularly in developing countries, data from developed countries like the US and EU estimate adverse drug events as the fourth to sixth leading cause of death. We are also aware of well-known cases of product quality associated with di-ethylene glycol which led to more than 700 reported deaths in nine countries

including two occurrences in Nigeria and a 1987 case in South Africa. Adverse drug events constitute a huge cost to the health system, estimated in the US at $177.4 billion in 2000.

A key responsibility of national medicines regulatory authorities (NMRAs) is to safeguard the public health of citizens from harm associated with the quality and safety of medicines. To do this, regulatory authorities require the necessary infrastructure and resources including laws, systems and structures, human resources (in terms of numbers, knowledge and skills) and financial resources to execute their mandate. In addition, they need to work closely with all stakeholders and more so with industry, public health programs, research and academic institutions and global health initiatives contributing to improving access.

Looking at the study report on safety of medicines in Sub-Saharan Africa that has been just launched today and other assessment reports published by WHO, it is clear that although there are some pharmacovigilance systems in place, there are still gaps that need to be addressed. The reports therefore provide a baseline data that will assist in developing appropriate interventions to improve the pharmacovigilance systems in a holistic manner through comprehensive health systems strengthening programs with a focus on patient safety.

Luckily, there are already existing tools that have been developed by various partners to address the identified challenges including:

- Policies, laws, regulations and guidelines to address medicines safety monitoring issues;
- Indicator based pharmacovigilance assessment tool (IPAT) which covers the full spectrum of medicines safety, product quality, ADRs and medication errors, and customized system improvement strategies for countries to address identified gaps including passive and active surveillance mechanisms;
- Data management and signal generation tools such as Vigiflow (UMC), Eudra Vigilance (EMA), Med Watch (US-FDA);
- Risk management and communication tools.

Therefore using the available tools instead of re-inventing the wheel is more productive to address the problem in a well-coordinated and harmonized manner. We are also aware of the existing implementation challenges and application of the available tools including enforcement and compliance to existing regulations.

One thing that must be emphasized here is that, pharmacovigilance is not a luxury for Africa; it is not to be thought of as a distraction or as a subordinate to access. It is both a necessity and a responsibility. Now is the time to confront the potential harm from medicine use by coming up with appropriate, effective, practical and sustainable strategies to address the problem with clear coordination mechanisms at country and regional levels if need be.

All stakeholders including governments, policy makers, regulatory agencies, the pharmaceutical industry, academia and research institutions, development partners and funding agencies have a role to play in advancing the pharmacovigilance agenda in the continent. There is need to collectively work towards a common goal and be serious about the need for monitoring the quality and safety of medicines as key to protection of the public health and economic development.

2. DISCUSSION POINTS:

Access to medicines is a human right; however, access without safety monitoring is a disservice as it may do more harm than good to public health.

Strengths:

- 41% of the 46 countries national medicines policies in place and 74% have pharmacovigilance centers; there are 5 WHO pre-qualified laboratories in SSA.
- Available metrics approach to measure return on investment and cost saved through robust pharmacovigilance systems as means to inform policy and decision making.

Challenges:

- Resources (financial and human) are needed to support pharmacovigilance activities in the sub-region given the current trend of increased access to medicines through various global supply chain management and public health programs.
- Antimicrobial resistance due to a lack of robust pharmacovigilance systems; increasing trends of counterfeits and substandard medicines; NMRAs limited capacity to evaluate, manage risks associated with ADRs and adverse events, and to communicate related risks.
- Lack of a comprehensive pharmaceutical care approach which integrates pharmacovigilance as part of a comprehensive health care delivery system to assist generation of data that provides patient safety profile.
- Regulators perceived as demons by the public due to lack of or ineffective communication.
- Lack of sustainable financing mechanisms for pharmacovigilance activities.
- Limited collaboration between agencies and countries and ethical responsibilities by sponsors.

3. RECOMMENDATIONS:

3.1. Regulatory capacity building and systems strengthening

- NMRAs must execute their mandate to ensure robust safety monitoring systems are established
- Training of regulatory staff on PV with incentive mechanisms that will ensure retention of staff

- Need for strengthening collaboration among various stakeholders (NMRA, public health programs, research and academic institutions, hospitals) in-country and across countries in the region
- Public health training institutions to include pharmacovigilance in training curriculum for pharmacists, medical doctors, nurses etc.
- Work sharing among NMRAs in the region e.g. East African Community (EAC), Southern African Development Community (SADC), Economic Community of West African States (ECOWAS), Economic Community of Central African States (ECCAS)
    - Introduce staff exchange and twining programs that promote collective learning, work sharing and evaluation of risk management plans
- Consider adopting ICH guidelines on pharmacovigilance
- Need to strengthen capacity of Accra WHO Collaborating Centre to provide training on pharmacovigilance in SSA

3.2. Reduce preventable adverse events

- Epidemiological studies to be conducted.
- Documentation of cases using existing data.
- Strengthen monitoring mechanisms, adopt a systems approach to recognize the problem, identify gaps and develop appropriate intervention to address the gaps-
    - Capacity building through training programs aimed at addressing knowledge gaps
    - Use of existing guidelines (e.g. WHO)

3.3. Address the role of the industry

- Industry should train and monitor how their medical representatives fulfill their responsibilities towards adverse event reporting and compliance with regulations related to promotion and advertisement of products.
- Introduce mandatory reporting on adverse drug reactions and serious drug events.
- Promote voluntary compliance.
- Establish reporting mechanisms that ensure unbiased dissemination of information.
- Industry to invest in investigation of risks by providing the financial resources to allow hospitals and/or academic or research institution to undertake the study/research.

3.4. Build sustainable pharmacovigilance system

- Invest on Information Communication Technology (ICT) to assist capturing data on non-communicable and/or chronic diseases which will assist in informing policy and communication strategies.
- Strengthen pharmaceutical information management system.
- Strengthen active surveillance to assist in generating signals.

- Consider introducing fees for pharmacovigilance services and advocate for pharmacovigilance activities as part of standard health care delivery system.
- SSA countries to emulate risk management plans, borrow leaf from EMA, US-FDA,
- Donations for public health programs to provide safety data and pharmacovigilance Plans.
- Develop and implement pharmacovigilance communication strategies -
    - NMRAs need to get close to the public by involving and engaging consumers through public education programs and mass campaigns

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