



PHARMACOVIGILANCE - FDIC NEWS

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Editor's Note

We wish to thank all our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safety of medicines in Nigeria. The NPC is committed to sending out quarterly newsletter to its stakeholders. The objectives of the Newsletter are to disseminate information on Pharmacovigilance activities nationally and globally, to educate stakeholders on drug safety issues, to promote rational use of drugs and to promote spontaneous reporting. This first quarter 2013 newsletter focuses on pharmacovigilance news and current happenings in the National Centre.

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions. Your valued comments and acknowledgement of receipt of this issue through our email addresses (nafdac_npc@yahoo.com; pharmacovigilance@nafdac.gov.ng) would be most appreciated.

Have a Blessed 2013 !

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*Text any DRUG RELATED PROBLEM to the **SHORT CODE 20543** (For free on **MTN, Glo and Etisalat**) for action by the Pharmacovigilance Centre*

NATIONAL PHARMACOVIGILANCE POLICY

The Nigerian National Pharmacovigilance Policy document has recently been approved by the Federal Executive Council in October, 2012 after ratification by the 55th meeting of the National Council on Health held in Abuja in September, 2012.

The aim of developing the National Pharmacovigilance Policy is to provide a strategic framework for the entrenchment of pharmacovigilance in the healthcare system in Nigeria and to ensure the overall safety in the use of medicines. It will serve as a tool for providing an enabling environment for effective planning, implementation, monitoring and evaluation of pharmacovigilance activities by all stakeholders. It provides Legal Framework and Road Map for Implementation. It also provides standards for measuring activities and holds individuals responsible and accountable through enforcement of developed regulations.

During the last meeting of National Centres on Pharmacovigilance held in Brasilia, Brazil from 11th to 14th November, 2012, the National Pharmacovigilance Centre made a presentation on **Developing a National PV Policy: The Nigerian Experience** where it was noted that Nigeria is the first country in the world so far to have a national government approved policy dedicated to pharmacovigilance.

THE PROCEDURE FOR DEVELOPMENT AND APPROVAL OF THE NIGERIAN PV POLICY

The process predates the launch of the Nigerian PV system in 2004 and input was developed and submitted to the Nigerian authority for Developing Policies – Federal Ministry of Health (FMoH). The FMoH with Support from NGO's and Development Partners organized series of Expert Committee and Stakeholder Meetings from 2009 to 2010 to make technical input & review submitted drafts. The Zero Draft was generated after three rounds of Committee meetings while

the Expert Consultant Committee reviewed the zero draft to produce 1st draft. The Final draft of the document was adopted in September 2010 and the document was reverted to Federal Ministry of Health for Government Approval.

NEXT STEPS:

- Using the PV Policy Implementation Plan as a Road Map and building on the recent upgrade of the PV department as a Directorate of PV/PMS, the NPC will support the Ministry of Health in disseminating widely the policy document.
- Undertake capacity building on PV implementation at all levels.
- Advocate for adequate funding for Pharmacovigilance.

The National Pharmacovigilance Policy is scheduled to be officially launched by the Honorable Minister of Health on 7th February 2013.

ESTABLISHMENT OF PHARMACOVIGILANCE AND POST MARKETING SURVEILLANCE DIRECTORATE IN NAFDAC

In order to reposition pharmacovigilance for greater efficiency, the Pharmacovigilance/Food & Drug Information Centre, a Unit in the Director General's Office (NAFDAC) has been upgraded to a full Directorate in NAFDAC named Pharmacovigilance and Post Market Surveillance (PV/PMS). The Directorate is charged with the following functions amongst others-:

- Promote rational and safe use of medicines in Nigeria
- Ensure Post marketing monitoring of regulated products

- Create awareness on pharmacovigilance among all healthcare providers, marketing authorization holders and the general public
- Support development of policies and provide science based advice and information on rational use of drugs
- Conduct outreach to stakeholders in conjunction with relevant departments
- Collect and analyze safety data about drugs and cosmetics that are already on the market, etc.
- Establish and maintain a functional national database on ADRs and other medicine related problems

ESTABLISHMENT OF ZONAL PHARMACOVIGILANCE CENTRES (ZPCs)

Having created awareness on the need for pharmacovigilance and generated a considerable level of interest in reporting of Adverse Drug Reactions among healthcare providers in Nigeria, it became pertinent to decentralize coordination of pharmacovigilance activities in the country. The zonal pharmacovigilance centres have been set up in collaboration with the National Malaria Control Programme (NMCP). Six healthcare institutions, one in each geopolitical zone , have been selected to host the Zonal Pharmacovigilance Centres in their respective zones. Their selection was based on their ability to meet most of the criteria used in assessing the pharmacovigilance capacity/activities of the institutions. Office equipment have been forwarded to the designated institutions within the last quarter of 2012 while the ZPC's are currently at various levels of functionality. They require the support of all Health Care Providers in the zones and the management of the host institutions to achieve the objectives of setting them up.

The selected ZPCs include:

- Ahmadu Bello University Teaching Hospital (ABUTH) for the North West,
- University of Illorin Teaching Hospital (UITH) for the North Central,
- University of Maiduguri Teaching Hospital (UMTH) for the North East,

- Lagos University Teaching Hospital (LUTH) for the South West,
- University of Benin Teaching Hospital (UBTH) for the South South
- Federal Medical Centre (FMC) Owerri for the South East.

OBJECTIVE OF SETTING UP ZONAL PHARMACOVIGILANCE CENTRES (ZPC)

The ZPCs are to coordinate pharmacovigilance activities at the zonal level thereby facilitating ease of conducting pharmacovigilance activities such as spontaneous reporting at institutional level and other active forms of pharmacovigilance within the different zones.

ZPC are expected to liaise closely with the NPC, NAFDAC in achieving this objective.

CAPACITY BUILDING WORKSHOP FOR PERSONNEL OF ZONAL PHARMACOVIGILANCE CENTRES AND STAFF OF ACTIVELY PARTICIPATING INSTITUTIONS

The National Pharmacovigilance Centre (NPC) in collaboration with the National Malaria Control Programme (NMCP) conducted a capacity building workshop between 24th -27th of April, 2012 for personnel of zonal pharmacovigilance centres (ZPCs) and actively participating institutions in pharmacovigilance. The number of health care providers trained was 45. They were trained on the concept and principles of pharmacovigilance. The workshop highlighted the knowledge and requisite skills necessary to enable the ZPCs function on a daily basis.

PHARMACOVIGILANCE RAPID ALERT SYSTEM FOR CONSUMER REPORTING (PRASCOR)

PRASCOR is an SMS Short Code system put in place by the National Pharmacovigilance Centre (NPC), NAFDAC for consumers to alert the NPC of adverse drug reactions and other medicine related problems experienced with the use of

any medicine in Nigeria. This system was set up to further promote consumer integration in the detecting and reporting of medicine related adverse events in the country.

How the SMS Short Code for Consumer Alert works

The short code service works in three (3) simple steps:

- Step 1: A consumer sends information with the name of the drug and the suspected ADR by SMS to the number (Short code) 20543 for free.

For example: Text, "I took paracetamol and cannot sleep" to the number 20543

- Step 2. An auto-response is sent to the consumer (sender) thanking him/her for the message and informing him/her that s/he will be contacted for more information if necessary.
- Step 3: The information including the sender's number is forwarded to NAFDAC by email or an application that can be accessed only by NAFDAC. Staff of the National Pharmacovigilance Centre, NAFDAC receive the information and contact the sender for more information that will be used to fill an Individual Case Safety Report (ICSR).

BENEFITS OF THE SERVICE

- Use of mobile technology to improve patient safety at no cost to the patient
- The Service can be accessed by over 75 million mobile network subscribers in Nigeria
- The number of the consumer who sent the report can be used by NAFDAC officials to contact the person for more information.
- Confidentiality of consumer report is maintained throughout the process.

CAPACITY BUILDING FOR MARKETING AUTHORIZATION HOLDERS (MAH)

The decision to approve the marketing of any drug is based on its risk-benefit ratio drawn from available information at the time of approval. The knowledge related to the safety profile of the product can change over time through expanded use in terms of patient background and the number of patients exposed. This situation makes the continuous monitoring of drugs by marketing authorization holders (MAHs) invariably necessary for an efficient pharmacovigilance system.

The training of Marketing Authorization Holders (MAHs) in Nigeria was held in two sessions (24th – 25th July and 9th – 10th October, 2012) with the following broad objectives:

- To build capacity of MAHs in Nigeria to contribute data to the National database
- To acquaint industry players with existing requirements and guide for effective post authorization surveillance on their products
- To enhance conformity with Good Pharmacovigilance Practice (GPP) by MAHs in Nigeria
- To facilitate a robust engagement with MAHs in order to achieve prompt risk evaluation and management.

Following the recently concluded mandatory capacity building workshop for MAHs in Nigeria to acquaint industry players with existing requirements and guide for effective post marketing surveillance of their products, the guidelines and requirements for compliance are as follows:

- September 01 to December 31, 2012 - All MAHs of pharmaceutical products should submit a pharmacovigilance plan to the National Pharmacovigilance Centre (NPC) including Name and contact details of pharmacovigilance responsible person (s) in Nigeria (with evidence of certificated PV training), distribution points for their products, list of marketed products in Nigeria including registration/renewal dates, and SOPs for product recall.

- January 01 to June 30, 2013 - Individual corporate bodies would receive assessment reports of their PV plans and additional reporting requirements (Periodic Safety Update Reports (PSUR), Risk Management Plan (RMP)).
- July 01, 2013 – PV audit commences to enforce PV requirements for further registration of products.

NAFDAC SAFEGUARDING THE HEALTH OF THE NATION