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### **INTRODUCING THE PVG/FDIC NEWSLETTER**

When the present NAFDAC management came on board in April 2001, the Agency recognized the absence of safety monitoring system as a big setback to, not only, detecting and preventing Adverse Drug Reaction (ADR) but other vital tools to regulatory decision-making. As a result, the Agency critically examined the past experiences on the attempt to establish Pharmacovigilance and effected necessary strategies through sheer commitment and determination.

On the 9<sup>th</sup> of September 2004, Pharmacovigilance was officially launched in Nigeria and NAFDAC established a Drug Safety Monitoring Centre (NPC) which has also been recognized as the 74<sup>th</sup> full member by the World Health Organization (WHO) Collaborating Centre for International Drug Safety Monitoring, The Uppsala Monitoring Centre (UMC). This epoch-making event brought together distinguished policy makers and other core stakeholders at the nation capital, Abuja.

In a bid to elicit the cooperation of core stakeholders, a training workshop was organized to build capacity for detecting and reporting ADR. This maiden edition of Newsletter therefore, serves as awareness creation on Pharmacovigilance and feedback mechanism on reports generated at the Centre. We are hoping that this quarterly publication would be upgraded to monthly publications in due course. Your input is highly welcome for the objectives of this Newsletter to be realized.

You are welcome!

## **OBJECTIVES OF THE PVG/FDIC NEWSLETTER**

- To disseminate information on Pharmacovigilance activities, nationally and globally.
- To educate stakeholders on drug safety issues
- To promote rational use of drugs
- To promote spontaneous reporting

## **NIGERIA MERGES THE NATIONAL PHARMACOVIGILANCE CENTRE WITH FOOD AND DRUG INFORMATION CENTRE.**

In June 2006, the National Agency for Food and Drug Administration and control (NAFDAC) carried out an important structural change for greater effectiveness of the pharmacovigilance programme. In this development, the Food and Drug Information Centre (FDIC) which hitherto carried out its operations from the laboratory complex of NAFDAC in Lagos under the Special Duties Division of the Agency was merged with the National Pharmacovigilance Centre situated in the office of the Director General in the Federal Capital Territory. Consequently, the Centre has changed its name to Pharmacovigilance/Food and Drug Information Center (PVG/FDIC).

This change was necessary to boost pharmacovigilance activities as well as effectively and efficiently coordinate the collection, analysis and dissemination of food and drug information. The new Centre is headed by Pharm. (Mrs.) A. I. Osakwe who reports directly to the Director General of NAFDAC, Prof. Dora Akunyili.

The Centre's activities are geared towards:

- Sensitizing stakeholders to elicit voluntary spontaneous reporting of Adverse Drug Reactions.
- Effective collation of such reports to form a national database.
- Assessment and review of received reports for transmission to WHO international drug safety monitoring network (Uppsala Monitoring centre ) and utilization of information for regulatory decision making and action.
- Guiding healthcare practitioners on rational drug use through alert notices
- Sourcing information nationally and internationally for collation,

storage, retrieval and dissemination through publications and direct contact.

- Reviewing periodic Safety Update Reports from drug manufacturers aimed at updating product information.
- Utilizing reported information in the detection of fake/counterfeit/substandard products.
- Providing drug information services to all categories of stakeholders thereby safeguarding public health.

The ultimate goals of the centre are to:

- Assess and communicate risks and benefits of drugs on the market.
- Promote rational and safe use of medicines.
- Educate and inform patients.

## **INAUGURATION OF A DRUG SAFETY ADVISORY COMMITTEE**

The National Pharmacovigilance centre has strengthened her resolve to use the vehicle of Pharmacovigilance to safeguard the health of the nation by constituting a National Drug Safety Advisory Committee comprising of experts in drug safety monitoring and use. The committee was inaugurated on the 26<sup>TH</sup> JULY, 2006

The Director General, NAFDAC, Prof. Dora Akunyili in her opening remarks stressed that the inauguration of the advisory committee is timely and urged the members to take their responsibilities seriously. She stated that the selection of the members was based on individual merit and not on organizational or other affiliations. She also thanked the committee members for accepting to serve on the committee without demanding for remuneration.

Highlights from the Director General's remarks include;

The appointment of Prof. Ambrose Isah as the Chairman and Prof. M.A.C. Aghaji as the Vice Chairman of the Advisory Committee. Please find below names and contact details of committee members.

<b>Names</b>	<b>Address</b>	<b>Phone no</b>	<b>Email</b>
Prof. A. Isah	Department of Medicine, University of Benin Teaching Hospital (UBTH), Benin City	0802-3394-081	<a href="mailto:ambroseisah@yahoo.com">ambroseisah@yahoo.com</a>
Dr. E. C. Chidomere	College of Medicine, Imo State University	0803-4516-449	<a href="mailto:evachido@yahoo.co.uk">evachido@yahoo.co.uk</a>
Prof. M. A.C. Aghaji	Department of Cardiac Surgery, University of Nigeria Teaching Hospital (UNTH), Enugu	0803-3334-295 0803-7909-555	<a href="mailto:macaghaji@yahoo.com">macaghaji@yahoo.com</a>
Dr. P.U. Bassi	University of Maidugari Teaching Hospital, Maidugari	0803-4945-067	<a href="mailto:pubassi@yahoo.com">pubassi@yahoo.com</a>
Prof. L.A. Bichi	Faculty of Medicine, Ado Bayero University Kano (BUK)	0803-7874-049	<a href="mailto:labichi1955@yahoo.com">labichi1955@yahoo.com</a>
Mr. R. K. Omotayo	Director, Food and Drug Services, Federal Ministry of Health, Abuja.	0803-7138-019 09-672-6136	<a href="mailto:kaytayo2000@yahoo.co.uk">kaytayo2000@yahoo.co.uk</a>
Mrs. H. Keri	Registration and Regulatory Affairs Directorate, NAFDAC, Lagos	0802-3123-432	<a href="mailto:hkeri@yahoo.com">hkeri@yahoo.com</a>
Mrs. A. I. Osakwe	National Pharmacovigilance/Food and Drug Information Centre, NAFDAC, Abuja.	0803-3154-512 09-670-2823 09 524-1108	<a href="mailto:addyosakwe@yahoo.com">addyosakwe@yahoo.com</a> nafdac_npc@yahoo.com

The Terms of Reference of the Committee includes but not limited to;

- Providing NAFDAC with on-going and timely medical and scientific advice on current and emerging issues related to registered drugs used in Nigeria;
- Evaluating safety, quality, and efficacy issues of registered drugs. Such evaluation will be based on information provided to the Committee, knowledge of drug literature, expertise and experience of members;
- Identifying safety, quality, and efficacy issues on registered drugs that need to be investigated and evaluated by NAFDAC;
- Recommending to NAFDAC, upon request, actions that may be taken to resolve issues or concerns related to the safety, quality, and efficacy of registered drugs;
- Assessing safety issues related to drug use including misuse, abuse or off-label use, and recommending actions to be taken by NAFDAC;
- Carrying out assessments including causality assessments of adverse drug reaction (ADR) reports selected by the Centre;
- Recommending pharmacoepidemiological or other researches related to safety of drugs to be undertaken by NAFDAC or by its partners or stakeholders;
- Recommending interventions and activities that will enhance professional and consumer awareness of safety, quality, and efficacy issues related to the use of drugs.
- Advising NAFDAC on specific issues raised by the Centre.

On a final note, the Director General, NAFDAC urged the members to see their work as a national assignment which has the potential of improving healthcare delivery and enhancing attainment of health for our people.

## **WITHDRAWAL OF BAUSCH AND LOMB'S EYE SOLUTION**

ReNu MoistureLoc® is a soft contact lens, multi-purpose solution intended for rinsing, disinfecting, cleaning and storing soft contact lenses. However this product has been implicated in an increase in ocular *Fusarium* infections that occurred in Hong Kong, Singapore and the US.

As a result of this situation Bausch & Lomb ReNu Moisture Loc contact lens Solution was withdrawn from the market by its manufacturer on the 15<sup>th</sup> of May 2006. This step was a necessary precautionary measure taken by the manufacturer because reports following its usage have been linked to a rare eye infection ***fusarium keratitis*** which may lead to blindness.

### **What is *fusarium Keratitis*?**

*Fusarium* is a fungus commonly found in our everyday environment, especially in plants and the soil. It is a relatively rare source of eye infections, but a serious one. It typically enters the eye through some sort of trauma or injury to the cornea, resulting in an inflammation of the cornea, i.e. *keratitis*. If diagnosed and treated late, significant loss of vision can result, sometimes leading to the need for a corneal transplant. Symptoms of *Fusarium* infection can include redness, pain, foreign body sensation, tearing, increased light sensitivity, blurry vision, discharge or swelling. Often the onset of symptoms is not acute but occurs over several days/weeks.

A different reaction to the withdrawal of the drug exists as the UK Medicines and Healthcare Regulatory Agency MHRA does not think there is currently any increased risk of *Fusarium keratitis* in the UK because:

- Until the start of the product withdrawal in the UK, there had been no reports of *Fusarium* eye infection in the UK to either MHRA or Bausch & Lomb. The number of incidents of

- There has not been an unusual incidence of *Fusarium* cases referred to the UK Health Protection Agency.
- The ReNu MoistureLoc® sold in Hong Kong, Singapore and the US is made in Bausch & Lomb's US plant. Europe, the Middle East and Africa are supplied by the plant in Milan, Italy. All ReNu multi-purpose solutions manufactured in Milan use different bottle components and a different sterilisation method for these components, than the US manufacturing process. No unusual trends for fungal *keratitis* have been reported within Europe, the Middle East and Africa.
- *Fusarium* infection is less common in the UK climate than the tropical or subtropical climates prevalent in the Asian countries and most of the affected US States.

### **The Nigerian situation**

Presently Bausch and Lomb ReNu Moisture Loc multipurpose solution is not registered by the National Agency for Food and Drug Administration and Control NAFDAC but it is available in some leading pharmaceutical and other stores. However the National Pharmacovigilance Center has issued an Alert notice which would be sent to all the concerned health care providers and the general public informing them of the withdrawal of this product from all markets by its manufacturer. This would serve as preventive measure in order to avoid any occurrence of *fusarium Keratitis* amongst its users.

**Source:** [www.mhra.gov.uk](http://www.mhra.gov.uk)

## **FREQUENTLY ASKED QUESTIONS**

### **WHAT IS PHARMACOVIGILANCE?**

Pharmacovigilance is the science and activities relating to the knowledge, detection, assessment and prevention of adverse effects or any drug-related problem.

### **WHAT IS AN ADVERSE DRUG REACTION (ADR)?**

The World Health Organization defines an adverse drug reaction as a response which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases, or for the modification of physiological function.

The important point to note is that patient experiences an unwanted and/or harmful reaction following drug therapy.

### **WHAT IS DIFFERENCE BETWEEN AN ADR and A SIDE EFFECT?**

A side effect can be defined as any unintended effect of a pharmaceutical product occurring at doses normally used in humans, which is related to the pharmacological properties of the drug. Such effects may or may not be beneficial. Side effects are related to the known properties of the drug and can often be predicted.

**However, when a side effect occurs above the usual/expected level, it becomes an Adverse drug reaction.**

**It must be stressed that in Pharmacovigilance we are interested in all drug related reactions – this includes side effects and suspected adverse drug reactions.** Health professionals are therefore requested to report all drug related problems to the National Pharmacovigilance Centre.

### **WHAT ARE THE BENEFITS OF ADR REPORTING TO HEALTH PROFESSIONAL?**

- Guarantees Patient Safety
- Improves Quality of Care Offered to Patients
- Enhances Patient Confidence in Practitioners
- Contributes to Global Knowledge on Drug Safety issues

### **ARE THERE ANY NEGATIVE CONSEQUENCES ON THE HEALTH WORKER OR THE PATIENT FOR REPORTING AN ADR?**

There are no negative consequences for reporting an adverse drug reaction. The adverse drug reaction report does not constitute an admission that a health professional or the drug contributed to or caused the event in any way.

The details of an ADR report are stored in a confidential database in Nigeria and the analyzed report sent to the Uppsala Monitoring Center (UMC). The names of the reporter or any other health professionals named on a report and the patient are removed before any detail about a specific adverse drug reaction are used or communicated to others.

**The information obtained from an ADR report is not to be**



**used for commercial purposes. The information is only meant to improve our understanding and use of the medicines in Nigeria.** ADR reports cannot be used in a court of law under any circumstances.

### **WHO SHOULD REPORT ADVERSE DRUG REACTIONS?**

All health care professionals/workers, including doctors, dentists, pharmacists, nurses, traditional medicine practitioners and other health professionals are to report all suspected adverse reactions to drugs including Western medicines vaccines, X-ray contrast media, medical devices, cosmetics, traditional and herbal remedies.

### **WHERE DO I SEND COMPLETED ADR CASE REPORT FORM(S)?**

The completed ADR form is to be sent to the National Pharmacovigilance Centre, personally, by post or by fax. It can also be sent to the nearest NAFDAC state office or to any of the National Advisory Committee member. A copy should be kept by the health professional for documentation and reference, but the original is to be sent to the NPC.

### **WHAT IS DONE WITH THE INFORMATION ON THE COMPLETED ADR FORM?**

The information obtained from the completed ADR report is entered into National/international adverse drug reaction database and analysed by expert reviewers. A well-completed adverse drug reaction reporting form submitted to the NPC and subsequently to the WHO monitoring Centre in Uppsala, Sweden could result in any of the following:

- Additional investigations into the use of the medication in Nigeria.
- Educational initiatives to improve the safe use of the medication.
- Appropriate package insert changes to include the potential for the reaction reported by Nigerian health professionals and workers.
- Changes in the scheduling or manufacture of the medicine to make the medicine safer.
- Other regulatory and health promotion interventions as the situation may warrant including change in supply status or withdrawal.

## **HOW CAN I GET AN ADR REPORTING FORM?**

Prepaid ADR forms can be obtained from and submitted / mailed to

- The National Pharmacovigilance Center NPC, National Agency for Food and Drug Administration and Control (NAFDAC) Plot 2032 Olusegun Obasanjo Way, Wuse Zone 7, Abuja, PMB 5032 Wuse Abuja
- NAFDAC offices Nationwide.
- NAFDAC Drug Safety Advisory Committee members in the zones.

Forms can also be downloaded from

<http://www.nafdacnigeria.org/pharmacovigilance.htm>

## **ALERT NOTICES**

### **NPC ALERT ON Paroxetine (PAXIL<sup>®</sup> or Seroxat<sup>®</sup>)**

NAFDAC wishes to alert healthcare practitioners that recent studies have revealed that maternal exposure to Paroxetine especially during the first trimester increases the risk of congenital malformations particularly cardiovascular malformations. This study revealed increased risk of babies being born with heart defects following the use of PAXIL<sup>®</sup> by their mothers during pregnancy.

Glaxosmithline, manufacturers of PAXIL<sup>®</sup> or Seroxat<sup>®</sup> in view of this current report has updated their product labelling information for PAXIL<sup>®</sup>. There are also concerns over the potential for paxil/seroxat to cause suicidal behaviour following the publication of recent findings that suggested that the increased suicidal behaviour seen in children and adolescents receiving certain antidepressants may also be present in adults.

In the light of the above emerging information regarding the safety of PAXIL<sup>®</sup>, NAFDAC advises that healthcare practitioners read the new product information label attached to PAXIL<sup>®</sup> and weigh the options before prescribing the drug.

Detected Adverse events on Paroxetine or any other drug should be reported on the ADR reporting form and sent to the National Pharmacovigilance Centre (NPC), NAFDAC, Abuja.

The general public should please use Paroxetine strictly on prescription by a Doctor.

NAFDAC will provide updates on safety of Paroxetine or any other drugs as more information become available.

**NPC ALERT ON BAUSCH & LOMB's ReNu MOISTURE LOC® CONTACT LENS SOLUTION FROM CIRCULATION**

The attention of the National Agency for Food and Drug Administration and Control{NAFDAC} has been drawn to the immediate and permanent withdrawal of ReNu Moisture Loc® Contact Lens Solution by the manufacturer, Bausch and Lomb Inc, USA, as a result of its implication in an out break of rare fungal infection{Fusarium Keratitis} causing blindness.

Currently, ReNu Contact Lens Solution is neither registered nor approved for distribution and use in Nigeria.

NAFDAC hereby alerts concerned health care providers and consumers of this product, to discontinue its use hence forth and return same to the nearest NAFDAC office nation wide for destruction.

The general public and all health care providers are well advised to insist on NAFDAC **registered or authorized** brands of drugs and other regulated products.

**PHARMACOVIGILANCE/FDIC NEWS : A MONTHLY NEWSLETTER  
OF NATIONAL PHARMACOVIGILANCE CENTRE(NPC). NATIONAL  
AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL  
(NAFDAC)**

**PLOT 2032 OLUSEGUN OBASANJO WAY, WUSE ZONE 7, ABUJA,  
PMB 5032 Wuse Abuja**

**Telephones: +234-(0)9-6702823; +234-(0)8037863048**

**Fax: +234-(0)9-5241108**

**E-mail: [nafdac\\_npc@yahoo.com](mailto:nafdac_npc@yahoo.com)**

**Web Site <http://www.nafdacnigeria.org/pharmacovigilance.htm>**