



# PHARMACOVIGILANCE - POST MARKETING SURVEILLANCE 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 safe use 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 medicine safety issues, to promote rational use of drugs and to promote spontaneous reporting.

This first quarter 2015 newsletter focuses on rational use of drugs and developments 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](mailto:nafdac_npc@yahoo.com); [pharmacovigilance@nafdac.gov.ng](mailto:pharmacovigilance@nafdac.gov.ng)) would be most appreciated.

Have a prosperous year!

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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*

## **RATIONAL USE OF MEDICINES**

The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community. Hence, in promoting rational use of medicines, appropriate consideration and attention must be given to factors such as the indication, administration, dosage, duration and of course appropriate patient information and evaluation.

On the other hand, Irrational or non-rational use is the use of medicines in a way that is not compliant with rational use. All medicines whether prescription, or over the counter and controlled can be irrationally used. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread occurrence of adverse drug reactions. Examples of irrational use of medicines include: use of too many medicines per patient ("poly-pharmacy"); inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimes.

### **WHO advocates 12 key interventions to promote more rational use:**

- Establishment of a multidisciplinary national body to coordinate policies on medicine use
- Use of clinical guidelines
- Development and use of national essential medicines list
- Establishment of drug and therapeutics committees in districts and hospitals
- Inclusion of problem-based pharmacotherapy training in undergraduate curricula

- Continuing in-service medical education as a licensure requirement
- Supervision, audit and feedback
- Use of independent information on medicines
- Public education about medicines
- Avoidance of perverse financial incentives
- Use of appropriate and enforced regulation
- Sufficient government expenditure to ensure availability of medicines and staff.

There is global recognition of the problem of irrational use of medicines and concerted efforts to promote their rational use. It was in view of the effort to promote the rational use of medicines that NAFDAC organised a round table meeting on rational use of drugs.

### **ROUND TABLE MEETING OF STAKEHOLDERS ON RATIONAL USE OF DRUGS**

The National Agency for Food and Drug Administration and Control (NAFDAC) in actualizing its mandate to ensure the circulation of safe, effective and quality medicinal products in Nigeria organized an advocacy meeting with heads of health professional associations and councils at national hospital auditorium Abuja, Wednesday 26<sup>th</sup> November, 2014. The objective of the meeting was to promote the rational use of medicinal products in general and sedative-hypnotics in particular in Nigeria. Rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost to them and the community. The purpose of the round table discussion was to enlist the support of the heads of professional associations and councils who are decision makers in the medical practice and use of drugs in both the private and public healthcare sectors in Nigeria. In addition, the

participation of these professional leaders will serve as a platform for step down trainings for other stakeholders, and further increase awareness creation on rational use of medicines in their various institutions.

Several organizations participated including:

- Roche
- SWIPHA
- National Drug Safety Advisory Committee (NDSAC)
- Pharmaceutical Society of Nigeria (PSN)
- Medical Laboratory Science Council of Nigeria (MLSCN)
- Federal Ministry of Health
- Medical and Dental Council of Nigeria (MDCN)
- Nigerian Medical Association (NMA)
- Pharmacists Council of Nigeria (PCN)

After series of discussions and presentations, the meeting resolved on the way forward via these action points.

- Need for improved teaching of Rational Pharmacotherapy at the undergraduate and postgraduate level which will include proper interaction and collaboration between the members of the various disciplines i.e. Doctors, Pharmacists, all Health care providers in the undergraduate/post graduate level. To enable establishment of an early means of communication and collaboration between different levels of Health care providers.
- Need to audit hospital premises to create a conducive environment for rational use of medicines by dispensers

- Need to squarely address the problem of unregistered drug outlets and traditional medicine practitioners who provide services to a very significant proportion of the population. Also the uncontrolled advertisement of their products must be addressed.
- Need for the establishment of a social health insurance to ensure that Health Care Providers play their peculiar roles and are rewarded for these roles
- Need to vigorously pursue the development and implementation of a national prescription policy
- Need to address the problem of cost of medicines by advocating for a pricing mechanism in line with what obtains in other countries
- Need to evaluate diagnosis, treatment and outcomes through clinical utility studies
- Need for comprehensive training and funding of Health Care Providers at all levels and making available standard treatment guidelines to improve prescribing and also hospital formularies. Also ensuring that these documents are well circulated in health facilities.
- Need for education of consumers on rational use of medicines.
- Need to ensure that hospitals and other Health facilities provide drug information services through a Drug Information Centre
- Need to have a regular forum for representative of Regulatory bodies, Professional association and Councils. E.g. empowering and funding committee of health regulatory bodies.
- Identified heavy work load due to the very high Health Care Provider-patient ratio as contributing to the long patient waiting time and short pharmacy and dispensing time.
- Need to have an effective Consumer Protection Agency to hold Health Care Providers accountable for their practice
- Need to begin to enforce the various policies and drug laws by stating punitive measures for those that abuse the policies

- ADR soliciting by Industry personnel.
- Need to ensure access to health insurance at reduced cost since there is a guarantee that someone is paying for the services
- Need for effective drug distribution guideline and its implementation to promote rational use of medicines.

The meeting concluded on a good note with commitments from all organizations in attendance to support NAFDAC in its mandate to promote safe use of medicines and to support a step down training on the round table resolutions.

### **ZONAL TRAINING ON RATIONAL USE OF MEDICINES**

Sequel to the round table meeting, a step down training in form of a Zonal workshop on Rational Use of Medicines was organized by NAFDAC & stakeholders on 26<sup>th</sup> & 27<sup>th</sup> in 16 centres: Kaduna, Kano, Sokoto, Kwara, Plateau, Benue, Lagos, Ibadan, Ekiti, Imo, Enugu, Onitsha, Edo, Rivers, Akwa Ibom and FCT. Participants were health care workers comprising full complement of doctors, pharmacists, nurses and medical laboratory scientists as well as Heads of Zonal Pharmacovigilance centres. The workshop objectives were as follows:

- To further discuss and mainstream the need for rational use of medicines
- To examine the challenges faced by healthcare professionals in the practice field
- To discuss the collective and individual roles of HCPs towards promoting rational use of medicines
- To elicit possible step down workshops and further awareness creation on rational use of medicines

Irrational use of drugs can culminate in the experience of different types of adverse drug reactions (ADRs). Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by complying with the basic principle of rational use of medicines and having a medicine safety monitoring team in place. Using the SOP below will help ensure RUM and prevent ADRs.

## **SOPS FOR PREVENTING ADVERSE DRUG REACTIONS (ADRs)**

- Take full medical/drug history of patients.
- Ensure proper diagnosis based on Laboratory findings.
- Ensure proper documentation.
- Avoid polypharmacy (prescribe as few drugs as possible).
- Encourage the use of oral medications rather than injectables.
- Address other possible contributing factors like diet, lifestyle, alcohol, smoking, herbal medicines etc.
- Avoid the use of drugs when they are not required while encouraging non-pharmaceutical approach
- Be mindful of drug-drug, drug-food and drug-disease interactions.
- Adjust doses of drugs in special cases like in children, elderly, pregnancy and other disease conditions like renal/hepatic impairments etc.
- Beware of cautions/precautions necessary in the use of some drugs.
- Ask your patients to come back to you, if they have any problems with their medications.
- Always look out for and report all ADRs in your patients -**FILL THE YELLOW FORM IN SUCH CASES.**
- Call any of these numbers for any assistance or for more information: Telephone: 08086899571 or 07098211221

## **CASE REPORT OF ADVERSE REACTIONS DUE TO IRRATIONAL USE OF MEDICINES**

### **Death following administration of Buvanest Spinal and Asam Tranexamat Generic**

Two patients on hospital admission in Indonesia died following administration of Buvanest Spinal (an anaesthetic) and Asam Tranexamat Generic (an antihemorrhagic). The incident occurred during urological surgery on one patient and C-section on another.

The Food and Drug Monitoring Agency (BPOM) investigators at the hospital suspect that an accidental swap of the two drugs caused the deaths. The patients who were prescribed 4 milliliter of buvanest spinal injection received Asam Tranexamat Generic instead, from ampoules that had been mislabeled by the manufacturer as buvanest.

The BPOM had ordered the producer of the drugs, Kalbe Farma, the largest pharmaceutical firm in the country, to recall and stop producing the drugs. BPOM is still conducting a cross-sectoral investigation.

### **SECOND AFRICAN SOCIETY OF PHARMACOVIGILANCE (ASOP) CONFERENCE**

2<sup>nd</sup> Annual ASop Conference will be held from 25<sup>th</sup> – 27<sup>th</sup> November 2015 in Accra, Ghana, under the theme "Pharmacovigilance in Africa; new methods, New Challenges, New Opportunities". ASop 2015 will discuss the challenges facing pharmacovigilance in Africa and explore new methods and opportunities for enhancing pharmacovigilance in the continent. Participation is open to all with an interest in pharmacovigilance in Africa from both the public and private sectors including the pharmaceutical industry, technical Agencies, National regulatory authorities, donors, Ministries of health and individuals both in Africa and beyond.

Scientific papers will also be published/ presented at the conference.

Please check [www.asop2015.com/about](http://www.asop2015.com/about) and [info@asop2015.com](mailto:info@asop2015.com) for more information.



