PHARMACOVIGILANCE/FDIC NEWSLETTER

2007 Vol. 2

NPC AND CAPACITY BUILDING

ZONAL TRAINING WORKSHOP FOR INSTITUTIONAL DRUG SAFETY MONITORING OFFICERS

The National Pharmacovigilance Centre organized zonal training workshops to build capacity for Institutional Drug Safety Monitoring Officers in the six zones of the country from 20th February to 27th of March 2007.

The objectives of the zonal training were;

- To acquaint participants with the concept of pharmacovigilance (notably Adverse Drug Reactions)
- To sensitize participants on the importance and relevance of reporting suspected drug related problems.
- To build the capacity of practitioners to function as institutional drug safety monitoring officers for setting up, strengthening and running pharmacovigilance units in their institutions.
- To harness and coordinate pockets of pharmacovigilance activities in the country into one national system for improving regulatory decision making on drug safety issues and for greater international impact.
- To enhance networking among healthcare practitioners for greater collaboration in rational use of medicines and drug safety monitoring for improved patient safety as well as enhance the working relationship with NAFDAC.
- To obtain contributions/suggestions from participants on the way forward for pharmacovigilance in Nigeria.

INDICATORS FOR FOLLOW UP PROGRAMME

The following indicators were identified to be used to monitor the outcome of the training and these are to be measured quarterly:

- Availability of a functional unit for PVG in the institution.
- Availability and accessibility of ADR reporting forms to practitioners in the institution.
- Availability and clear understanding of Standard Operating Procedure (SOP) on reporting ADRs within the institution.
- Number of ADR case reports received by NPC from the institution.

ADRS RECEIVED BY THE NPC

From September 2004 till date, the National Pharmacovigilance Centre, NAFDAC, Abuja received 651 ADR reports under 13 specific drug classes. Out of this total, antimalarial drugs accounted for (34.60%) of the reported ADRs. The categorization of the ADRs is summarized in the table below.

THE PHARMACOLOGICAL CLASSIFICATION OF ADVERSE DRUG REACTION (ADR) CASE REPORTS RECEIVED BY THE NATIONAL PHARMACOVIGILANCE CENTRE (NPC) NAFDAC FROM SEPT.2004 TILL DATE.

DRUG CLASS	FREQUENCY	PERCENTAGE
Antimalaria	221	33.95
Antibiotic	91	13.98
Atiretroviral	69	10.60
Antipsychotic	14	2.15
Antiulcer	2	0.30
Anti TB	12	1.84
Antihypertensive	35	5.37
Antiinflammatory	7	1.07
Antihistamine	3	0.50
Antiasthmatic	8	1.22
Antidiabrtic	7	1.07
Antiemetic	5	0.77
Antiepileptic	2	0.30
Anticancer	1	0.15
Anticoagulants	1	0.15
Antihelmintic	2	0.30
Antifungal	1	0.15
Analgesic	95	14.59
Muscle Relaxant	7	1.07
Multivitamine	2	0.30
Vaccine	8	1.22
Herbal Preparations	12	1.84
Antiprotozoal	2	0.30
Drugs used in Erectile Dysfunction	3	0.50
Contraceptives	2	0.30
Antileprosy	1	0.15
Others/Invalid entry	38	5.83
Total	**651**	100

Due to the recent change in the policy of management of malaria in Nigeria, and coupled with the number of ADRs received by the centre on antimalarial relative to the other categories of drugs, the National Pharmacovigilance Centre deemed it topical to highlight the ADRs attributable to the different types of drugs for malaria treatment used in Nigeria with special focus on ACTs. A summary of ADRs due to antimalarials is presented in the table below:

S/N	TYPE OF ANTIMALARIALS	REPORTED ADVERSE DRUG REACTION (ADRs)	FREQUENCY	OUTCOME	REMARKS
1a	SULPHADOXINE/ PYRIMETHAMINE	Steven Johnson's syndrome (SJS); Jaundice, Blurring of vision, Exfoliative dermatitis, Erythema multiform, Toxic Epidermal Necrolysis (TEN); Anemia, Vomiting, Maculo papular rash, Angioedema, Hyperpigmentation, black patches, Pruritis at the cap of penis forming a wound; Oral dermatitis and inflammation; Patchy lesions on the lips and skin; Generalized clonic tonic convulsion with palpitation and dizziness	50	DEATH: 6 Hospitalized: 14 Recovered with disability: 3 Ongoing 5 Resolved: 15 Unknown: 7	**6 deaths were recorded; all were as a result of SJS** ADR's ranged from mild cases which resolved, to severe cases that needed hospitalization. .

1b	SULPHADOXINE / PYRIMETHAMINE + SEPTRIN	Burning sensation around the mouth and body Persistent occipital headache, Giddiness, Postural hypotension	2	Resolved: 2	
2	ARTEMISININ (***Monotherapy***)	Ulcer type pain, Excessive vomiting, weakness, GIT upset, Headache, Pruritus, Generalised rashes, Extrapyramidal symptoms i.e Pseudo parkinsonism; twisting of the tongue, Profused sweating	24	Recovered with disability: 2 Unknown/On going:4 Resolved: 17 Others: 1	ADR's ranged from mild cases which resolved, to severe cases; 2 cases resolved with disability.

2b	DIHYDROARTEMISININ (***Monotherapy***)	Swollen lips, Angina-like pain in the chest, Confusion blisters, Maculo papular rash, Urticaria rash, Hypertonia, Hallucination, Insomnia, Choreo athetoid movement, Numbness.	8	Hospitalized: 1 Unknown/On going:2 Resolved: 5	ADR's ranged from mild cases which resolved, to severe cases 1 case was hospitalized.
3a	ARTESUNATE / MEFLOQUINE <Artequin> (***ACT***)	Excessive vomiting Abdominal discomfort, Restlessness, Numbness of skin, Tightening of the chest, Pruritus, Rashes, Weakness, Insomnia, Anorexia, Dizziness, Protrusion of tongue, *SLUMPED, FOAMING IN THE MOUTH WITH PROTRUDING TONGUE.	18	DEATH: 1 Unknown/On going:1 Resolved: 15 Others: 1	ADR's ranged from mild cases which resolved. One death case was recorded.

3b	ARTESUNATE + AMODIAQUINE (***ACT***)	Hallucination, Twitching of mouth, Drowsiness, Fainting, Weakness, Lethargy, Light headedness, Nausea, Vomiting, Insomnia, Swelling of the lips, Itching, Pruritus, Headache, Dizziness, Tremor, Blisters, Flushing, Fatigue, Confusion, Hypertonia, Hyper-reflexia, Twisting of the tongue, Anorexia	29	Hospitalized: 2 Unknown/On going:4 Resolved: 22 Others: 1	ADR's ranged from mild cases which resolved, to severe cases that needed hospitalization. No case of death was recorded
3c	ARTHEMETER/ LUMEFANTHRINE (***Coartem***) (***ACT***)	Swelling of the eye, Serious constipation, Insomnia, Blurring of vision, Headache, Blisters with purulent exudates, Rashes, Pruritus, itching of the eyelids, Periorbital oedema	10	Hospitalized: 2 Unknown/Ongoing: 1 Resolved: 7	ADR's ranged from mild cases which resolved, to severe cases that needed hospitalization
3d	DIHYDROATEMISININ/PIPERAZINE/TRIMETHOPRIM (Artecom) (ACT)	Hyperpyrexia, weakness, headache, and nausea	8	Recovered with disability: 1 Resolved: 7	1 case resolved with disability

4	CHLOROQUINE	Generalized Itching, Vaginal bleeding, Uticaria, Maculopapular rash, vomiting	12	Resolved:6 Unknown:5 Hospitalized:1	A case of vaginal Bleeding was reported in one of the cases which we considered unusual .
5	LAPDAP (CHLOPROGUANIL + DAPSONE)	Jaundice. Anaemia, Haematurea, Apnea Dizziness, Weakness, Fainting, Hepatitis	47	Hospitalized: 19 Recovered with disability: 1 Unknown/On going:9 Resolved:18	Many of the reported cases required hospitalization. **The Manufactures voluntarily withdrew the drug due to its serious hepatic implications**
6	HALOFANTHRINE	Jaundice, Fatigue, Tachycardia, Chest pain, Intravascular Haemolysis, Abdominal pains.	7	Hospitalized:1 Unknown/On going:1 Resolved: 5	
7	QUININE SULPHATE	Headache, Dizziness, Nausea, Salivation, Stomach upset, Insomnia	2	Unknown:1 Resolved:1	

8	Others/Not recorded		4		This includes 1 Arthemeter and other antimalarials whose names were not recorded.

PHARMACOVIGILANCE NEWS

ADVOCACY VISIT OF THE NATIONAL DRUG SAFETY ADVISORY COMMITTEE (NDSAC) TO THE MEDICAL AND DENTAL COUNCIL OF NIGERIA (MDCN) 1ST AUGUST, 2007

In line with the national pharmacovigilance centre's strategy of widening participation in pharmacovigilance by relevant health care professionals, the members of the National Drug safety advisory committee (NDSAC) undertook an advocacy visit to the MDCN on the 1st August, 2007.

The NDSAC delegation was headed by the Chairman NDSAC, Prof .A. Isah and had other members of the committee as well as the Head of unit and Staff of the National Pharmacovigilance Centre (NPC) NAFDAC in attendance.

The purpose of the visit was to advocate for the incorporation of Pharmacovigilance training into the curriculum of medical students and as a module in the continuing education training of practicing medical practitioners. It is believed that the training would acquaint practitioners with current trends on drug safety issues and the need to detect and report adverse drug reactions experienced by patients on therapeutic products.

The chairman highlighted that prompt detection and reporting of ADR's helps Regulatory Authorities take effective regulatory decisions and also promote rational use of drugs in the interest of the patient.

The committee also suggested to the registrar of the MDCN of the possibility of using the oath taking ceremony for medical students and the Continuous Professional Development Programme for doctors and dentists as a medium for communicating Pharmacovigilance.

REMARKS BY THE REGISTRAR MDCN

The Registrar of the Council, Dr. F.O.A. Oshoba expressed appreciation for the visit and called for improved collaboration between health regulatory agencies.
He also emphasized the importance of establishing pharmacies in all private hospitals so as adhere to the prescription only medication initiative.
The registrar observed the need to review the curriculum of medical education to reflect the challenges of the 21st century.
He concluded by promising to incorporate Pharmacovigilance into the continuous professional development programme for professionals.

The DD-PVG/FDIC presented instruction and information materials on Pharmacovigilance to the Registrar of council on behalf of the visiting team

FURTHER COMMENTS AND SUGGESTIONS BY STAFF OF MDCN

- Suggested that Pharmacovigilance Unit should be established in teaching hospitals through out the federation because of the crucial role played by these institutions in Healthcare delivery.

- It was suggested that policy issues, such as the advocated introduction of pharmacovigilance into the curriculum of medical students and continuing professional development programme, be discussed and maintained strictly between regulatory bodies so as to avoid political and sectional interests.

- Pharmacovigilance should be incorporated as an aspect in the Disease notification system.

- Locally manufactured regulated products lack sufficient information on ADR's

The chairman NDSAC thanked the Registrar for the warm reception and useful deliberation during the meeting and further explained how case reports are being collated Analyzed and Inputted into the International data base all for the purpose of making effective regulatory decisions. He concluded by impressing the need for professional harmony and consultation.

LAUNCH OF A PHARMACOVIGILANCE CENTRE IN AHMADU BELLO UNIVERSITY

The Nigeria Association of Pharmacist in Academia, Ahmadu Bello University, Zaria Branch commissioned their Drug Information and Pharmacovigilance Centre on the 10th of July, 2007. At the commissioning ceremony, a public lecture titled: "**Integrating Pharmacovigilance to Quality Health Care Delivery Services"** was delivered by Pharm. (Mrs.) A.I. Osakwe, Coordinator, National Pharmacovigilance Centre NAFDAC Abuja. The Pharmacovigilance launch was Chaired by the Chief Medical Director ABUTH Zaria, Prof. I.Abdul-Aguye, while the Chief Host, the Vice Chancellor ABU was represented by the Dean of Faculty of Pharmaceutical Sciences, ABU Zaria, Dr. M.I. Sule.

The Chairman of the launch commended NAFDAC's efforts in setting a sound platform for Drug Information and Pharmacovigilance {Drug Safety issues} in Nigeria. He highlighted that for pharmacovigilance to take proper roots, collaborative efforts of healthcare practioners and health institutions is required to complement the efforts of the Agency. The Chairman pledged that ABU Teaching Hospital will do all within its resources to entrench the culture of Pharmacovigilance in the institution and environs.

The Chairman of the Nigeria Association of Pharmacist in Academia Ahmadu Bello University, Zaria Branch delivered a presentation on; ***who a pharmacist is and what is expected of him with regards to provision of drug information and ensuring safety of medicines***.

The launch presented an opportunity for the audience to ask questions from the Coordinator, National Pharmacovigilance Centre NAFDAC Abuja on issues of drug safety, legal implications of pharmacovigilance, ADRs associated with herbal medicines, interactions between herbal and orthodox drugs and sources of data for pharmacovigilance. These issues were addressed and the organizers and participants expressed their appreciation to NAFDAC for its' efforts at ensuring quality and safety of regulated products.

EMEA RECOMMENDS RESTRICTIONS FOR PIROXICAM USE

The European Medicine Evaluation Agency {EMEA} has recommended restrictions on ***piroxicam*** - containing products due to a risk of GI adverse effects and serious skin reactions.

According to the press release, the Agency's Committee for Medicinal Products for Human Use (CHMP) has short –term painful and inflammatory conditions.

Piroxicam is still able to be used to relieve symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis, but should not be used as a first line treatment for these disorders. Piroxicam should be initiated by physician with experience in the treatment of such conditions and the drug should be used at the lowest dosage (should not be more than 20mg/ day) for as short a time as possible. Treatment should be reviewed after 14 days.

Additionally, the CHMP has recommended new contradictions and has strengthened warnings for piroxicam in order to ensure that it is not used for patients at higher risks for adverse effects. Patients who have been receiving short- term piroxicam for acute pain or inflammation should not receive it again, and those on long term piroxicam should seek medical advice for a treatment review. If piroxicam is to be continued, it should not be taken with any other drug of the same type, such as aspirin for pain relief and other OTC NSAIDs. Tropical medications containing piroxicam are not included in the new restrictions.

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ALERT NOTICES

RECALL OF VIRACEPT 25OMG

The Attention of the National Agency for Food and Drug Administration and Control (NAFDAC) has been drawn to the recent **Recall** of an anti retroviral drug **Viracept** tablets and powder produced by Roche Bassel Plant in Switzerland, because it contains Ethyl Mesylate, which is capable of altering human genetic make up.

Swipha, Nigeria's representative of Roche has informed NAFDAC that they have communicated the recall of Viracept to all the institutions that they supplied the drug in Nigeria.

All institutions and retail outlets stocking Viracept manufactured by Roche Bassel Plant should submit them to the nearest Swipha or NAFDAC office. Prescription of Viracept should be discontinued immediately and all patients on Viracept should discontinue the use and contact the Doctor for an alternative prescription.

For further enquiry, contact the National Pharmacovigilance Centre, NAFDAC Head Quarters Abuja on the following numbers: **096702823; 095241108; 08035960514**

PUBLIC ALERT NOTICE

The Attention of the National Agency for Food and Drug Administration and Control (NAFDAC) has been drawn to the circulation of toothpastes containing a toxic Substance, **Diethylene Glycol**, an antifreeze and solvent. Diethylene Glycol causes injury to the kidney and liver.

The implicated products include toothpaste manufactured in China and all brands of Colgate toothpaste.

NAFDAC wishes to bring to the attention of the General Public that no foreign manufactured toothpaste is registered by NAFDAC and as such their quality and safety cannot be guaranteed.

The Public is hereby advised to ***purchase and use only*** toothpastes manufactured in Nigeria and registered by NAFDAC**.**

For further enquires please contact the following telephone numbers: **096702823; 095241108; 0805960514; 08033154512**

INTRODUCING NAFDAC AS PART OF WORLD HEALTH ORGANIZATION'S INTERNATIONAL FOOD SAFETY AUTHORITIES NETWORK (INFOSAN)

The rapid globalization of food production and trade has increased the potential likelihood of international incidents involving contaminated food. Food safety authorities all over the world have acknowledged that ensuring food safety must not only be tackled at the national level but also through closer linkages among food safety authorities at the international level.

In view of the need for all countries to promote the exchange of food safety information and improve collaboration among food safety authorities at national and international level, WHO launched the International Food Safety Authorities Network (INFOSAN).

The INFOSAN network provides a mechanism through the **INFOSAN Focal Points** located in every country for the exchange of information on routine and emerging food safety issues. Every country on the INFOSAN network also has an **INFOSAN EMERGENCY POINT** that is responsible for providing access to information during food safety emergencies.

NAFDAC is the INFOSAN FOCAL Point and the INFOSAN Emergency contact point in Nigeria. Part of our responsibilities as the INFOSAN emergency contact point is to notify food safety authorities about food borne outbreaks or food contamination events of international significance. The INFOSAN Emergency contact point is to also respond on behalf of the government to queries from WHO when these food borne outbreaks occur within the country.

The INFOSAN Emergency contact point in Nigeria can be contacted when there is a food borne outbreak or any other food safety emergency with the following numbers and email address:

09 5241108, 6702823, nafdac_npc@yahoo.com

PHAMACOVIGILANCE/FDIC NEWSLETTER:

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