Pharmacovigilance Newsletter

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Editorial Board:

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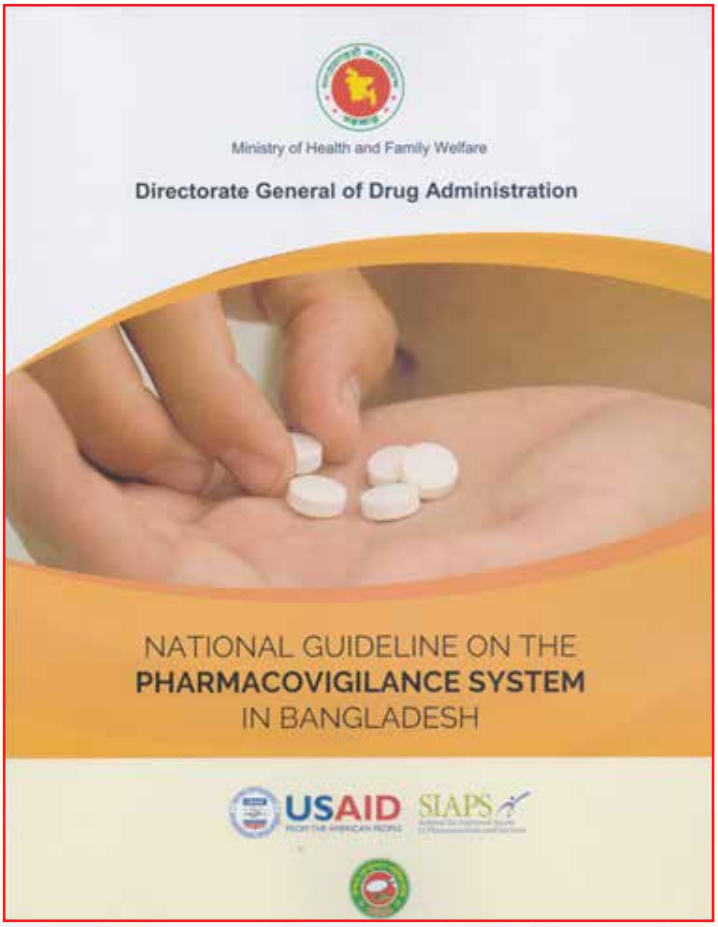
National Pharmacovigilance Guideline Approved and Published:

Directorate General of Drug Administration (DGDA) has started Pharmacovigilance activity in 1996. DGDA formed Adverse Drug Reaction Monitoring (ADRM) cell in 2013. Ministry of Health and Family Welfare (MOHFW) declared ADRM cell as National PV center for Bangladesh.
MOHFW formed ADR Advisory committee (ADRAC) to work in conjunction with ADRM cell to provide technical guidance for implementation of PV activities, evaluation of adverse event reports and also give recommendations to the licensing authority of Drugs for implementing necessary regulatory decisions.

The National Pharmacovigilance Guideline is one of the remarkable achievement of the regulatory authority as Pharmacovigilance is the one of the key activities of DGDA. MOHFW has approved this National guideline in January 2018 and it has been published with the USAID funded SIAPS program.



Picture 1: PV guideline

Summary and result of the 8th ADRAC meeting:

Total 531 ADE reports were evaluated by ADRM cell. After primary evaluation of the reports, ADRM cell places 497 reports to Technical Sub-committee (TSC). Out of 497 reports 183 reports were found Certain, Probable and Possible by the WHO Causality Assessment scale and these reports were placed before the 8th ADRAC meeting for review.The committee has also recommended on the safety information published in the WHO Pharmaceuticals Newsletter-1, 2107

Table 1: Summary and result of ADR reports in 8th ADRAC meeting

SL. No.	Committee	Number of evaluated reports	Opinion
1.	ADRM Cell	531	Complete reports-497 Incomplete reports-34
2	Technical sub-committee (TSC)	497	Certain, Probable and Possible report-183 Unlikely and Unclassifiable reports -314
3.	ADRAC	183	Has opined these 183 reports as ADR

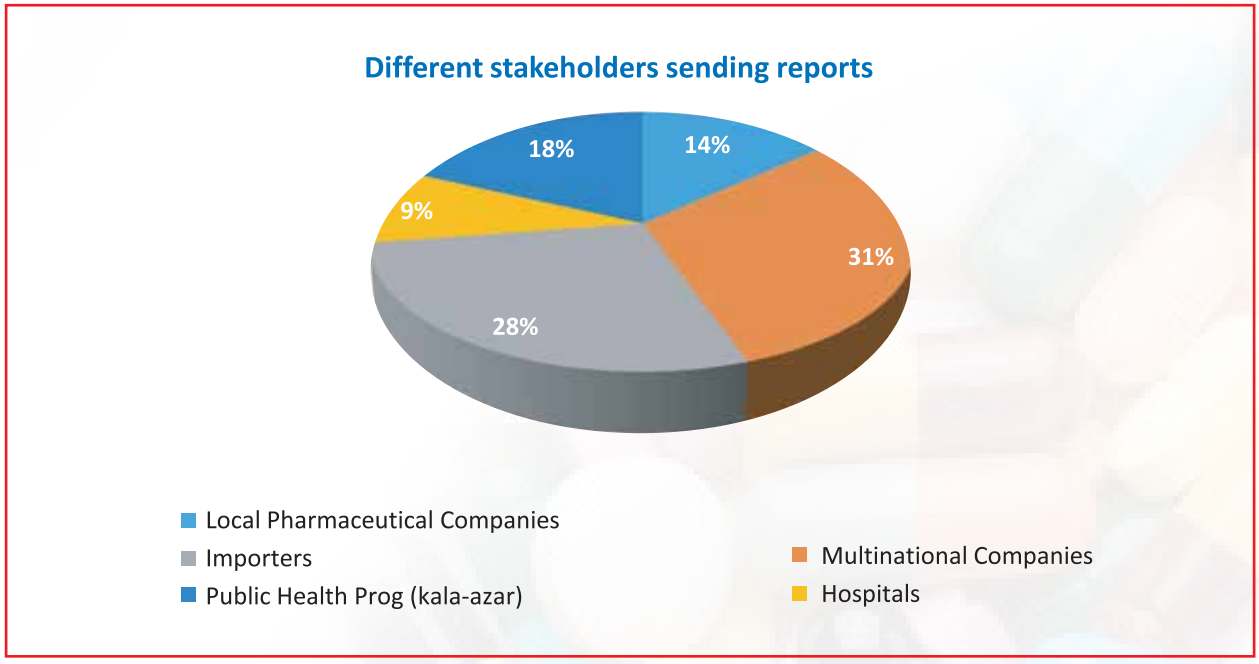


Figure 1: Number of Suspected AE reports received from different stakeholders for 8th ADRAC

ADVERSE EVENT (AE) REPORTING: WHAT, HOW, WHY

What to report: Patients should report all suspected adverse reactions to drugs, undocumented or unexpected reactions, serious adverse drug reactions, unexpected therapeutic effects, product quality problems, treatment failures, and medication errors to health providers (physicians, pharmacists, and nurses) or directly to the ADRM cell of DGDA.

How to report: Suspected and observed drug-related reactions must be reported using the electronic version of the reporting form available in a fillable pdf available on the DGDA website (www.dgda.gov.bd)
Also submitted to the ADRM Cell by email (adrmcell.dgda@gmail.com/dgda.gov@gmail.com), post, or fax (+8802 9880854). In emergency cases or when forms are not readily available, reports can also be made to the ADRM cell by phone (+8802 9880803).

Why to report: All suspected and observed drug-related reactions must be reported immediately when encountered; delays in reporting can cause harm to users or patients and impair health care providers' abilities to deliver safe, effective treatment.

Recommendations made by 8th ADRAC based on regulatory decisionsofdifferent NRAs published in WHO Pharmaceuticals Newsletter-1, 2017

Table 2: Regulatory decisions of DGDA as per recommendations of 8th ADRAC Meeting

Sl. No	Name of Medicine	Indication	Adverse Drug Reaction	Decision/Comments/Recommendation of the Meeting Members
1.	**Amiodarone (intravenous)**	•Arrhythmias in adults. •Treatment of life threatening arrhythmias in foetus& newborn when other medication not worked.	Potential risk of developing adverse effects in the heart, nervous system and affect growth & development of foetus and newborns.	**a.** **DGDA** will instruct manufacturers / importers to update the product information/ promotional materials/Package insert including cardiovascular risks in new-borns. **b.** Bangladesh Cardiac Society, Bangladesh Paediatric Association (BPA), Association of Physicians of Bangladesh and Bangladesh Medical association (BMA) should be informed
2.	**Direct-acting antivirals for hepatitis C treatment:**	Chronic HCV infection in adult patients.	Potential risk of HBV reactivation in patients co infected with both HBV and HCV and Interaction with vitamin K antagonists and changes in INR value	a. DGDA will address this issue and notify to the relevant Manufacturers, b. Bangladesh Gastroenterology Society (BGS), Association of Physicians of Bangladesh, Bangladesh Society of Medicine, and Bangladesh Medical association (BMA) should be informed
3.	**Fluoroquinolones**	Urinary tract infection Respiratory tract infection Skin and soft issue, bones and joint infection Abdominal cavity infection.	Risk of Retinal detachment.	**DGDA** will instruct that Safety information to be provided by the Manufacturers to the Health care providers in Packaging Materials (Insert/Leaflet)/promotional materials & Inserts. a. Association of Physicians of Bangladesh, and Bangladesh Medical association (BMA) should be informed Packaging Materials (Insert/Leaflet)/Promotional material. b. Manufacturer should add the following sentence in the insert/leaflet as a precautionÒClose Monitoring of the patients after 2 to 3 week of use" c. Bangladesh Society of Medicine, Association of Physicians of Bangladesh, Bangladesh Medical association (BMA), Bangladesh Association for child & adolescent mental Health (BACAMH) should be informed.

Ref: WHO Pharmaceuticals Newsletter No 1, 2017, page-5, 9, 12 & 14

Memorandum of Understanding (MOU) with NTP:

Pharmacovigilance work of DGDA steps ahead in Public Health Program by signing MOU between National Pharmacovigilance Center (NPC) and National Tuberculosis Program in December 2017.

Major General Md. Mustafizur Rahman, Director General, DGDA; Dr. Ehteshamul Haque, Additional Director General (DGHS) and Line Director of NTP; Dr. RousuliHaque, Director, MBDC; Nayer Sultana, Director and Head of ADRM cell, DGDA; Mr. Zahedul Islam, Country Project Director SIAPS/MSH and Dr. Afsana Alamgir Khan, Technical Advisor SIAPS/MSH were present.

Picture 2:
MOU signing with National Pharmacovigilance Center (NPC) and National Tuberculosis Program

UMC-WHO SIGNAL for specific Medicines (April 2018)

SIGNAL contains summaries of analyses of individual case safety reports (ICSRs) in VigiBase, the WHO global database of ICSRs, made by the UMC and the UMC signal review panel.

The information in SIGNAL is derived Form national pharmacovigilance centers in countries participating in the WHO Programme for International Drug Monitoring.

This issue contains signals from three different screenings of VigiBase.

Five Risk group signals

Aflibercept - Deep vein thrombosis and pulmonary embolism - Males
Ceftriaxone - Hepatitis - Patients 75 years and older
Glibenclamide - Palpitations - Asian population
Levofloxacin - Myoclonus - Patients over 75 years
Omalizumab - Anaphylactic shock - Females

Six Medication errors

Agomelatine - Inappropriate schedule of drug administration
Brivudine and 5-fluorouracil - Persistence of a fatal drug-drug interaction
Edoxaban - Incorrect dose administered
Metamizole - Documented hypersensitivity to administered product
Methotrexate - Incorrect drug administration rate
Phenprocoumon - Accidental overdose

One Vaccine Signal

Rotavirus vaccine - Hepatic enzyme elevation

PV Activities Monitoring Visit and Meeting with Stakeholders

As part of regular monitoring of the ongoing PV activities, a team of ADRM cell, DGDA visited National cancer Hospital, Mohakhali, Dhaka and Popular Medical College Hospital, Dhaka. ADRM cell also visited The ACME Laboratories Ltd. During the visit, the team followed up with the ADE reporting status and shared with the PV teams, how they can strengthen medicine safety reporting, their planning on risk management and risk mitigation. ADRM cell also emphasized on conducting the activities and awareness on PV as per plan and schedule of the facilities/institutions. The Management and PV team officials of those hospitals & companies highly cooperated and appreciated DGDA's support and directives for the PV program and committed to continue ADE reporting related activities.

Picture 3

Picture 4

Dr. Md. Akter Hossain, Assistant Director, DGDA and Focal Point of ADRM Cell visited The ACME Laboratories Ltd (Picture 3) and Popular Medical College Hospital, Dhaka (Picture 4) as a part of PV awareness activities.

Analysis of ADR reports uploaded by DGDA to UMC:

ADRM cell has been working as a functional National PV center from 2014. The below slides were showing 463 ADR reports committed to UMC from 2014 till 2017 from ADRM cell, DGDA.

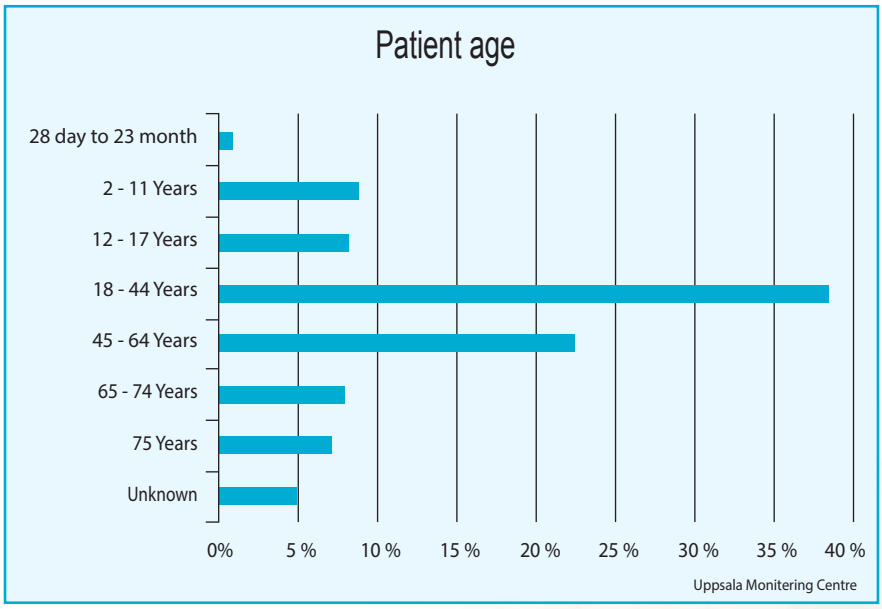


Figure 2: Occurrence of ADRs developing according to Age

Figure 2 shows that 18-44 years age group are having highest (nearly 40%) ADRs, also alarming that 23% of 45-64 years age group and nearly 10% of 2-11 years age group having ADRs.

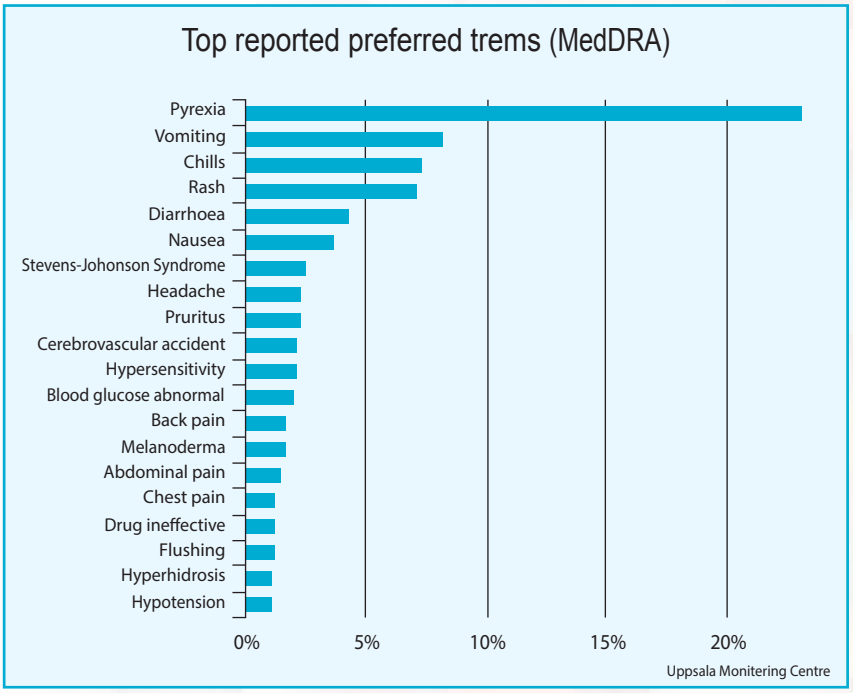


Figure 3: Top 20 Adverse events developed

Figure 3 shows that Pyrexia, Vomiting, Chills, Rashes, Diarrhoe are the common ADRs in patients

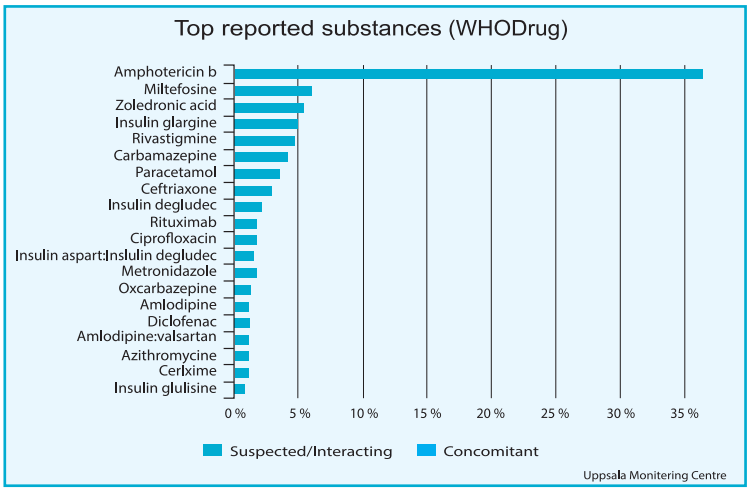


Figure 4: Medicines causing ADRs

Figure 4 shows Amphotericine B, miltefosine,most common medicines developing ADRs as ADRM cell are having lot of reports from National Kal-Azar Program. Besides them Zoledronic acid, Insuline Glargine, Carbamazipine are some highlighted medicines which also develope ADRs.

ADRM Cell members attend Pharmacovigilance Seminar 2018 in Tokyo, Japan:

PMDA-ATC invited DGDA officials to attend at the Pharmcovigilance Seminar 2018 in Tokyo Japan from February 5-8, 2018. Four members of ADRM cell joined the seminar. They are Dr. Md. Akter Hossain, Assistant Director and Focal Point of ADRM cell, Mohammed Nayeem Golder, Assistant Licensing Officer, Nipa Chowdhury, Superintendent of Drugs and ATM Golam Kibria Khan, Superintendent of Drugs.

Some important topics of the seminar were :

- Overview of Pharmacovigilance
- Regulation on Labeling in ASIA/EU/USA
- Safety specification and Pharmacovigilance Plan
- Risk Management Plans from Industry perspective
- Benifit-Risk Assessment through product life cycle
- Risk communication of safety information with patients and Healthcare professionals.
- Future Direction on Pharmacovigilance, etc.

Picture-5:
ADRM Cell members attend Pharmacovigilance Seminar 2018 in Tokyo, Japan