PHARMACOVIGILANCE NEWSLETTER

Issue 2, October 2017

PHARMACOVIGILANCE IN BANGLADESH: AN OVERVIEW

The Directorate General of Drug Administration (DGDA) introduced pharmacovigilance (PV), also known as drug safety, in Bangladesh in 1999. However, due to a shortage of manpower and a lack of financial support, the program became dormant. In January 2013, DGDA established the Adverse Drug Reaction Monitoring (ADRM) cell with the technical assistance from the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health. Later that year, the Ministry of Health and Family Welfare (MOHFW) declared DGDA as the National PV Center (NPC) for Bangladesh and gave ADRM cell the responsibility to oversee the center's activities. The MOHFW also set up an independent committee known as the Adverse Drug Reaction Advisory Committee (ADRAC) that works in conjunction with the ADRM cell to provide technical guidance for PV activities, evaluate adverse drug event (ADE) reports, and make recommendations for regulatory decisions and actions by the DGDA, the country's licensing authority for drugs. In December 2014, Bangladesh became the 120th member of the World Health Organization's International Drug Monitoring Centre (WHO-UMC).

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

"Act on Pharmacovigilance Today, Don't Wait for Tomorrow"

The aim of this newsletter is to disseminate information about the PV activities of the DGDA and to communicate with health providers any concerns about drug safety for locally manufactured and imported drugs.

ADE 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) and 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 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.

"Reporting ADEs is Mandated by the MOHFW"

The responsibility for reporting suspected adverse drug reactions for quality treatment lies with you.

HOW THE ADE REPORTING FLOWS

Patient, who suffers from ADEs, reports to physicians/ pharmacists/nurses.

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ADE reports are sent to DGDA (ADRM cell) through hand delivery/online reporting/mail.

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ADRM cell evaluates all ADE reports; in case of incomplete reports, the cell sends an official letter to the sender for providing the missing information.

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National PV center reviews all completed reports through technical sub-committee and ADRAC.

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Any recommendation and suggestion made by ADRAC is informed to national regulatory authority (DGDA).

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Based on recommendation/suggestion, national regulatory authority takes actions as needed.

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NPC uploads the reports to WHO through UMC-Vigiflow.

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UMC reviews the data . If there is any plausible link between medicines and adverse event, UMC communicates a signal to WHO and all member countries.

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Regulatory authorities around the world decide if actions/signal should be taken in to consideration. In such case, the information is published and made available to health professionals and consumers.

ACTIVITY UPDATES FROM THE NATIONAL PV CENTER

Pharmacovigilance-MNCH in BSMMU: New Step in Drug and Patient Safety

A half day workshop on Maternal, Newborn and Child Health (MNCH) PV was organized by the DGDA at Bangabandhu Sheikh Mujib Medical University (BSMMU) on August 10, 2017. The workshop, facilitated by SIAPS, aimed at introducing MNCH focused ADE reporting in BSMMU through which safe and quality MNCH medicines can be ensured to address Bangladesh commitment for ending preventable child and maternal death by 2035.

Photo credit: Dr. Afsana Alamgir Khan, SIAPS/MSH

During the workshop, some important issues were discussed which are as follows:

- Professor Meshbah from Pharmacology department of BSMMU gave emphasis on developing a web portal for the hospital where ADE reports can be uploaded and sent to DGDA directly. He also said that a mobile app may be developed through which physicians can be encouraged to report ADEs.
- Professor Shahidullah suggested that the BSMMU should include PV in the curriculum for the post-graduation students and as part of that course, two ADE case reports have to be submitted.
- Director General of DGDA Major General Md. Mustafizur Rahman said that the directorate is committed to ensure medicine safety for the people of Bangladesh and therefore, seeks active participation from all including health care providers, pharmacists and patients to make the efforts fruitful. He requested BSMMU to report suspected adverse drug reactions of MNCH medicines to the ADRM cell for proper actions.

Photo credit: Dr. Afsana Alamgir Khan, SIAPS/MSH

At the event, participants expressed their commitments to incorporate PV activities in their respective departments and appoint focal persons who will continuously monitor and submit ADE reports to DGDA.

ADRAC Meeting and Key Decisions

ADRAC had two meetings on December 2016 and May 2017 to evaluate ADE reports and made the following recommendations for regulatory decisions and actions accordingly:

- Following the decision of the specialists' committee, steps need to be taken to ensure that Zolendranate is being administered into patent's body under direct supervision of the consultant physician as per appropriate procedures (with caution). Also all pharmaceutical and related companies should be instructed to put clear information about the use and administrative methods of this medicine with guidance for cautionary on the packets.
- All manufacturers, importers, and distributors of Insulin glargine, Insulin degludec, Insulin degludec+Insulin aspart and Carbamazepine should be instructed to send suspected adverse event reports; take necessary steps to aware physicians and consumers about the adverse effects of these medicines and follow precautions while prescribing and using.
- Letters should be sent to the EPI, NTP, Malaria and HIV pro- grams under the Directorate General of Health Services with request to send suspected ADE reports to the DGDA.
- Follow up letters will be sent to the local manufacturers and importers of Carbamazepine, Rivastigmine and Insu- lin so that they properly monitor adverse effects of these medicines and send suspected ADE reports to DGDA

PV Activities Monitoring Visit

As part of regular monitoring of the ongoing PV activities, a team comprising DGDA officials and SIAPS technical advisors visited "Anwar Khan Modern Medical College and Hospital" on July 2017 During the visit, the team followed up with the hospital's ADE reporting status and shared with the PV focal persons and the professors how they can strengthen medicine safety reporting. The hospital officials highly appreciated DGDA's support and directives for the PV program and committed to continue ADE reporting related activities.

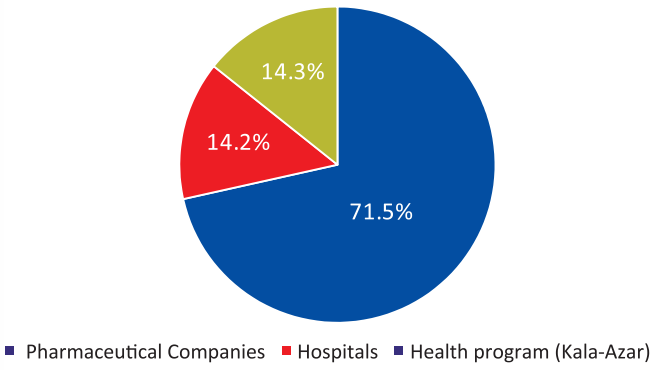
Photo credit: Dr. Afsana Alamgir Khan, SIAPS/MSH

AT A GLANCE PROGRESSES MADE IN THE PV PROGRAM

Total Number of ADE Reports Received from Different PV Implementing Partners

DGDA is following a system oriented approach to keep the national PV program functional and effective. As of June 2017, DGDA has received 1880 ADE reports from the selected hospitals and pharmaceutical companies, and the Kala-Azar health program. Of these, 1429 ADE reports had complete information. The highest number of reports (71.5%) came from pharmaceutical companies (Figure 1)

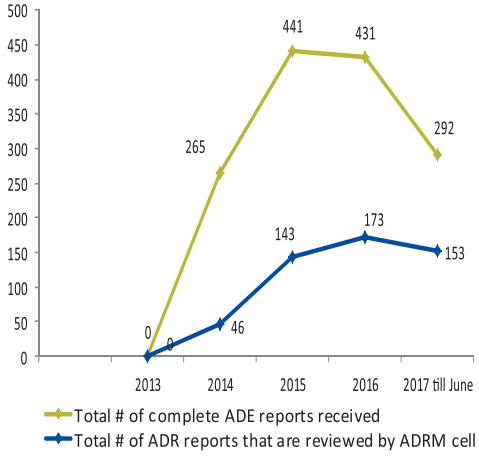
Figure 1: Category wise reporting rates of different PV implementing partners



Growing Number of ADR Reports Reviewed by ADRAC

Till date, ADRAC has reviewed 515 ADR reports. Figure 2 shows that the number of ADR reports reviewed by ADRAC has been increasing every year. Up to April 2017, DGDA uploaded 393 ADR reports to the WHO VigiFlow database and the rest of the reviewed reports are gradually being uploaded.

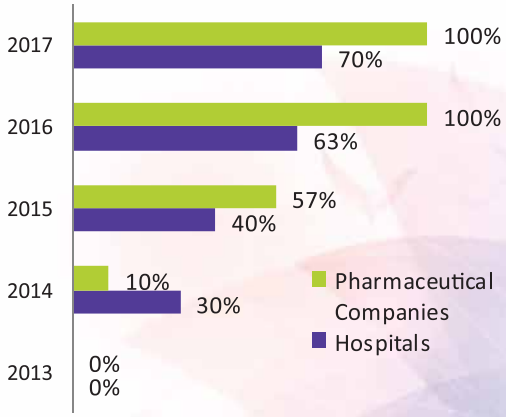
Figure 2: Year-wise cumulative numbers of ADE reports receieved and reviewed



Increased Number of Reporting Sites

Till date, 21 hospitals are regularly reporting ADEs, that is 70% of the total selected health facilities. For pharmaceutical companies, the rate is 100%. (Figure 3)

Figure 3: Percentage of sites that are reporting ADEs



CHAMPIONS OF THE NATIONAL PV PROGRAM

Currently, 32 hospitals and 30 pharmaceutical companies with designated PV focal points are working as "sentinel surveillance sites" to implement PV interventions under the DGDA. Among them, few selected hospitals and pharmaceutical companies are truly promoting medicine safety through regular PV activities in their individual organizations. Square Hospital Limited (SHL) is one such example and SHL's PV focal person Md. Jahidul Hasan is one of DGDA's PV champions.

Photo credit: Liza Talukder, SIAPS/MSH

As a pharmacist, Jahidul Hasan has worked in few different hospitals, but not until he joined SHL that he came across the term PV. Since the PV program started in Bangladesh in 2013, DGDA organized many training for the PV focal persons of selected hospitals and pharmaceutical companies to build their skills and knowledge on PV and increase the number of ADE reporting from these institutions. After participating in one such training in 2014, Jahidul, shared his newly gained knowledge with the SHL's pharmaceuticals and therapeutic committee (PTC) to see how the hospital can incorporate PV in their regular activities.

Jahidul said, "At first things were slow, but gradually the wheel started to move and PV took a stronger shape in SHL. We developed our own reporting flow for ADEs. Every doctor and nurse, at the time of joining, is given orientation about PV. We also keep emergency contact numbers and name of the PV focal person hanging on the notice boards of each ward so duty nurses can promptly report if any ADE occurs." He adds proudly, "Every event must be reported—this is how PTC focuses on PV now."

According to the DGDA, SHL is one of the facilities that is regularly submitting ADE reports. For its commitment to ensuring medicine safety, SHL stands as a model for other private and public hospitals in the country.

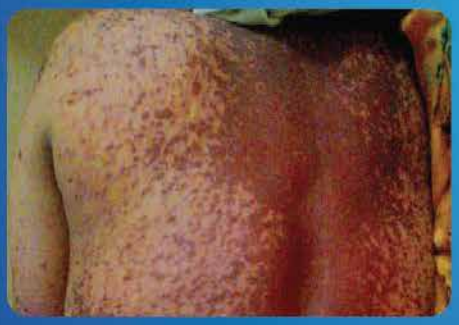
DRUG SAFETY UPDATES BY WHO

Sl. No	Name of Medicine	Indication	Adverse Drug Reaction	Regulatory actions/ recommendation taken by NRAs
1.	Fluoro-quinolones	a. Urinary tract infection b. Respiratory tract infection c. Skin and soft issue, bones and joint infection. d. Abdominal cavity infection	Retinal detachment.	*Singapore. The HSA has instructed to update the package inserts of fluoroquinolones containing products.*
2.	Selective serotonin reuptake inhibitors (SSRIs)	Antidepressants	a. Risk of suicidal thinking and behavior. b. Potential risk of autism in child whose mothers used elective Serotonin Reuptake Inhibitors (SSRIs) during pregnancy. (Canada)	a. Australia. The TGA has issued a reminder to health-care professionals relating to suicidal thinking and behavior in children and adolescents & directed to include in the Product Information documents of all SSRIs registered for use in Australia. b. Canada. Health Canada has aware Potential risk of autism in child whose mothers used SSRIs.
3.	Carbamaz-epine	Epilepsy and other conditions such as bipolar disorders, alcohol-withdrawal syndrome, trigeminal neuralgia, diabetic neuropathy and diabetes insipidus.	Severe cutaneous adverse reactions (SCARs).	Singapore. The HSA has recommended health-care professionals for HLAB* 1502 genotyping prior to the initiation of Carbamazepine therapy in patients of AsianAncestry, to minimize that risk.
4.	Pioglita-zone containing Drugs	Control of Blood sugar Along with diet and exercise, in adults with type 2 diabetes.	Risk of bladder cancer	USA. The US FDA has updated the product information for pioglitazone-containing medicines to include an additional Adverse effect to existing warnings, about the increased risk of bladder cancer.

STAY AWARE IN MEDICINE USE

BESIDE SIDE EFFECTS, ANY UNWANTED PHYSICAL PROBLEM THAT MAY OCCUR AFTER THE USE OF MEDICINES IS CALLED AN ADVERSE DRUG REACTION

LEARN ABOUT SIDE EFFECTS AND COMPLICATIONS BEFORE USING MEDICINE



INFORM YOUR DOCTOR IMMEDIATELY ABOUT ANY PHYSICAL PROBLEM AND REACTION AFTER USING MEDICINE

ASSIST YOUR DOCTOR TO FILL OUT THE ADR FORM FOR REPORTING ADVERSE DRUG EVENTS

YOU CAN ALSO REPORT DIRECTLY TO THE DIRECTORATE GENERAL OF DRUG ADMINISTRATION (DGDA)

FOR DIRECT REPORTING CONTACT

Directorate General of Drug Administration
Oushad Bhaban, Mohakhali, Dhaka-1212.

Tel: +8802-9880854
Fax: +8802-9880864
Website: www.dgda.gov.bd
email: dgda.gov@gmail.com

Web Link: http://dgda.gov.bd/littledms/ApplicationForms/bangladesh-ade-form-021014-form-distributed.pdf

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