Pharmacovigilance NEWSLETTER

5th Issue, October, 2019

The Aim of the newsletter:

- Dissemination of drug safety information.
- Dissemination of regulatory dicisions.
- Sharing activities of national pharmacovigilance centre (ADRM cell) with stake holders.
- Focusing capasity building, training & awareness programs on pharmacovigilance.

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Introduction

The Pharmacovigilance newsletter provides the latest information on the safety of medicine & regulatory decisions of the Directorate General of Drugs Administration (DGDA), the national drug authority of Bangladesh. It is one of the important means of communication with the Pharmacovigilance stakeholders of Bangladesh (i.e. doctors, nurses, pharmacists, drug manufacturers, importers and for the medicine consumers) and international organizations.

This newslwtter includes the outcome of 10th ADRAC meeting. Evaluation of multiple ADR reports coming from different sources & different workshops & awareness programs on Pharmacovigilance organized by DGDA.

Awareness program on Pharmacovigilance (PV) held in Rajshahi Medical College Hospital (RMCH):

Directorate General of Drug Administration (DGDA) arranged awareness programs on Pharmacovigilance among the stakeholders. Successful Awareness Program on Implementation of pharmacovigilance to ensure safety of medicine in Bangladesh held in RMCH conference room on 27th June 2019. The Director General of DGDA Major General Md. Mahbubur Rahman has attended there as a chief guest. Director of DGDA Mr. Md. Ruhul Amin and some other officers of DGDA were present in the program.

Figure 1: Chief Guest Major General Md. Mahbubur Rahman, DG of DGDA

Brig Gen Md. Jamilur Rahman presided over the awareness program.

Figure 2: Awareness Program on PV in Rajshahi MCH

In remarks DG mentioned that DGDA is working hard to maintain the safety and quality of medicine in Bangladesh for a long time. DGDA is also working and performing raids to detect the Spurious Substandard and Fake (SSF) medicines. The officers of DGDA are continuously arranging awareness program and campaigns to make a mass awareness about SSF medicine. He also mentioned that regarding the safety of medicines the ADRM Cell is working in organized way. He invited the doctors, nurses, pharmacists and other health care professionals of Rajshahi Medical College to keep a close look /sharp eye on the adverse effects of any medicines and should be reported to National Pharmacovigilance Center timely. He also mentioned that the health facilities and Healthcare providers are the main stakeholders for ADR reporting to ensure the safe use of medicines that impacts on Patient Safety.

The program was very interactive. Director Md. Ruhul Amin and Assistant Director Salahuddin provided answers of some questions raised from the audience. Dr Md. Akter Hossain, Assistant Director and Focal Point of ADR Monitoring Cell, DGDA presented a brief presentation on Pharmacovigilance and ADR reporting system in Bangladesh and also demonstrates about how to fill the online ADR reporting form.

Figure 3: Awareness Program on PV in Rajshahi MCH

Details of reports received at ADRM Cell, DGDA from September 2018-June 2019

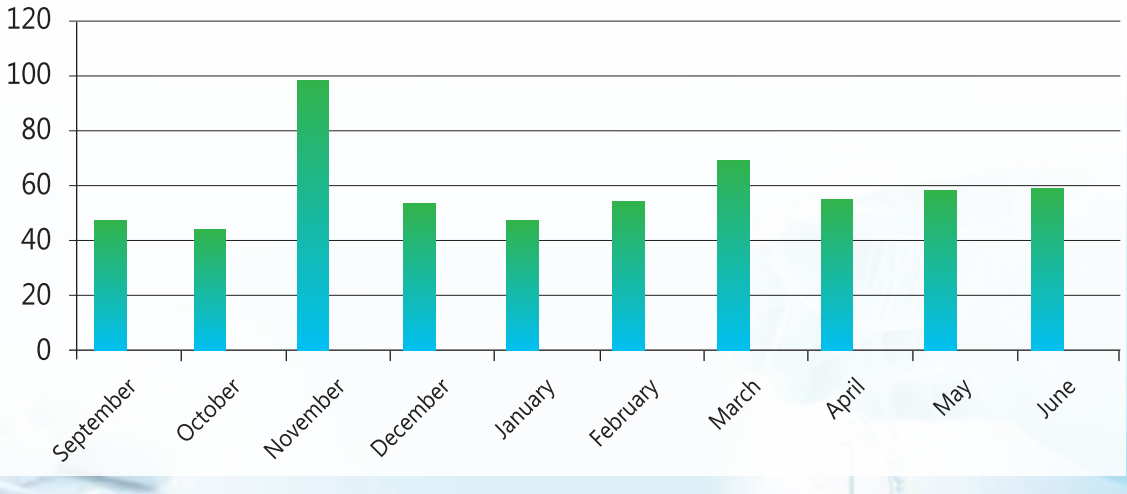

Figure 4: Total 582 reports received at ADRM cell from Sep/18 to June/19

Sources of Reports
Total Number of Reports: 582

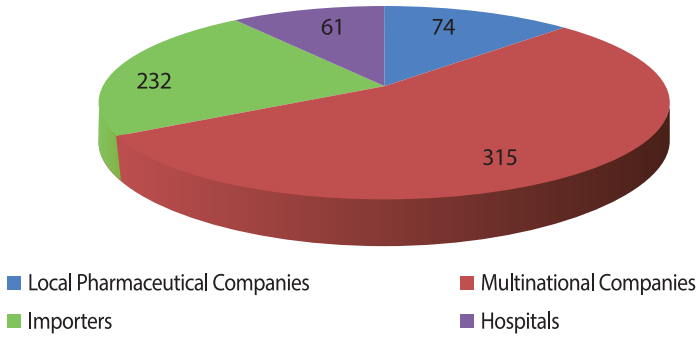

Figure 5: Sources of report received at DGDA

Breakdown of reports evaluated (Sep-2018 to June-2019)

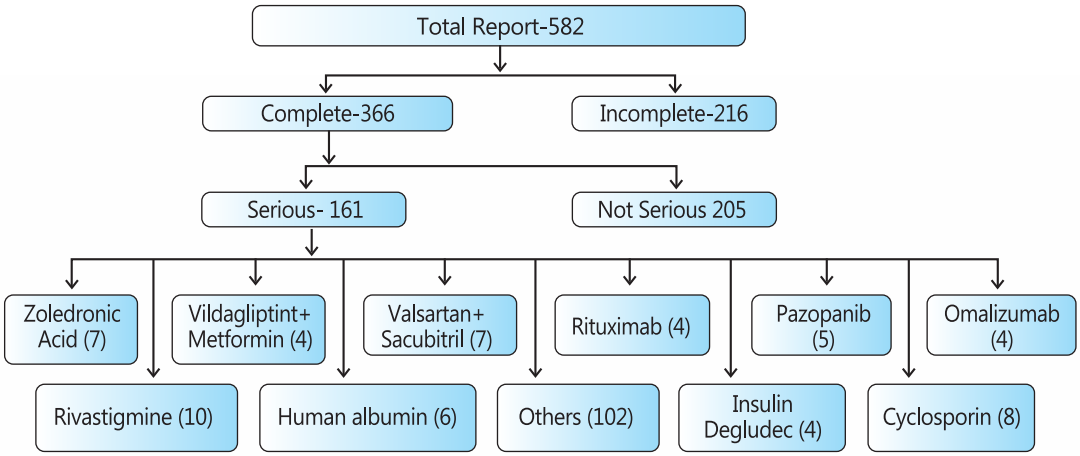

Figure 6: Breakdown of reports evaluated (Sep-2018 to June-2019)

Outcome of the 10th Adverse Drug Reaction Advisory Committee (ADRAC) meeting:

10th ADRAC meeting was held on 27th August 2019 at DGDA. Major General Md. Mahbubur Rahman, DG of DGDA and Chairman of ADRAC presided over the meeting. National Pharmacovigilance Centre of Bangladesh received total 582 reports from different stakeholders. All these reports were primarily evaluated by ADRM cell. Out of these 366 reports were found complete/partial complete and 216 reports were found incomplete for lacking of minimum information. After primary evaluation of the reports, ADRM cell placed 366 reports before Technical Sub-committee (TSC), where 161 reports were serious and 205 reports were not-serious. Out of the 161 serious cases 53 cases were found Certain, Probable and Possible and 108 cases were found Unlikely/Unclassifiable as per WHO Causality Assessment scale. Finally these reports were placed before 10th ADRAC meeting for review and the honorable members of ADRAC agreed with the assessment done by the members of TSC. The committee has also recommended on the safety information published in the WHO Pharmaceuticals Newsletter- Issue No. 1 & 2, 2019 (Drug safety information).

Table 1: Evaluation of reports by different committees

SL. No.	Committee Name	Number of evaluated reports	Opinion
1.	ADRM Cell	582	Complete reports-366 Incomplete reports-216
2.	Technical sub-committee (TSC)	366	Serious-161 & Non -serious- 205 Certain, Probable and Possible report-53 } Serious cases Unlikely and Unclassifiable reports -108 }
3.	ADRAC	161	Has agreed with the assessment done by the members of TSC.

Discussion on Serious Events & standard skeleton and contents of Insert/ Patient Information Leaflet (PIL).

In the meeting there was a discussion on the serious cases found and the causality assessment done by the Technical Sub-Committee (TSC) of ADRAC. All 53 reports with Certain, Probable and Possible comments were discussed thoroughly specially death cases. Reports show that Human normal Immunoglobulin causes cultivation of product solution and Ceftriaxone causes Breathlessness allergic, Respiratory distress occurs resulting Hospitalization or Prolongation of Hospitalization of the patients. The specialists of ADRAC committee had come to decision that these adverse reactions may be caused due to administration technique (faulty technique). That's why they suggested to update the packaging materials and insert to add the information "The drug should be administered during at least 5 minutes."

One case for Dapsone causes development of Dapsone Syndrome to a patient resulting death. This case was investigated and confirmed the causal relation with the drug by the report providing hospital. The report providing companies couldn't collect more information regarding serious events. Members of the committee emphasised on collecting more information and quality reports for assessment.

ADRAC has formed a sub-committee for preparing a standard skeleton and contents (i.e. what information should be provided in Insert) of the Insert/PIL of medicinal products for more understandable to the patients and public

Some important regulatory decisions has been taken in the 10th ADRAC meeting:

Ceftriaxone IV injection ঔষধটি কমপক্ষে ০৫ মিনিট ব্যাপি প্রয়োগ করার জন্য চিকিৎসক, নার্স এবং হেলথ্ কেয়ার প্রোভাইডারদেরকে অবহিত করার ব্যবস্থা গ্রহণ করতে হবে। বিষয়টি Patient Information Leaflet (PIL)-এ অন্তর্ভূক্ত করতে হবে। ঔষধের একটি ঝঃধহফধৎফ চধঃরবহঃ ওহভড়ৎসধঃরড়হ খবধভষবঃ (চওখ) এ কোন্ কোন্ বিষয়াবলি কিভাবে থাকা প্রয়োজন, সে বিষয়ে সুপারিশ প্রণয়নের জন্য একটি সাব-কমিটি গঠণ করা হয়।

কিডনি (Renal Impairment) রোগীদের জন্য Dapsone নামীয় ঔষধটি Prescribe করার ক্ষেত্রে সাবধানতা অবলম্বন এবং যে কান রোগীকে প্রয়োগের পূর্বে এ-6PD test করা প্রয়োজন- বিষয়টি সংশ্লিষ্ট চিকিৎসকবৃন্দকে অবহিত করার সিদ্ধান্ত গৃহীত হয়।

সংখ্যাতিরিক্ত রিপোর্ট সংশ্লিষ্ট জেনেরিকসমূহের উপর সতর্ক দৃষ্টি রাখা হবে, আরও রিপোর্ট পাওয়া গেলে পরবর্তীতে বিবেচনা করতঃ সিদ্ধান্ত গ্রহণ করা হবে।

Vaccine Gi AEFI Report এর মূল্যায়ণের ক্ষেত্রে ঊচও এর Expert Review Committee (ERC) কে ADRAC এর সাব-কমিটি হিসেবে অন্তর্ভূক্তির সুপারিশসহ মন্ত্রণালয় বরাবরে পত্র প্রেরণ করার বিষয়ে সর্বসম্মতিক্রমে সিদ্ধান্ত গৃহীত হয়।

২৯/১০/২০১৯ তারিখের দৈনিক প্রথম আলো পত্রিকায় প্রকাশিত সেফট্রিয়াক্সন ইঞ্জেকশন প্রয়োগের নিয়ম সংক্রান্ত খবর ঃ

ইনজেকশনটি ধীরে ধীরে দিতে হবে

সেপট্রিয়াক্সন

ওষুধের পার্শ্বপ্রতিক্রিয়া নিয়ে ২ হাজার ৯৮৯টি অভিযোগ এসেছে ঔষধ প্রশাসন অধিদপ্তরে।

শিশির মোড়ল, ঢাকা

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পাতা-৬, প্রথম আলো

Table-2: Recommendations made by 10th ADRAC based on regulatory decisions of different NRAs published in WHO Pharmaceuticals Newsletter-1 & 2, 2019.

Sl No	Name of Medicine	Indication	Adverse Drug Reaction	Regulatory Action/ recommendation taken by other NRAs	ADRAC Decision
1.	Calcitriol injeciton	Osteoporosis, Hypoparathyroidism, Hypocalcemia, Osteomalacia rickets, Renal osteodystrophy, Chronic kidney dialysis.	Shock and anaphylaxis	Japan. The MHLW and the PMDA have announced that the Package insert for the injectable form of calcitriol (Rocaltrol Injection®) should be revised to include shock and anaphylaxis as adverse drug reactions.	More information and data should be collected regarding Calcitriol injection.
2.	Carbimazole	Carbimazole is indicated for the treatment of hyperthyroidism, preparation for thyroidectomy, and pre and post-radioiodine treatment.	Acute Pancreatitis	MHRA announce to update Product information to include risk of Acute Pancreatitis.	Acute pancreatitis should be included in the PIL of Carbimazole.
3.	Febuxostat	Febuxostat is indicated to treat gout.	Increased risk of death	USA. The US Food and Drug Administration (FDA) has added a boxed warning for febuxostat (Uloric®) indicating an increased risk of death compared to its alternative, allopurinol.	The PIL can be updated including the information of increase risk of death due to Febuxostat and letter should be sent to ragrding doctors' associations.
4.	Febuxostat	Febuxostat is indicated to treat gout.	Increased risk of death	USA. The US Food and Drug Administration (FDA) has added a boxed warning for febuxostat (Uloric®) indicating an increased risk of death compared to its alternative, allopurinol.	The PIL can be updated including the information of increase risk of death due to Febuxostat and letter should be sent to ragrding doctors' associations.

DGDA Organized Meeting with Stakeholders on Pharmacovigilance facilitated by USAID MTaPS:

Ms. Comfort Ogar, Principal Technical Advisor - Pharmacovigilance, MTaPS, USAID visited Dhaka from 9 to 20 June 2019 for Awareness building, Training and Strategy development on Pharmacovigilance in Bangladesh.

DGDA organized a Technical Review Workshop on Building Awareness & Strategies for Nationwide scale-up of Pharmacovigilance held on 13 June at DGDA Conference Hall with Technical support of Medicines, Technology and Pharmaceuticals Services (MTaPS) Program of USAID. About 60 participants from different PV stakeholders including DGDA officials were present in the workshop. DG of DGDA Major General Md. Mahbubur Rahman presided over the meeting. Ms. Comfort, Dr. Md. Akter Hossain and Mr. Ismail Ramzy were the resource persons.

Figure 7 : A workshop on "Building Awareness and Strategies of PV Program and Nationwide Scale-up".

DGDA Organized Workshop and Training on Pharmacovigilance facilitated by USAID MTaPS:

On 17 June, a day long training was held at Hotel Canary Park, Gulshan-1, Dhaka on "Good Vigilance Practice' and "Causality Assessment" for a total of 22 participants from ADRAC members, TSC members and ADRM cell members. Ms Comfort Ogar was there as a resource person.

Figure-8 & 9 : A workshop & training on Pharmacovigilance Conducted by Ms Comfort Ogar

Celebration of World Patient Safety Day:

This year for the first time WHO has celebrated World patient safety day. In accordance with WHO DGDA has also celebrated the world patient safety day 17th September 2019. A round table discussion has been arranged by DGDA in BRAC Center inn, Mohakhali, Dhaka on this occasion with the support of Roche Bangladesh Limited. Many participants from different stakeholders including media personnel have been invited to the program.

Figure-10: Celebration of World Patient Safety day by blowing up the Balloons at Aushadh Bhaban, DGDA.

Director and Head of ADRM cell, DGDA Mrs. Nayer Sultana has inaugurated the program. On her opening remarks she told that DGDA is proud to participate in this first initiative taken by WHO and DGDA is working for the patient safety for long time with limited manpower and facilities. Different stakeholders are providing reports to the National vigilance center and on the basis of those information and the safety information published in WHO Newsletters DGDA takes many safty measers as per ADRAC recommandation.

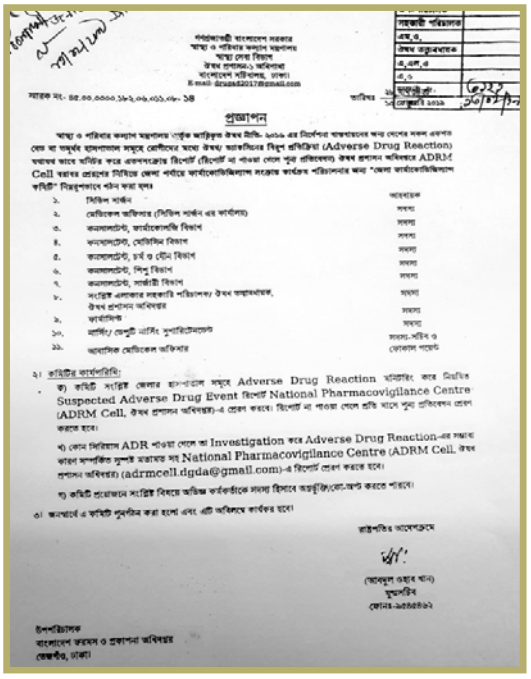
Figure-11: Round Table Discussion on World Patient Safety Day

Professor Sitesh C. Bachar from University of Dhaka, Technical Advisor, Essential Medicine, WHO Bangladesh, Mohammed Ismail Ramzy, BAPI representative and Managing Director of Delta Pharmaceuticals Ltd. Dr. Md. Zakir Hossain, MTaPS officials and other PV experts participated in the discussion and delivered their valuable speech in the said occasion.

In closing remarks national PV focal person and Assistant Director of DGDA Dr. Md. Akter Hossain said that DGDA is working heart and soul to keep the safety of medicine apart from some limitations. He thanked all for arranging, participating and making the program successful.

Government has formed District Pharmacovigilance Committee:

Govt. has formed District PV Committee; Ministry of Health and Family welfare has formed District Pharmacovigilance Committee for conducting PV activities (i.e. Monitoring Adverse Reaction of Drug and Vaccine and to report in this regard to the National PV Centre, ADRM cell of DGDA) in all the 100 or more beded hospitals for implementation of instructions of the National Drug Policy-2016 for Pharmacovigilance. The 11 membered committee is headed by the District Civil Surgeon. DG Health Service has also served letters to the 100 or more beded hospitals to form team and to conduct PV activities. Currently DGDA is working with 50 tertiary and (both public & private) medical college hospitals. It has been planned to extend this activities nationwide.



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PV Activities Monitoring Visit:

ADRM cell members of DGDA are visiting different Hospitals and Marketing Authorization Holders (MAH) of Bangladesh. During the visit, the team monitors the ADE reporting status and PV systems within the organizations. They share and exchange the ideas about how to strengthen medicine safety reporting, 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. As part of regular monitoring DGDA has visited National Institute of Cancer Research and Hospital on July 08th 2019, Dhaka Shishu Hospital on October 22nd 2019 and Beacon Pharmaceuticals Ltd on 30 Oct 2019.

Figure-12: PV Focal person & Assistant Director of DGDA Dr. Md. Akter Hossain is giving his speech in NICRH.

Pharmacovigilance Team visited Pharmaceutical Company:

PV team of DGDA visited Beacon Pharmaceuticals Ltd. for exchange of views on PV and to know about the way how they are conducting safety monitoring activities of their marketed drugs.

Figure-13: Training and discussion

Figure-14: Meeting and Presentation from Beacon side

Managing Director and Senior Managers were present during the session. Focal Point of the company Miss Nishat Sultana presented on company's running PV activities.

Hospital Visit for monitoring Pharmacovigilance activities

Figure-15: PV Team of DGDA visited Dhaka Shishu Hospital and delivered speech on AE reporting system in a big gathering of senior doctors and management personnnels.

External Training on Pharmacovigilance:

ADRM cell of Directorate General of Drug Administration (DGDA) and Novartis (Bangladesh) Limited has collaborated and organized a training on 'Requirements of Pharmacovigilance System: Bangladesh perspective' for DGDA officials on 30 April 2019 at DGDA Conference Hall. Ms. Chwee Ping Phua, Head of Patient Safety, Region Asia-Pacific, Novartis Patient Safety and Dr. Md. Akter Hossain, AD, DGDA were resource persons.

Figure-16: Open discussion in the training session and a group photo after closing.

ADR Advisory Committee Meeting:

Figure-17: 10th ADRAC meeting held at DGDA conference hall for review the serious events and regulatory recommendations regarding drug safety issues.

Figure-18: Discussion meeting of ADRM cell members and PV responsible persons of the Multinational Companies focusing more information and investigation of the Serious Events (Specially Death cases) held at DGDA Conference Hall.

AEFI WHO Causality Assessiment Meeting:

Figure-19: Evaluation of the Adverse Effect Following Immunization (AEFI) reports of vaccines used in EPI is done by the Expert Review Committee (ERC) meeting at EPI Bhabon, Dhaka regular basis.

Bangladesh attended WHO 42th Annual Meeting on Pharmacovigialnce:

WHO has invited Bangladesh to participate in 42nd Annual Meeting of Representatives of National Pharmacovigialnce Centres participating in the WHO Programme for International Drug Monitoring in Bogota, Colombia from 28 October to 1 November 2019. Dr. Rajib Hassan, Medical officer of DGDA attended there from Bangladesh. Many experts from WHO and Uppsala Monitoring Center (UMC) took part in exchange of views, discussions and hand on training on relevant important topics in Pharmacovigilance.

Figure-20: Bangladesh attended the 42th Annual Meeting of Representatives of National Pharmacovigialnce Centres participating in the WHO Programme for International Drug Monitoring.