Pharmacovigilance NEWSLETTER

6th Issue, June 2020

The Aim of the newsletter:

- Dissemination of drug and vaccine safety information.
- Dissemination of regulatory decisions
- Sharing activities of national pharmacovigilance centre (ADRM cell) with stakeholders
- Focusing capacity building, training & awareness programs on pharmacovigilance.

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Introduction:

Pharmacovigilance promotes public health by insuring safety, efficacy and quality of medical products. ADRM Cell of DGDA is working as national pharmacovigilance center since 2013. It is one of the most important means of communication with the Pharmacovigilance stakeholders of Bangladesh (i.e. doctors, nurses, pharmacists, drug manufactures, importers and for the medicine consumers) and international organizations.

This newsletter includes the outcome of 11th ADRAC meeting. Evaluation of multiple ADR reports coming from different sources & different workshops & awareness programs on Pharmacovigilance organized by DGDA.

Summary & Result of the 11th ADRAC meeting

11th ADRAC meeting:

11th ADRAC meeting was held on 18th May 2020 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 364 reports from different stakeholders. All these reports were primarily evaluated by ADRM cell. Out of these 250 reports were found complete/partial complete and 114 reports were found incomplete for lacking of minimum information. After primary evaluation of the reports, ADRM cell placed 250 reports before Technical Sub-committee (TSC), Where 83 reports were serious and 167 reports were not-serious. Out of the 83 serious cases 27 cases were found Certain, Probable and Possible and 56 cases were found Unlikely/Unclassifiable as per WHO Causality Assessment scale. Finally these reports were placed before 11th ADRAC meeting for review and the respected 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. 3, 4 & 5, 2019 (Drug Safety information).

Table 1: Evaluation of reports by different committees:

Serial no	Committee name	Number of evaluated reports	Opinion
1	ADRC Cell	364	Incomplete - 114 Complete - 250
2	Technical Sub-Committee (TSC)	250	Not Serious - 167 **Serious - 83** Certain – 03 Probable – 11 Possible – 13 Unlikely – 46 Unclassifiable - 10
3	ADRAC	83	Has agreed with assessment done by the members of TSC

Medicine's safety issues published in WHO Newsletter and the opinion of TSC:

Sl No	Name of Medicine	Indication	Adverse Drug Reaction	Regulatory Action/ recommendation taken by other NRAs	Opinion of TSC
1.	Dopamine receptor agonists	To treat a variety of conditions, for example Parkinson's disease.	Risk of drug withdrawal syndrome	**Japan**. The Ministry of Health, Labor and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package inserts for dopamine receptor agonists should be revised to include drug withdrawal symptoms such as apathy, anxiety, depression, fatigue, sweating and pain as adverse drug reactions.	Expert opinion of the medicine and neurology specialists will be needed regarding this issue.
2.	Tofacitinib	Rheumatoid arthritis, psoriatic arthritis and ulcerative colitis	Increased risk of blood clots and death with higher dose	**USA**. The US FDA has approved a Boxed Warning informing of an increase in the risk of blood clots and death with the 10 mg twice daily dose	Boxed warning can be imposed

3.	Magnesium sulfate	Magnesium sulfate is indicated for the prevention of further seizures associated with eclampsia in pregnancy and for the treatment of magnesium deficiency in hypomagnesaemia	Risk of skeletal adverse effects in neonates	**United Kingdom**. The MHRA has announced that the product information for products containing magnesium sulfate will be updated to warn of skeletal adverse effects observed with administration for more than five to seven days during pregnancy. WHO Pharmaceuticals Newsletter No. 4, 2019 Regulatory Matters In 2013, the US FDA issued a safety recommendation against the use of magnesium sulfate for more than five to seven days when used as a tocolytic (an indication not authorized in the UK). Such prolonged exposure may result in significantly higher cumulative doses than those encountered with use in the UK for eclampsia or foetal neuroprotection.	Currently Magnesium sulfate is not used for 5-7 days like the previous days. It was mainly used to prevent premature delivery. More information can be collected regarding the adverse reaction of this drug.
4.	Propofol	Used to make a patient relax, calm, sleepy (sedation) or unconscious (anesthesia) during surgery or medical procedures in children and adults.	Potential risk of priapism	**Canada**. Health Canada has requested that the manufacturers of propofol containing products update the Canadian product safety information to include information on potential link between propofol containing products and the risk of priapism.	More information can be collected about safety and dosage issues.
5.	Opioid pain medicines	Manage pain when other analgesic treatments cannot be taken or are not able to provide enough pain relief.	Risk of uncontrolled pain and withdrawal symptoms following sudden discontinuation	**USA**. The US Food and Drug Administration (FDA) has required changes to the prescribing information for opioid pain medicines to warn of serious withdrawal symptoms, uncontrolled pain, psychological distress and suicide following sudden decrease in dose.	To check PIL and incorporate the information is necessary.

6.	Tranexamic acid	To prevent or reduce bleeding in certain conditions, such as dental surgery in people with hereditary blood clotting disorders, cervical surgery, heavy menstrual bleeding, nose bleeds and bleeding inside the eye.	Risk of seizure/convulsion	**India**. The NCC-PvPI, IPC has made a recommendation to incorporate seizure/convulsion as a clinically significant adverse drug reaction into the PIL for tranexamic acid marketed in India	More information can be collected about dose & timing.
7.	Vildagliptin	Type 2 diabetes.	Risk of hepatotoxicity	**New Zealand**. Medsafe has announced that hepatotoxicity is the most significant risk of harm with vildagliptin.	To check PIL and other options to treat diabetes should be chosen.

Snapshot taken during TSC meeting

Regulatory decision taken by 11th ADRAC

1. Letters will be issued to MAHs and Hospitals for sending adequate information along with investigation reports, laboratory test reports and opinions of Pharmacovigilance committee of respective organization when to send SAE reports specially death cases.

2. Measure should be taken to alert the related marketing authorization holders regarding certain, probable and possible ADR reports. Generic of these case reports should be kept in concern and measures will be taken for collecting more reports.

3. DGDA will request to Directorate General of health Services, related Hospitals and respected Health care Professionals for sending ADR of Emergency/off label used medicine like Hydroxychloroquine, Oseltamivir, Favipiravir, Remdesivir, Toclizumab.

4. According to decisions taken by different National Drug Regulatory Authorities/Agencies including US-FDA depending on Adverse Drug Events published in WHO Pharmaceutical Newsletter, Issue No. 3, 4 & 5, 2019 (Drug Safety Information), ADRAC has recommended the Licensing Authority (Drugs) to take necessary action for imposing Boxed waning and upgrading PIL of Tofacitinib and Opioid Pain Medicine.

Training Programs on Pharmacovigilance

Officers from DGDA head office and district office visited Japan to attend PMDA-ATC Pharmacovigilance seminar.

Snapshot taken during training facilitated by USAID MTaPS on Causality assessment and good vigilance practices for staff of DGDA and ADRAC members.