DRUG REGULATORY AUTHORITY OF PAKISTAN
NATIONAL PHARMACOVIGILANCE CENTRE

PHARMACOVIGILANCE NEWSLETTER

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DRAP launched VigiMobile in Urdu Language

VigiFlow is a web-based system for managing adverse event reports that incorporates standardised medical terminologies, developed by the Uppsala Monitoring Centre for the National Pharmacovigilance Centres of the member states. The Drug Regulatory Authority of Pakistan (DRAP) in collaboration with the Uppsala Monitoring Centre (UMC) has launched VigiMobile App, available for download on Android and iOS platforms. The form is now also available in Urdu language, making it even more user friendly for everyone including patients and their caregivers to report adverse drug reactions (ADRs) experienced with medicines to the National Pharmacovigilance Centre, DRAP.

Scan the QR code to access VigiMobile App.

Strengthening Pharmacovigilance in Public Health Programmes

The National Pharmacovigilance Centre, Division of Pharmacy Services on 18th of January, 2024 - convened a significant meeting at Drug Regulatory Authority of Pakistan (DRAP) to address the development and strengthening of the Pharmacovigilance System in Pakistan in general and more specifically in public health programmes. Representatives from esteemed organizations, including the Project Management Unit, Global Fund HIV Grant, United Nations Development Programme (UNDP), the Common Management Unit (CMU), United States Pharmacopeia (USP) PQM+, Directorate of Malaria Control (DoMC), and Islamabad Pharmacovigilance Centre (IPC), attended the meeting.

The session began with a welcome note from Chief Executive Officer-DRAP, Mr. Asim Rauf, who emphasized DRAP's commitment to attain World Listed Authority (WLA) Level III status, stressing the necessity of fortifying the pharmacovigilance system at every level in accordance with Pharmacovigilance Rules, 2022. CEO-DRAP highlighted recent developments, including the transition to a paperless environment, the launch of electronic submission through E applications, the implementation of the E-office in totality; and DRAP's commitment to achieve Pharmaceutical Inspection Co-operation Scheme (PIC/S) membership. He underscored the crucial role of coached audits in implementing new regulatory standards aligned with international practices.

Dr Obaidullah, provided an overview of DRAP's pharmacovigilance journey, outlining the development of guidelines, forms, rules, procedures, and the acquisition of standardized tools such as VigiFlow for collection, management and reporting of adverse drug reactions (ADRs). He emphasized potential collaboration areas with the UNDP, CMU, the Directorate of Malaria Control, and Regional Pharmacovigilance Centres to strengthen pharmacovigilance across all levels in the larger benefit of the country. Furthermore, he also informed the UNDP about the last year visit of WHO for WLA level III benchmarking of the DRAP and the recommendations made during the visit for the functionalization of the pharmacovigilance system in the country. He said that support in respect of infrastructure and capacity building from UNDP for the functionalization of the pharmacovigilance system across all levels will be highly beneficial.

Mr. Soso Gesadze from the Global Fund highlighted the regulatory function's priority and suggested active coordination between UNDP and DRAP for the functionalization of the pharmacovigilance system of Pakistan. Training and capacity-building programmes for personnel dealing with pharmacovigilance were emphasized in order to implement indicators timely. Ms. Heather Doyle, Mr.Osama Musa Bella Hussain, and Mr.Saqlain Abbas from Global Fund HIV Grant, UNDP expressed their commitment to support DRAP in regulatory system strengthening, particularly in the pharmacovigilance domain. It was suggested that NPC needs to determine the areas of pharmacovigilance where support is required. They highlighted ongoing HIV grants and proposed the inclusion of a pharmacovigilance component in the coming year.

Mr. Sardar Shabbir Ahmed, Focal Person Regional Pharmacovigilance Centre, Islamabad, emphasized the need for active stakeholder involvement, including the public sector and drug sale points, in enhancing report. Mr Sabir Qureshi from CMU stressed the need for active data sharing specifically from the Public Health Programmes to NPC and emphasized active surveillance for new drugs launched in public health programmes. Mr. Muhammad Mukhtar, Director of the Directorate of Malaria Control, shared the positive outcome of coordination with the National Pharmacovigilance Centre which resulted in the formalization of an MoU.

At the end of the meeting, an MoU was signed between the DRAP and DoMC with the purpose of establishing pharmacovigilance centres of the Malaria Control Programme and subsequent reporting of ADRs to the NPC-DRAP through the VigiFlow Platform.

The event concluded with high expectations & aspirations.

Ensuring Patient Safety through Pharmacovigilance

The Drug Regulatory Authority of Pakistan (DRAP) in collaboration with the Pakistan Pharmacist Association (PPA) organized a one-day pharmacovigilance symposium on "Ensuring Patient Safety through Pharmacovigilance" at Dr. Akbar Niazi Teaching Hospital (ANTH), on the 8th of May 2024 in Islamabad. Focal Persons of Pharmacovigilance from public and private hospitals of Islamabad, representatives from PPA and healthcare professionals from ANTH attended the sessions.

Mr. Asim Rauf, Chief Executive Officer (CEO) DRAP and Chief Guest of the session emphasized the crucial role of pharmacovigilance in ensuring patient safety, which is vital for the DRAP to achieve World Listed Authority (WLA) Level III status. Mr. Sardar Shabbir Ahmed, President of PPA and Focal Person of the Islamabad Pharmacovigilance Centre (IPC) updated participants on the current pharmacovigilance efforts in the Federal Capital and expressed hope for arranging more training sessions through PPA's platform. Mr. Yasir Khan Niazi, CEO of ANTH, committed to swiftly implementing pharmacovigilance activities in the hospital, pledging to organize additional sessions and participate in the VigiFlow login pilot project in Islamabad initiated by DRAP.

Dr. Obaiduallah, Director, Division of Pharmacy Services, Mr. Abdul Mateen, Deputy Director, NPC-DRAP and Mr. Rehan Anjum, Director, Pharmacy Residency Programmes, Shifa International Hospital were the trainers of the session, who provided insights into the development journey of pharmacovigilance system in Pakistan, the current status of the activities, the pharmacovigilance process, and development of the system in the hospital.

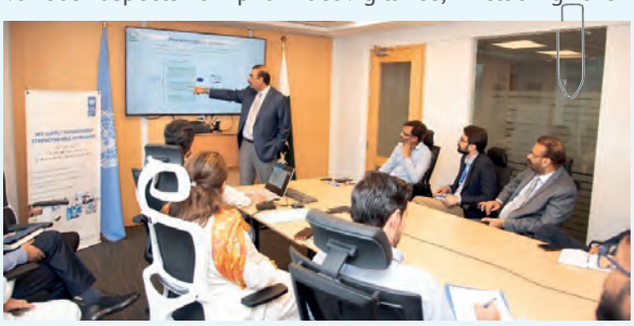
At the end of the session, the Pharmacovigilance Centre of ANTH was inaugurated by Mr. Asim Rauf with the hope of its prompt functionalization and subsequent integration with the IPC and NPC through regular reporting of adverse drug reactions.

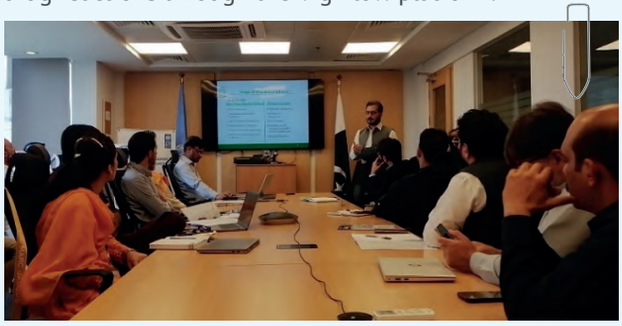
Session on Pharmacovigilance System-HIV Supply Management Strengthening Workshop

Officers from the National Pharmacovigilance Centre (NPC), Division of Pharmacy Services, Drug Regulatory Authority of Pakistan (DRAP) participated in a pharmacovigilance training session organized by the Project Management Unit, Global Fund-HIV Grant, United Nations Development Programme Pakistan (UNDP). The session included representatives from the National AIDS Control Programme (NACP) at both federal and provincial levels, the Common Management Unit (CMU), the National TB Control Programme (NTP), and the Federal Directorate of Immunization (FDI).

Dr. Obaidullah, Mr. Abdul Mateen and Ms. Aqsa Hashmi of NPC-DRAP were the trainers. Participants were trained in various aspects of pharmacovigilance, including the establishment of pharmacovigilance centres, the formation of pharmacovigilance committees, and the collection, assessment and reporting of pharmacovigilance data to the NPC. They were also briefed on the Pharmacovigilance Rules, 2022, and the importance of implementation for ensuring patient safety.

Likewise, it was decided that DRAP would provide VigiFlow logins to the pilot group of antiretroviral therapy (ART) centres of NACP and Programmatic Management of Drug-Resistant Tuberculosis (PMDT) sites of NTP. After the successful implementation of VigiFlow at these sites, the logins will be extended accordingly. In this regard, the participants were also provided the necessary training for data entry of adverse drug reactions through the VigiFlow platform.





4th Meeting of Pharmacovigilance Risk Assessment Expert Committee (PRAEC)

The 4th meeting of PRAEC was held on the 26th of February, 2024 in the Drug Regulatory Authority of Pakistan (DRAP) at its Islamabad headquarters. The meeting was Chaired by Brig. (R). Dr. Akbar Waheed, Professor of Pharmacology, Islamic International Medical College, Islamabad and Co-Chaired by Dr. Obaidullah, Head of the National Pharmacovigilance Centre (NPC) / Director, Division of Pharmacy Services. Mr. Abdul Mateen, Deputy Director, Pharmacovigilance was the Secretary of the meeting. The committee discussed ten cases of reliance on the safety review reports issued by Reference Regulatory Authorities and so far eight safety alerts have been issued through the website. During the 3rd PRAEC meeting, it was decided that NPC, will collaborate with vertical programmes for the establishment of their pharmacovigilance centres and constitution of pharmacovigilance committees/expert safety review panels etc. Therefore, representatives from public health programmes were invited to the 4th meeting to discuss progress and develop a future course of action in line with WHO recommendations.

Initially, Dr. Obaidullah, detailed the evolution of Pakistan's pharmacovigilance system and outlined plans for its enhancement, including adopting VigiFlow for ADR reporting and launching a Pharmacovigilance Newsletter. He also informed the participants about the details of the meeting chaired by the CEO DRAP, emphasized achieving World Listed Authority Level III status and highlighted collaborations with organizations like the Global Fund, UNDP.

Thereafter, Mr. Muhammad Mukhtar informed about the recent development related to the signing of an MoU between the Directorate of Malaria Control (DoMC) and DRAP for the enhancement of the pharmacovigilance system and committed to acquiring the VigiFlow access and constituting Pharmacovigilance Centre at DoMC. Dr. Zafar Iqbal and Dr. Basharatullah Baig from the Federal Directorate of Immunization (FDI) discussed AEFI reporting and the integration of pharmacovigilance with DRAP during COVID-19, highlighting the adoption of VigiFlow and its use for routine immunization and plans to reactivate the AEFI Review Committee. Mr. Sabir Qureshi stated that the Common Management Unit will establish a pharmacovigilance system for public health programmes, starting with VigiFlow logins for PMDT sites, and will collaborate with DRAP to enhance surveillance and form pharmacovigilance committees.

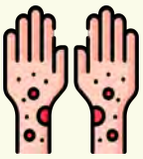
It was decided that the NPC will guide for the establishment of pharmacovigilance centres in public health programmes, adopt the VigiFlow as a uniform database, and sign MoUs; while the FDI will reactivate the National AEFI Review Committee and implement VigiFlow for routine immunization. The DoMC will coordinate for the VigiFlow logins and establish a PV Committee, and the CMU will facilitate pharmacovigilance systems establishment and active surveillance for new drugs in public health programmes, with updates shared with PRAEC after six months.

Members of PRAEC stressed implementing the earlier decisions of the committee for patient safety, urging coordinated efforts among registration holders and DRAP forums to update labelling and execute regulatory measures while emphasizing enhanced communication between the NPC and relevant entities (both inside and outside DRAP).

PRAEC Members also highlighted the challenge of data reporting due to the absence of provincial pharmacovigilance centres in spite of functional PV systems in some hospitals of provinces. Therefore, it was decided that the NPC would initially coordinate with provincial health departments to establish centres and allocate VigiFlow logins to hospitals; if delays occur, the NPC will directly provide the logins to potential hospitals across Pakistan.

International Safety Issues

Risk of Rare & Serious DRESS with Levetiracetam & Clobazam.



In November 2023, the United States Food and Drug Administration (FDA) issued a safety warning that the antiseizure medications levetiracetam and clobazam can cause a rare but severe reaction known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which may begin as a rash but can quickly progress, potentially damaging internal organs, necessitating hospitalization, and even leading to death. Symptoms can include fever, rash, swollen lymph nodes, and organ injury (liver, kidneys, lungs, heart, or pancreas). Consequently, the FDA decided to add warnings about DRESS to the prescribing information and medication guides of these medicines. The warnings will note that early symptoms of DRESS, such as fever or swollen lymph nodes, can occur even without a rash, distinguishing it from other serious skin reactions like Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). The case was discussed in the 4th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the DRAP which decided that registration holders should include information about rare and serious DRESS reactions in warning and precaution sections of the prescribing information/label of medicines containing levetiracetam and clobazam.

Levetiracetam is an antiseizure medicine used alone or with other medicines to treat partial, myoclonic, and tonic-clonic seizures in adults and children.
Clobazam, a benzodiazepine, is used with other medicines to control seizures in adults and children (2 years and older) with Lennox-Gastaut syndrome, a severe form of epilepsy.

Healthcare professionals are informed that levetiracetam and clobazam can cause a rare, life-threatening reaction called DRESS, which may occur 2-8 weeks post-treatment and lead to severe inflammation and organ damage. Patients should be advised about DRESS symptoms, including fever, rash, and organ damage, and to seek immediate medical attention if these occur. Patients should also not stop these medications abruptly, and consult healthcare professionals as needed for concerning symptoms.

Risk of Neurodevelopmental Disorders in Children during Pregnancy with Topiramate

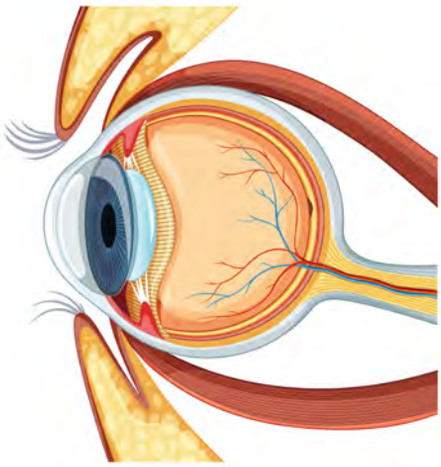
In April 2023, New Zealand's Medsafe updated topiramate (Topamax®) product information to highlight the risk of neurodevelopmental disorders and birth defects in children exposed during pregnancy, based on data from Nordic pregnancy registries which captured information from over 24,000 children. Australia's TGA added similar warnings in June 2023. The European Medicines Agency (EMA) began a review in July 2023, leading to further restrictions by its safety committee, PRAC, in September 2023 i.e. pregnancy prevention programme. PRAC recommended that topiramate should not be used for migraine prevention or weight management during pregnancy and required effective contraception for women of childbearing potential. For patients using topiramate for the treatment of epilepsy, the PRAC recommended that the medicine should not be used during pregnancy unless there is no other suitable treatment available. Product information will be updated with visible warnings, and educational materials will be provided to patients and healthcare professionals. In the 4th meeting of the DRAP's PRAEC it was decided that topiramate prescribing information must include risks of fetal neurodevelopmental disorders and warnings for women of childbearing potential. It should also include information about not using Topiramate in pregnancy for the treatment of epilepsy unless there is no other suitable treatment available.

Topiramate is a medicine used to treat epilepsy in adults and children aged two years and older.

Healthcare professionals should use topiramate for epilepsy in pregnancy only if the benefits outweigh the risks; pregnancy testing is recommended before treatment, and effective contraception is advised for women of childbearing potential. Topiramate for migraine prophylaxis is contraindicated in pregnancy. Patients should not stop topiramate without consulting their doctor due to fear of potential harm to fetal development; effective contraception is essential for those planning for pregnancy. Consultation with a doctor is advised for pregnant women or those planning

Risk of Ocular Adverse Events with Miltefosine

On April 12, 2023, the WHO alerted healthcare professionals and regulatory authorities about ocular adverse events linked to miltefosine use, especially during post-Kala-Azar Dermal Leishmaniasis (PKDL) treatment with the drug in South Asia region in both men and women, including in children under 18 years old, and mostly beyond 28 days of treatment. An ad-hoc Multidisciplinary Technical Group (MTG) established by WHO, with support from the German National Regulatory Authority (BfArM) and Uppsala Monitoring Centre (UMC), acknowledged a plausible link between miltefosine and ocular issues, advising caution. Despite most cases resolving post-miltefosine withdrawal, some led to permanent vision loss. The frequency of ocular events during miltefosine treatment remains unclear. Previously, recommendations for warnings in product information were provided by the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) in December 2022.



Accordingly, in the 4th meeting of the PRAEC it was decided that registration holders of Miltefosine-containing medicines must update labels/prescribing information to include warnings about ocular adverse events. Additionally, it was also recommended to the National Pharmacovigilance Centre to issue a safety advisory concerning these risks.

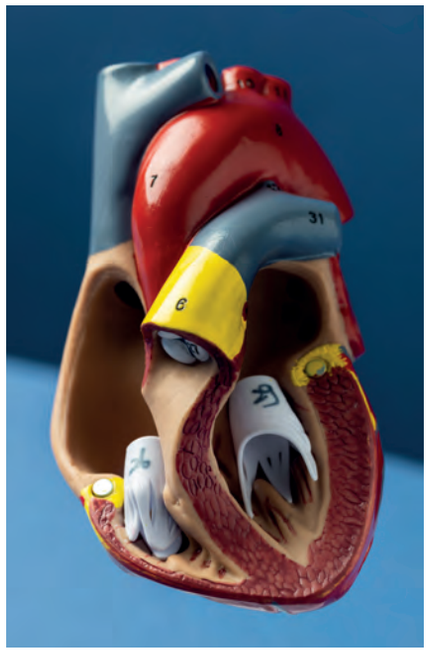
Miltefosine is an oral anti-infective which is effective against various forms of leishmaniasis.

Healthcare professionals should assess patients for eye disorders before starting miltefosine, advising immediate discontinuation and medical consultation if ocular issues arise during treatment with miltefosine. Ophthalmologist consultation is recommended for patients with pre-existing eye conditions due to potentially irreversible damage from miltefosine's long half-life. Patients are advised to consult their doctors if they experience any sort of reaction/problem in their eyes after the start of the miltefosine treatment and also inform healthcare professionals about any pre-existing eye diseases

Risk of Myasthenia Gravis and Ocular Myasthenia with Statins

In February 2023, EMA's PRAC committee recommended adding myasthenia gravis risks to the product information of statins. In a few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. Likewise, the MHRA-UK in September 2023 informed healthcare professionals and patients about new warnings for myasthenia gravis risks with statins, with updates agreed upon by the Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM). It was decided that product information of all statins will list myasthenia gravis as an adverse reaction with frequency 'not known', along with new warnings in Summaries of Product Characteristics and Patient Information Leaflets.

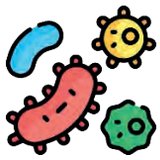
During the 4th meeting of PRAEC it was decided that registration holders of statins must update product warnings. This includes adding risks of myasthenia gravis and ocular myasthenia, listing them as adverse reactions with frequency 'not known'.



Statins such as atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin, are HMG-CoA reductase inhibitors that effectively lower LDL cholesterol levels. They are widely accepted as safe and crucial in treating atherosclerotic cardiovascular disease.

Healthcare professionals should refer suspected new-onset myasthenia gravis cases on statin therapy to neurology specialists, potentially requiring statin discontinuation based on individual risk assessment. Patients should be vigilant for symptom aggravation and consult healthcare professionals for any statin-related issues, avoiding discontinuation without doctor consultation. Before starting statins, inform your doctor of myasthenia gravis history and seek immediate medical help for severe statin-related symptoms like breathing or swallowing difficulties.

Risk of Haemophagocytic Lymphohistiocytosis (HLH) with Sulfamethoxazole & Trimethoprim drug combination.



Health Canada updated safety information for sulfamethoxazole and trimethoprim combination products in May 2023, noting a risk of haemophagocytic lymphohistiocytosis (HLH) after a European Medicine Agency (EMA) labelling update. Following a review of ten cases, a possible link between the medication and HLH was identified by Health Canada, prompting healthcare professionals to assess patients for signs of pathologic immune activation and discontinue treatment if HLH is diagnosed. The PRAC of the EMA previously supported a warning statement in the product information for the sulfamethoxazole/trimethoprim combination based on available evidence. In the 4th meeting of the DRAP's Pharmacovigilance Risk Assessment Expert Committee it was decided to update the warning section of sulfamethoxazole and trimethoprim combination by including the risk of HLH.

Sulfamethoxazole plus Trimethoprim is a prescription antibiotic medicine indicated for the treatment of various bacterial infections, such as urinary tract infections, respiratory tract infections, and gastrointestinal infections.

Healthcare professionals are advised that rare cases of HLH are reported with co-trimoxazole (Sulfamethoxazole+Trimethoprim). HLH is a severe immune activation syndrome characterized by systemic inflammation symptoms e.g. fever, hepatosplenomegaly, hypertriglyceridaemia, hypofibrinogenaemia, high serum ferritin, cytopenias and haemophagocytosis. Early signs warrant immediate evaluation, and if diagnosed, treatment should be discontinued. Patients should not stop medication without medical advice and must promptly report any HLH symptoms during sulfamethoxazole+trimethoprim treatment.

Risk of PRES & RCVS with Pseudoephedrine Medicines.

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicine Agency (EMA) proposed updated safety measures for pseudoephedrine-containing medications following a comprehensive review of the evidence, including post-marketing data, which highlighted risks of Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS). They advised against pseudoephedrine use in patients with severe or uncontrolled high blood pressure, or severe kidney conditions. PRAC also discussed disseminating this information directly to healthcare professionals. On January 25, 2024, the Committee for Medicinal Products for Human Use (CHMP) endorsed these measures, reaffirming restrictions on pseudoephedrine use. The CHMP's opinion has been forwarded to the European Commission for legal implementation.

In the 4th meeting of PRAEC-DRAP it was decided that registration holders should update the warning and precaution sections of labels/prescribing information of pseudoephedrine-containing medicines to include risks of PRES and RCVS, and to issue direct communications to healthcare professionals emphasizing these risks.

Pseudoephedrine is a stimulant that is often used as a decongestant in people who have a cold or allergies.

Healthcare professionals are informed that a review has found an association between pseudoephedrine-containing medicines and risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), based on a comprehensive review. They are advised against using these medicines in patients with high blood pressure that is severe or uncontrolled (not being treated or resistant to treatment) or if they have severe acute (sudden) or chronic (long-term) kidney disease or failure. Patients should discontinue treatment and seek medical help if they experience symptoms such as sudden, severe headaches, nausea, vomiting, confusion, seizures, or visual disturbances.

Risks Associated with the use of Valproic Acid in Women of Childbearing Potential & Minor Potential Risk in Male Patients.

The WHO, in a statement in May 2023, advised against prescribing valproic acid to women of childbearing potential due to high risks of birth defects and developmental disorders in children exposed in the womb. Lamotrigine or levetiracetam was recommended as a first-line monotherapy for both generalized and focal onset seizures. It was advised that those currently using should be counselled on continuous, effective contraception and informed of associated pregnancy risks. Planning for pregnancy should involve consultations with healthcare providers trained in managing epilepsy and bipolar disorder during pregnancy to explore alternative treatments if necessary. The EMA's PRAC in January 2023 recommended precautionary measures for male patients using valproate due to potential neurodevelopmental risks in children born to men treated with valproate during the three months before conception. Recommendations include specialist supervision for treatment initiation, regular reviews, and dissemination of healthcare professional communications to address these risks. The PRAC also discussed a DHPC to be forwarded to the CMDh Coordination Group. When adopted, the DHPC will be disseminated to healthcare professionals.

Similarly, the MHRA also introduced new safety measures for valproate, emphasizing risks of fetal harm during pregnancy and impaired male fertility. It was informed that healthcare professionals must integrate updated materials into practice, restrict valproate use in women of childbearing potential, and ensure thorough risk assessments annually. The Commission on Human Medicines (CHM) also highlighted ongoing concerns, urging caution in prescribing valproate due to potential teratogenic risks and emphasised the need for informed decision-making regarding alternative treatments. In its 4th meeting the PRAEC decided that registration holders of sodium valproate should update contraindications and initiate a Pregnancy Prevention Programme, and update warnings to include risks of birth defects and neurodevelopmental disorders.

Valproate (sodium valproate/valproic acid) is authorised for use in epilepsy and bipolar disorder.

Healthcare professionals are advised against prescribing valproate to pregnant women and women of childbearing potential under 55 unless no alternative treatment is available, with a documented benefit-risk assessment. Patients are informed that valproate use in pregnancy is linked to high risks of birth defects and neurodevelopmental disorders, and there is also a minor risk when fathers use valproate before conception. Male patients planning a family should discuss treatment options with their doctors, and all patients should not stop or alter valproate doses without specialist advice.

Risk of Medication Errors resulting due to inadvertent intrathecal Tranexamic Acid Injection

The WHO in its medical product alert on March 16, 2022, warned of the risk of administration errors with tranexamic acid (TXA) injections, highlighting reports where TXA was mistakenly given intrathecally instead of spinal anaesthesia, leading to severe neurological consequences and high mortality. The WHO also noted that TXA is often stored near similar-looking local anaesthetics, increasing the risk of such errors. Therefore, PRAEC in its 4th meeting recommended NPC to issue a safety alert/ advisory related to the risk of medication errors due to inadvertent intrathecal tranexamic acid injection.

Tranexamic acid (TXA) is used to prevent and treat haemorrhages from fibrinolysis, including gynaecological surgery and postpartum haemorrhage.

Healthcare professionals working in operation theatres should verify TXA labelling before administration to avoid accidental intrathecal injection, which can cause severe neurotoxicity. Reviewing and adjusting drug handling practices, including storing TXA away from the anaesthetic drugs trolley, is recommended to reduce this risk. Healthcare Commissions/Healthcare Regulatory Authorities are also advised to take necessary measures to minimize the harm due to inadvertent use of injection TXA by disseminating this information to the relevant healthcare facilities.

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How to download the Med Safety App:

GET IT ON Google Play

Download on the App Store

1. Open the Play Store (Android) or the App Store (iOS)

2. Search for `Med Safety`
3. Tap the `Med Safety` Icon
4. Tap to `install` to the download the App
5. Tap `Open`
6. Select a region, in this case **Pakistan**. Sometimes it selects automatically depending on the settings you already have on your phone

7. Click `continue as guest" or "create an account"
8. Report suspected adverse reactions to medicines that have been used

Guidelines for Installing VigiMobile App on Smart Phones

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