Greetings from Drug Information Bulletin!

Pharmacists are waiting to play more important role in the health care system as National Health Policy 2017 (NHP-2017) stated that “11.4. Mid-Level Service Providers: For expansion of primary care from selective care to comprehensive care, complementary human resource strategy is the development of a cadre of mid-level care providers. This can be done through appropriate courses like a B.Sc. in community health and/or through competency-based bridge courses and short courses. These bridge courses could admit graduates from different clinical and paramedical backgrounds like AYUSH doctors, B.Sc. Nurses, Pharmacists, GNMs, etc and equip them with skills to provide services at the sub-centre and other peripheral levels. Locale based selection, a special curriculum of training close to the place where they live and work, conditional licensing, enabling legal framework and a positive practice environment will ensure that this new cadre is preferentially available where they are needed most, i.e. in the under-served areas”.

Though other cadres have already been engaged in the new role as “health care providers” pharmacists are waiting to be engaged in the new role. Pharmacists have better knowledge and skill and some of them are already engaged in primary health care in some of the states like Odisha and a huge number of pharmacists are passing out from large number of pharmacy colleges every year they are left out. Hope policy makers will take immediate to engage as “health care providers” as mandated by NHP-2017.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291
To
All State Governments/UTs
All Pharmacy Councils

Sub: Qualification of President and Vice President of the State Pharmacy Council-reg.

Sir/Madam,

With reference to the subject cited above. In this connection, it is intimated that –

1. The Pharmacy Council of India (PCI) is a statutory body working under the Ministry of Health and Family Welfare, Government of India, New Delhi. It is constituted under the Pharmacy Act, 1948 and is responsible for regulation of –
   • pharmacy education for the purpose of registration as a pharmacist.
   • practice of profession of pharmacy in the country.

2. State Pharmacy Councils are constituted by the State Governments under Section 19 of the Pharmacy Act, 1948 and are entrusted with the responsibility of registration of pharmacists. Section 19 (a) and (b) of the Pharmacy Act, 1948 are quoted below:
   a. six members, elected from amongst themselves by registered pharmacists of the State;
   b. five members, of whom at least [three] shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or [registered pharmacists], nominated by the State Government;

3. It is noted that sometimes the President/Vice-President of the State Pharmacy Council are persons without Pharmacy qualification. As a result issues relating to pharmacy profession may face challenges.

4. Hence, 115th Central Council meeting of the PCI held on 9.5.2022 and 10.5.2022 decided to write to all the State Governments and State Pharmacy Councils that elected and nominated members of the State Pharmacy Councils u/s 19(a) and 19(b) holding the pharmacy qualification shall be the President and Vice President of the State Pharmacy Council.

This will be in the interest of profession.

Yours faithfully

ARCHANA MUDGAL
Registrar-cum-Secretary
New Drug: Vericiguat Tablets
VERQUVOTM (Vericiguat) tablets, for oral use
Initial U.S. Approval: 2021
WARNING: EMBRYO-FETAL TOXICITY: • Do not administer VERQUVO to a pregnant female because it may cause fetal harm. • Females of reproductive potential: Exclude pregnancy before the start of treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment.
INDICATIONS AND USAGE: VERQUVO is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.
DOSAGE AND ADMINISTRATION: • The recommended starting dose of VERQUVO is 2.5 mg orally once daily with food. • Double the dose of VERQUVO approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient. • Tablets may be crushed and mixed with water for patients who have difficulty swallowing.
DOSAGE FORMS AND STRENGTHS: Tablets: 2.5 mg, 5 mg and 10 mg
CONTRAINDICATIONS: Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators.
ADVERSE REACTIONS: Most common adverse reactions reported in ≥5% are hypotension and anemia. (6.1) DRUG INTERACTIONS: • PDE-5 Inhibitors: Concomitant use is not recommended.
USE IN SPECIFIC POPULATIONS: • Lactation: Breastfeeding is not recommended.
Ref. USFDA
Status in India: CDSCO approved Vericiguat tablets 2.5mg/ 5mg/ 10mg indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45% on 25.02.2022. Industry source revealed that price of 30 tablets of 10 mg is 397 Euro. It is expected that this may be available at a lower price when this will be manufactured by Indian manufacturers as it has been approved by CDSCO recently.

Propylthiouracil and carbimazole Use in pregnancy
The TGA has announced that the pregnancy category for both propylthiouracil (PTU®) and carbimazole (Neo-Mercazole®) is being changed from being suspected of harmful effects on the human foetus by the pharmacological effects to the being associated with an increased incidence of human foetal malformations. Propylthiouracil is an antithyroid drug indicated for the treatment of hyperthyroidism or prior to surgery or radioactive iodine therapy in these patients. Carbimazole is also an antithyroid drug indicated for hyperthyroidism. It is used as a definitive therapy for the induction of a permanent remission in either primary or secondary thyrotoxicosis. It is also used in preparation for thyroidectomy before and after radioactive iodine treatment. The risks relating to congenital abnormalities in neonates are known for these medicines. The TGA reviewed reported cases of congenital abnormalities for propylthiouracil and carbimazole in the postmarketing setting. Healthcare professionals should be advised that propylthiouracil and carbimazole should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.
Reference: Medicines Safety Update, TGA, 15 September 2021 (link to the source within www.tga.gov.au)

Magnesium sulfate Risk of rickets-like bone lesion in neonates at birth
The MHLW and the PMDA have announced that the product information for magnesium sulfate (injection) indicated for eclampsia should be revised to include the risk of rickets-like bone lesion in neonates at birth with prolonged administration of this drug during pregnancy. The MHLW and the PMDA reviewed cases of rickets-like bone lesion reported in neonates born to patients treated with magnesium sulfate in Japan and concluded that a causal relationship between the drug and event was reasonably possible in all
the cases. The shortest duration of administration with magnesium sulfate (injections) to the mother was 18 days.

Reference: Revision of Precautions, MHLW/PMDA, 20 June 2021 (link to the source within www.pmda.go.jp/english/)

Tofacitinib, Baricitinib and Upadacitinib Risk of serious heart-related events, cancer, blood clots, and death

1. USA. The US FDA has requested that the boxed warnings for tofacitinib (Xeljanz®/Xeljanz XR®), baricitinib (Olumiant®) and upadacitinib (Rinvoq®), are updated to include the risk of serious heart-related events, cancer, blood clots, and death. Tofacitinib, baricitinib and upadacitinib are janus kinase (JAK) inhibitors and are used to treat inflammatory conditions such as rheumatoid arthritis. A review of safety data for tofacitinib was recently completed in USA. Based on this review increased risks of serious heart-related events, cancer, blood clots, and death were identified for tofacitinib compared with TNF blockers in the treatment of patients with rheumatoid arthritis. Baricitinib and upadacitinib, also used for inflammatory conditions in the same class, are considered to have a risk similar to that of tofacitinib. Healthcare professionals should consider the benefits and risks for individual patients prior to initiating or continuing therapy with these medicines. Patients should be advised to seek emergency medical attention if they experience signs and symptoms of a heart attack, stroke, or blood clot. Patients should tell their

2. United Kingdom. The MHRA has announced that the product information for tofacitinib will be updated with the information that tofacitinib should not be used in patients older than 65 years of age, people who are current or past smokers, or individuals with other cardiovascular (e.g., diabetes or coronary artery disease) or malignancy risk factors unless there are no suitable alternative treatments. The MHRA reviewed the results of a clinical safety trial to evaluate the safety of tofacitinib compared with TNF blockers and identified these risk factors. Reference: Drug Safety Update, MHRA, 6 October 2021 (link to the source within www.ema.europa.eu)

3. Japan. The MHLW and the PMDA have announced that the package insert for tofacitinib should be revised to include the risk of cardiovascular events, such as myocardial infarction. The MHLW and the PMDA reviewed the results of a clinical safety trial to evaluate the safety of tofacitinib compared with TNF blockers and identified these risk factors. Reference: Revision of Precautions, MHLW/PMDA, 12 October 2021 (link to the source within www.pmda.go.jp/english/) (See also WHO Pharmaceuticals Newsletter No.4, 2021: Risk of cardiovascular events and cancer in Europe)