Retaining the brand name same even after changing the active constituent with other therapeutic category is a common practice in India. For an example- that there are five products like- Itraconazole Capsule, Esomoprazole Gastro-Resistant Tablets IP, Albendazole Tablets IP, Metronidazole Oral Suspension BP and Pantoprazole for Injection 40 mg under a particular “Brand name”. There are several examples of such products. This is well debated because it is creating confusion amongst all stakeholders. Sometimes it creates severe health problems due to dispensing error also.

Several memorandums have been sent to the concerned authorities for quick solution of the problem to protect the health of the people. This issue has been discussed in several meetings of DCC where DCC unanimously resolved that “the change of formulation composition without changing the brand name is not only misleading but may also result in undesirable pharmacological effects as the consumer would take the formulation assuming that it has the earlier composition. DCC further recommended that such type of practice needs to be discouraged and the state drug controllers should ensure that the same brand name should not be permitted to retain by the manufacturers, if the composition of the API(s) in the new formulation changed “and as a result DCGI has requested Drugs Controllers of all states and UTs to take steps in this matter.

Health activists are surprised to note that DCGI only conveyed the decision of DCC on such an important issue Unfortunately same situation prevails till now with a plea that it is contravening patent provisions. Therefore suitable measures to be taken by the concerned authority.
Notification for implementation for provision for registration certificate to sell, exhibit or offer for sale or distribute a medical device including in vitro diagnostic

New Drug: Bempedoic Acid

Bempedoic Acid Tablet first approved by USFDA in 2020

INDICATIONS AND USAGE: NEXLETOL is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.
Limitations of Use: The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

DOSAGE AND ADMINISTRATION: Administer 180 mg orally once daily with or without food.

DOSAGE FORMS AND STRENGTHS: Tablets: 180 mg

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS:
• Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.
• Tendon Rupture: Tendon rupture has occurred. Discontinue NEXLETOL at the first sign of tendon rupture. Avoid NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

ADVERSE REACTIONS: Most common (incidence ≥ 2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

DRUG INTERACTIONS:
• Simvastatin: Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.
• Pravastatin: Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.

USE IN SPECIFIC POPULATIONS:
• Pregnancy: Based on mechanism of action, may cause fetal harm.
• Lactation: Breastfeeding is not recommended with NEXLETOL.

Ref: USFDA

Status in India: Bempedoic acid bulk and Bempedoic acid tablet 180 mg has been approved by CDSCO indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Limitation of use: The effect of the drug on cardiovascular morbidity and mortality has not been established on 09.05.2022.

Different brands are available in India marketer by different companies’ like-Torrent, Dr. Reddys, Lupin, Cadila, Sun, Biocon, Zydus etc. price ranging from Re.239-Rs. 280 per strip of 10 tablets.

Paclitaxel Caution for medication error United
The MHRA has requested health-care professionals to take caution not to confuse Paclitaxel formulations with nabpaclitaxel. Nabpaclitaxel indicated for the treatment of certain cancers of the breast, pancreas, and lung. Paclitaxel is indicated for the treatment of cancers of the ovary, breast, and lung, and advanced AIDS-related Kaposi’s sarcoma. They have different indications, pharmacokinetics, dosages, and preparation and administration instructions; therefore, they are not interchangeable. Although the UK has not received a case report to suggest harm has occurred in the countries due to a mix-up of these paclitaxel formulations, errors in dosing or administration could have potential consequences for clinical response and increased toxicity or adverse reactions. Health-care professionals should make a clear distinction between paclitaxel formulations when prescribing, dispensing, administering, and communicating about these medicines. The use of brand names is advised for nabpaclitaxel formulations.

Reference: Drug Safety Update, MHRA, 18 January 2022 (link to the source within www.gov.uk/mhra)

Metformin Permitting use in pregnancy
The MHRA has announced that the product information for metformin is to be updated to permit its use during pregnancy and the periconceptional phase as an addition or an alternative to insulin, if clinically needed. Metformin is indicated for the treatment of type-2 diabetes, and good blood glucose control in pregnancy reduces the risk of congenital abnormalities, pregnancy loss, pregnancy induced hypertension, preeclampsia, and perinatal mortality. A review was conducted using new safety data from a study investigating immediate and longer-term effects of metformin in-utero exposure on children born to pregnant women with pre-existing diabetes. The results of the study were reassuring, with no safety signals of
Concern identified for use of metformin in pregnancy relating either to those who were pregnant or their baby. Reference: Drug Safety Update, MHRA, 15 March 2022 (link to the source within www.gov.uk/mhra)

Clindamycin Potential risk of acute kidney injury
The TGA has announced that the product information for clindamycin capsules and injections have been updated to include a warning about the potential risk of acute kidney injury. Clindamycin products are indicated for the treatment of serious infections caused by susceptible strains of streptococci, pneumococci, staphylococci and anaerobic bacteria. Product information for topical clindamycin products will not be updated. The TGA reviewed five reports of renal impairment and five cases of acute kidney injury associated with systemic clindamycin. Health-care professionals are advised to monitor the renal function during clindamycin therapy in patients with preexisting renal dysfunction or patients taking concomitant nephrotoxic drugs. Renal function should be monitored if therapy with clindamycin is prolonged.

Reference: Medicines Safety Update, TGA, 3 February 2022 (link to the source within www.tga.gov.au)

Amoxicillin Potential risk of aseptic meningitis
Health Canada has announced that the product safety information for amoxicillin-containing products will be updated to include the potential risk of aseptic meningitis. Amoxicillin is an antibiotic indicated for the treatment or prevention of certain bacterial infections. Products may contain amoxicillin alone or in combination with other antibiotics. Health Canada reviewed the available information by searching national and international databases, and the published literature. Twenty-one case reports of aseptic meningitis in adult patients receiving amoxicillin containing products were obtained and all of them were found to be possibly or probably linked with the use of the amoxicillin-containing products. The review concluded that there may be a link between amoxicillin-containing products and the risk of aseptic meningitis.

Reference: Summary Safety Review, Health Canada, 10 December 2021 (link to the source within www.hc-sc.gc.ca)

DISCLAIMER:
The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.

61st National Pharmacy Week Celebration
Indian Pharmaceutical Association, Bengal Branch
Programme:
20.11.2022: Inauguration Programme
Indian Council for Cultural Relations, 9A Ho Chi Minh Sarani, Kolkata-700071
22.11.2022: Seminar at Brainware University, Barasat
23.11.2022: Students Day Celebration at JIS University, Agarpara.
24.11.2022: Scientific Day Celebration at Triguna Sen Auditorium, Jadavpur University, Kolkata-700032
26.11.2022: (a) Hospital Pharmacy Day Celebration at Barasat Zila Parisad Hall (b) Cultural Programme at IPA Auditorium
27.11.2022: Scientific Seminar at DSP Main Hospital, Durgapur