Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

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Regulatory Affairs Division (RAD), IPA

Volume: 11 ***Number: 17 & 18*** ***3rd December 2017***

Content

Editorial

56th National Pharmacy Week has been celebrated throughout India during 19th – 25th November 2017 with a theme- **"Know Your Medicines: Ask Your Pharmacist".** The theme was appropriately chosen by Indian Pharmaceutical Association. Pharmacists have made outstanding contributions to the pharmaceutical profession since its inception to develop Pharmaceutical Research, Education and Industry. Indian Pharmaceutical Industry is now known as **"Pharmacy of the Globe"** due to its magnificent growth and export potential. Presently this Industry exports to more than 250 countries including developed countries apart from making India self reliant in terms of medicine formulation. Presently we have more than 10 lakh community pharmacies reaching out medicines to different parts of our country, but there is still much scope to improve the quality of services of the community pharmacies. IPA has requested Principal Secretaries and Drugs Controllers of all states for speedy implementation of Pharmacy Practice Regulation 2015. It is expected cooperation from them in this matter for improving the health care system of our country. Over the last 10-15 years, a number of steps have been taken by IPA, which include conducting- GPP Training jointly with WHO, signing MOU between RNTCP-Govt. of India and IPA, development of a training Module jointly by RNTCP and IPA etc. IPA is representing as a member of the National working Group of the PvPI contributing to developing a Pharmacovigilance system in our country and PvPI has made significant contribution in the issue of safety of the drugs available in the market and now PvPI has earned the distinction of being a WHO collaborating centre.IPA has taken a multipronged approach to fight against the Antimicrobial Resistance (AMR) and is working for the last few years, Bengal branch is a major contributor of this activity. We are determined to continue our activities further for improving access to medicines.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

Message from Voctoria Rutter, Executive Director, Commonwealth Pharmacists Association

COMMONWEALTH PHARMACISTS ASSOCIATION

Indian Pharmaceutical Association

16th November 2017

Dear President and Pharmacist Colleagues,

Greetings from the Commonwealth Pharmacists Association (CPA) as India celebrates National Pharmacy Week 2017. This is an important opportunity to amplify awareness amongst the public, healthcare providers and the authorities of the good work that the profession is doing in India. It has been fantastic to see pharmacists around the Commonwealth represented so strongly on social media during recent awareness weeks. We thank Dr Rao Vadlamudi, your President, and you the members of the IPA for your continued support.

As an affiliated organisation of the Commonwealth, the CPA shares in a vision to work towards Universal Health Coverage for all. This is a huge challenge, especially upon a backdrop of an aging population, coupled with the epidemic scale increase in non-communicable diseases (NCDs) that we are now witnessing. It is also important to acknowledge very present global health threats such as antimicrobial resistance and the recent Zika and Ebola outbreaks. With the current global health challenges our world faces, never has it been so vital for us to be working together to improve the health and well being of our nations through striving for better access to quality medicines and improving the standards of pharmaceutical care. To facilitate this, it is our vision that a pharmacist should be present wherever there is a medicine – at every level of the medicines use process, and whatever that may involve in the future as technologies around speciality medicines and new niche services unfold.

Your theme of India's National Pharmacy Week 2017 *'Know your medicines: ask your pharmacist'* highlights not only how pharmacists are the experts in medicines, but also the opportunity for pharmacists to be the accessible, well-trained and highly skilled healthcare professionals at the heart of communities. In order to see progress, we need to own this niche with confidence. With medicines being the most frequently employed health intervention, pharmacists are in an excellent position to be part of the solution in managing the NCD epidemic we are facing.

As the world of pharmaceutical care rapidly and continually evolves, as a profession we must be committed to life long continuing professional development to ensure that we can keep abreast of change, innovate effective new services for the benefit of our communities and continue to provide excellence in pharmaceutical care to the people that we serve.

With warmest regards from myself and the team,

Victoria Rutter, Executive Director

COMMONWEALTH PHARMACISTS ASSOCIATION
66 – 68 East Smithfield, London E1W 1AW
Tel: + 44 (0)7761 574 284
Web: www.commonwealthpharmacy.org

New Drug-Midostaurin capsules, for oral use

INDICATIONS AND USAGE: RYDAPT is a kinase inhibitor indicated for the treatment of adult patients with: • Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutationpositive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (1.1). Limitations of Use: RYDAPT is not indicated as a single-agent induction therapy for the treatment of patients with AML. • Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
DOSAGE AND ADMINISTRATION: • AML: 50 mg orally twice daily with food. • ASM, SM-AHN, and MCL: 100 mg orally twice daily with food.
DOSAGE FORMS AND STRENGTHS: Capsules: 25 mg (3) CONTRAINDICATIONS: Hypersensitivity to midostaurin or any of the excipients.
WARNINGS AND PRECAUTIONS: • Embryo-fetal Toxicity: RYDAPT may cause fetal harm when administered to a pregnant woman. Advise of the potential risk to a fetus. • Pulmonary Toxicity: Monitor for symptoms of interstitial lung disease or pneumonitis. Discontinue RYDAPT in patients with signs or symptoms of pulmonary toxicity. Fatal cases have occurred.
ADVERSE REACTIONS: • AML: The most common adverse reactions (≥ 20%) were febrile neutropenia, nausea, mucositis, vomiting, headache, petechiae, musculoskeletal pain, epistaxis, device-related infection, hyperglycemia, and upper respiratory tract infection. • ASM, SM-AHN, or MCL: The most common adverse reactions (≥ 20%) were nausea, vomiting, diarrhea, edema, musculoskeletal pain, abdominal pain, fatigue, upper respiratory tract infection, constipation, pyrexia, headache, and dyspnea.
DRUG INTERACTIONS: • Strong CYP3A4 Inhibitors: Strong CYP3A4 inhibitors may increase exposure to midostaurin and its active metabolites. Consider alternative therapies that do not strongly inhibit CYP3A4 or monitor for increased risk of adverse reactions. (7.1) • Strong CYP3A4 Inducers: Avoid concomitant use as strong CYP3A4 inducers decrease exposure to midostaurin and its active metabolites. USE IN SPECIFIC POPULATIONS: Lactation: Advise females not to breastfeed
Reference: USFDA

Status in India: *Midostaurin 25 mg Capsules has been approved by the CDSCO on 09.11.2017 for the purpose of - • In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive.*
• For the treatment of adult patients with advanced systemic mastocycosis (Advanced SM)

WHO warns of substandard, falsified drugs in developing countries

A World Health Organization study estimated that more than 10% of medical products in low- and middle-income countries are counterfeit or substandard. Such medicines waste money, can be dangerous and threaten antimicrobial resistance, according to the agency, which noted the falsified or substandard products are nearly evenly split between branded and generic drugs. Some experts are not agreeing with the result of the study for several reasons.
Ref. The Economic Times (India)

New guidelines on GMP for advanced therapies issued by EC

A new set of guidelines on good manufacturing practices was issued by the European Commission, which will ensure that the advanced therapy medicinal products are consistently produced and controlled according to high-quality standards, as adapted from the European Union GMP requirements, for the safety and benefit of patients.
Ref. PharmaBiz (India)

Case Study: Patients with HIV at higher risk for heart attacks, kidney disease

Researchers from the University of Adelaide in Australia analyzed what types of adverse events could result from undergoing HIV treatments, and they found that patients with HIV who are already at high risk of having a heart attack or stroke are even at greater risk of contracting chronic kidney disease. The study's findings were published in a special issue of the journal PLOS Medicine, which will highlight advances in HIV treatment and research in preparation for World AIDS Day on Dec 1.

Ref. MD Magazine online

Venezuelan doctors say drug supply is insufficient for rise in malaria cases

Venezuela Vice Minister for Health Moira Tovar said 32 people died in one week in October from malaria, and government data released earlier this year indicates a 76% surge in malaria cases compared with those reported in 2015, with a majority of the cases located in the state of Bolivar. The World Health Organization sent more than 1 million anti-malaria pills in October, which doctors say is not enough to treat everyone who is sick.

Ref. Reuters

Antimicrobial resistance on the rise in Europe

The European Centre for Disease Prevention and Control reports that antimicrobial resistance is increasing in 30 countries in the European Union and European Economic Area, particularly for Escherichia coli and the Acinetobacter species. A significant decrease, however, was seen in rates of methicillin resistance among Staphylococcus aureus from 2013 to 2016.

Ref. Center for Infectious Disease Research and Policy

India updates rising number of dengue, malaria, chikungunya cases

The number of confirmed cases of dengue in India has reached 8,063, with 4,188 of those located in Delhi. Indian health officials also reported that the number of recorded cases of malaria as of Saturday stands at 1,106, while the number of chikungunya cases has reached 855.

Ref. The Indian Express (India)/Press Trust of India

FDA approves Abilify pills embedded with digital tracker

The FDA approved a formulation of Otsuka Pharmaceutical's mental health drug Abilify that contains a tracking device developed by Proteus Digital Health. The device is activated by stomach juices and sends a signal to a wearable patch, which transmits data to a smartphone application, in an effort to help with medication regimen compliance.

Reuters (11/14)

Doctor who doesn't use computer can't regain license-says Judge in US

A New Hampshire judge has denied an 84-year-old doctor's request to regain her license to practice, which she had surrendered partly over her inability to use a computer.

The state challenged Dr. Anna Konopka's record keeping, prescribing practices and medical decision making. They said her limited computer skills prevent her from using the state's mandatory electronic drug monitoring program, which requires prescribers of opioids to register in an effort reduce overdoses.

Konopka surrendered her license, but later requested permission to continue her practice. New Hampshire Public Radio reported Monday that a judge ruled Nov. 15 that she failed to show she was forced to give up her license as she alleged. Konopka has asked the judge to reconsider; he hasn't responded yet.

Konopka didn't immediately return a phone message.

For details:

https://health.economictimes.indiatimes.com/news/industry/judge-doctor-who-doesnt-use-computer-cant-regain-license/61829262