Drug Information Bulletin

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&
Regulatory Affairs Division (RAD), IPA

16th Anniversary

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Content

Editorial

Greetings from Drug Information Bulletin!

Like the past years Pharmacists of India are going to celebrate 13th World Pharmacist Day on 25th September with great enthusiasm. Pharmacy Council of India has decided that they will celebrate this day as Pharmacists Day in India every year and requested all State Pharmacy Councils, Pharmacy Institutions and professional organizations to celebrate the occasion since 2013. Pharmacists are one of the three main pillars of the health care systems with Doctors and Nurses. Though Doctors Day and Nurses Day are being celebrated since long back, no Pharmacists day was celebrated earlier till 2013 in India. This celebration will be a boost to the pharmacist as a health care provider and certainly recognition to their relentless service to the mankind. As per the sources this day will be celebrated with great enthusiasm throughout the country. There is information that Pharmacy Council of India, State Pharmacy Councils, IPA branches, SEARPharm Forum, IPA student Forum, several other Pharmacy associations, Pharmacy Colleges, Hospitals are going to celebrate the occasion in different ways like- Online interactive discussion, holding health care camps for general public, blood donation camps, Essay & poster competition etc. This year's theme is aptly chosen by the FIP **"Pharmacy strengthening health systems"** is very meaningful in this situation. Pharmacists have taken up this opportunity to serve patients by remaining in the frontline during Covid pandemic. IPA along with FIP is trying their best to establish Indian Pharmacists as one of the important player in health care system and pursuing the issue of making Indian pharmacists as a vaccinator like most of other countries.

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NMC put on hold their recent notification on "National Medical Commission Registered Medical Practioner (Professional Conduct) Regulation, 2023"

NATIONAL MEDICAL COMMISSION

(Ethics and Medical Registration Board)

NOTIFICATION

New Delhi, the 23rd August, 2023

No. R-12013/01/2022/Ethics.— In exercise of the powers conferred by Section 27(1)(b), read with Sections 10(1)(b) & (f), 16(2), 57(2) (zd), (zh), (zi) and (zl), of the National Medical Commission Act, 2019, (Act No. 30 of 2019), the National Medical Commission hereby makes the following Regulations to further amend the "National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023" namely:

1. These Regulations may be called the "National Medical Commission Registered Medical Practitioners (Professional Conduct) (Amendment) Regulations, 2023".
2. These Regulations shall come into force from the date of their publication in the Official Gazette.
3. That National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023, are hereby held in abeyance with immediate effect.
4. That for removal of doubts, it is clarified that the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023, shall not be operative and effective till further Gazette Notification on the subject by the National Medical Commission.
5. That the National Medical Commission hereby adopts and makes effective with immediate effect the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002", as if the same have been made by the Commission by virtue of the powers vested under the National Medical Commission Act, 2019 (Act No. 30 of 2019).
6. That for removal of doubts, it is clarified that Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, shall come into force with immediate effect.

Dr. VIPUL AGGARWAL, Secy.

[ADVT.-III/4/Exty./378/2023-24]

Note: These Regulations are being published in English and Hindi, the English version shall prevail in case of any doubt about the interpretation of these Regulations

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National Medical Commission notified on 23.08.2023 that the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 will kept in abeyance till further notification

The National Medical Commission (NMC) on 23.08.2023 put on hold its new guidelines that made it mandatory for doctors to only prescribe generic drugs and prescribed penal provision for non compliance of the said regulation.

The National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 was notified on 2nd August 2023 which was appreciated by several stake holders who thought that it is a right step for improving access to medicine to the people of our country. But some other groups like Indian Medical Association and Indian Pharmaceutical Alliance raised objection and NMC put on hold the said regulation but they made that the Indian Medical Council Registered Medical Practitioner (Professional Conduct) Regulations, 2002 will take effect immediately. This retrograde step has drawn severe criticisms from several healthcare stake holders.

New Drug: Niraparib capsules, for oral use

Initial U.S. Approval: 2017

INDICATIONS AND USAGE ZEJULA is a poly(ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION:

- Recommended dose is 300 mg taken once daily with or without food.
- Continue treatment until disease progression or unacceptable adverse reaction.
- For adverse reactions, consider interruption of treatment, dose• reduction, or dose discontinuation.

DOSAGE FORMS AND STRENGTHS: Capsules: 100 mg

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS:

- Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to ZEJULA, and some cases were fatal. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed.
- Bone Marrow Suppression: Test complete blood counts weekly for• the first month, monthly for the next 11 months and periodically thereafter for clinically significant changes.
- Cardiovascular Effects: Monitor blood pressure and heart rate• monthly for the first year and periodically thereafter during treatment with ZEJULA. Manage with antihypertensive medications as well as adjustment of the ZEJULA dose, if necessary.
- Embryo-Fetal Toxicity: ZEJULA can cause fetal harm. Advise• females of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS:

Most common adverse reactions (incidence ≥10%) are thrombocytopenia, anemia, neutropenia, leukopenia, palpitations, nausea, constipation, vomiting, abdominal pain/distention, mucositis/stomatitis, diarrhea, dyspepsia, dry mouth, fatigue/asthenia, decreased appetite, urinary tract infection, AST/ALT elevation, myalgia, back pain, arthralgia, headache, dizziness, dysgeusia, insomnia, anxiety, nasopharyngitis, dyspnea, cough, rash, and hypertension.

USE IN SPECIFIC POPULATIONS: Lactation: Advise women not to breastfeed during treatment and for 1 month after receiving the final dose.

Status in India: Niraparib Tablet 100mg approved by CDSCO with indication for monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO stage-III and IV) high grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum -based chemotherapy. as monotherapy for the maintenance treatment of adult patients with platinumsensitive relapsed high grade serous epithelial ovarian, fallopian tube , or primary peritoneal cancer who are in response (complete or partia) to platinumbased chemotherapy on 01.05.2023.

Ref. USFDA &CDSCO

Mefenamic acid, doxycycline Risk of fixed drug eruption

The Central Drugs Standard Control Organization WHO Pharmaceuticals Newsletter No. 3, 2022 • 10 Regulatory Matters (CDSCO) has approved the recommendation to revise the prescribing information leaflet (PIL) for mefenamic acid and doxycycline to include fixed drug eruption as an adverse drug reaction. Mefenamic acid is indicated for the treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhea, mild to moderate pain, inflammation, fever and dental pain. Doxycycline is used as a broadspectrum antibiotic. The National Coordination Centre – Pharmacovigilance Programme of India (NCCPvPI), Indian Pharmacopoeia Commission (IPC) reviewed 23 case reports of fixed drug eruption with use of mefenamic acid and 94 cases with the use of doxycycline, and found a strong causal relationship between each of the two drugs and the event.

Reference: Based on the communication from IPC, India, June 2022 (link1 and link2 to the source within cdsco.gov.in)

Iodine-containing contrast media (ICM) Risk of hypothyroidism

The US FDA has announced that the prescribing information for all iodinated contrast media (ICM) injections will be updated to include a new warning on the risk of underactive thyroid or a temporary decrease in thyroid hormone levels as well as new monitoring recommendations for use in children 3 years or younger. ICM injections are drugs containing iodine which is used to enhance the ability to see blood vessels, organs, and tissues on medical images such as X-rays or computed tomography scans. The US FDA reviewed research studies published in the medical literature evaluating the risk of hypothyroidism. Most cases of decreased thyroid hormone levels were temporary and did not require treatment. The reported rate ranged from 1 to 15 percent and tended to be higher in newborns, particularly those who were preterm. It is recommended that Healthcare professionals monitor patients from birth through to 3 years of age for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to ICM. Certain pediatric patients are at an increased risk, including newborns, babies with a of low birth weight, premature babies, or those that have a condition (including cardiac complications) that requires care in neonatal or pediatric intensive care units.

Reference: MedWatch, US FDA, 30 March 2022 (link to the source within www.fda.gov) (See WHO Pharmaceuticals Newsletters No.5, 2018: Risk of hypothyroidism in Singapore, No.1, 2018: Possible risk of hypothyroidism in infants in New Zealand and No. 6, 2015: Rare cases of underactive thyroid in infants in the USA)

Levothyroxine and ciprofloxacin Possible interaction: Increased risk of hypothyroidism

The Medsafe has announced that the product information for levothyroxine and ciprofloxacin are being updated to include information on the drug-drug interaction between levothyroxine and ciprofloxacin and the risk of hypothyroidism. Levothyroxine is indicated for the treatment of hypothyroidism. Ciprofloxacin is a fluoroquinolone antibiotic indicated in adults for infections caused by ciprofloxacin-sensitive pathogens. The Centre for Adverse Reactions Monitoring (CARM) received a report of hypothyroidism symptoms in a patient taking levothyroxine and a course of ciprofloxacin. The symptoms improved upon stopping ciprofloxacin and increasing the levothyroxine dose temporarily. In addition, a search in the literature identified a case report and study that reported or suggested this interaction. It is recommended that healthcare professionals should instruct patients to separate the administration times of these two concomitant medicines by leaving at least a six-hour gap between administration of both medicines. Patients should be informed about this potential interaction, advised on what signs and symptoms to look out for (e.g., fatigue, lethargy or feeling cold), and should be monitored them for any changes in thyroid function.

Reference: Prescriber Update, Medsafe, June 2022 (link to the source within www.medsafe.govt.nz/)