Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

The long pending demand of pharmacy professionals for inclusion of Pharmacy subjects in the Indian Administrative Examination (IAS) has been ignored by the concerned authority, creating dissension amongst the pharmacy community.

In India most of the students pursuing professional courses like Medical, Engineering courses are getting an advantage in the examination to be qualified for IAS. Pharmacy students are not getting this advantage as Pharmacy subjects are not included in the said examination. Resolutions have been taken in this respect on several occasions by the IPCA in the past but result is yet to be positive.

Similar situation is prevailing in case of examination for selecting Patent Examiners in which Pharmacy subject is not included though thirteen subjects like Chemistry, Chemical Engineering, Electric Engineering have been included. It may be noted that patent application on Pharmaceuticals have a major share on the total number of patent application in India. This issue has been raised by a certain quarter before the concerned authority but no positive results are yet visible.

In India most of the decisions are taken and executed by the bureaucrats, where the opinions of the technocrats are mostly ignored, absence of bureaucrats with pharmaceutical background is a disadvantage in taking decision in the matter of Pharmaceuticals.

These are two issues amongst several such that are deterrent to the development of the profession in our country. Policy makers require think over proper utilization of the huge manpower in pharmaceutical profession in India.

IPA is trying its best by submitting memorandum to the concerned authorities and trying to pursue the matter continuously, but expected result is yet to be achieved.

Therefore, it is high time for taking up these issues by all of the pharmaceutical professional organizations jointly.

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New Drug: Macitentan 10 mg Tablet

First approved by USFDA with brand name: OPSUMIT in 2013

HIGHLIGHTS OF PRESCRIBING INFORMATION WARNING: EMBRYO-FETAL TOXICITY • Do not administer OPSUMIT to a pregnant female because it may cause fetal harm (4.1, 5.1, 8.1). • Females of reproductive potential: exclude pregnancy before start of treatment, monthly during treatment, and 1 month after stopping treatment. Prevent pregnancy during treatment and for one month after treatment by using acceptable methods of contraception (2.2, 8.6). • For all female patients, OPSUMIT is available only through a restricted program called the OPSUMIT Risk Evaluation and Mitigation Strategy (REMS)

INDICATIONS AND USAGE: - OPSUMIT is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression. Disease progression included: death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). OPSUMIT also reduced hospitalization for PAH

DOSAGE AND ADMINISTRATION: • 10 mg once daily. Doses higher than 10 mg once daily have not been studied in patients with PAH and are not recommended

DOSAGE FORMS AND STRENGTHS: • Tablet: 10 mg

CONTRAINDICATIONS: • Pregnancy

WARNINGS AND PRECAUTIONS: • ERAs cause hepatotoxicity and liver failure. Obtain baseline liver enzymes and monitor as clinically indicated (5.3). • Fluid retention may require intervention (5.4). • Decreases in hemoglobin (5.5). • Pulmonary edema in patients with pulmonary veno-occlusive disease. If confirmed, discontinue treatment (5.6). • Decreases in sperm count have been observed in patients taking ERAs

ADVERSE REACTIONS: Most common adverse reactions (more frequent than placebo by ≥3%) are anemia, nasopharyngitis/pharyngitis, bronchitis, headache, influenza, and urinary tract infection (6.1).

DRUG INTERACTIONS: Strong CYP3A4 inducers (rifampin) reduce exposure to macitentan: avoid co-administration with OPSUMIT (7.1, 12.3). Strong CYP3A4 inhibitors (ketoconazole, ritonavir) increase exposure to macitentan: avoid co-administration with OPSUMIT

USE IN SPECIFIC POPULATIONS: Nursing mothers: discontinue OPSUMIT or breastfeeding.

For details: https://opsumit.com/opsumit-prescribing-information.pdf

Status in India: Macitentan Bulk and Tablets 10 mg was approved by CDSCO on 07.12.2017 for the treatment of Pulmonary arterial hypertension (PAH, WHO group I) to delay disease progression.

UK research shows potential of arthritis drug in skin cancer treatment

A research study conducted at the University of East Anglia in the UK demonstrated the potential of the rheumatoid arthritis drug leflunomide in the treatment of melanoma if combined with selumetinib. Leflunomide induced cell apoptosis and seemed to be effective against melanoma cells irrespective of the cancer mutation.

Ref. PharmaTimes (U.K.)

Singapore health agency new member of ICH

Singapore's Health Sciences Authority was named a new regulatory member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, allowing it to vote and participate in ICH expert working groups. Other regulatory members are Canada, Switzerland, the Republic of Korea, China and Brazil.

Ref. BioSpectrum Asia

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Novartis' MS therapy backed by NICE

The National Institute for Health and Care Excellence recommended the use of Novartis' self-injected Extavia, or interferon beta-1b, as a treatment for adult patients with relapsing-remitting multiple sclerosis or secondary progressive MS with continued relapses. The regulator ruled that the drug's benefit was cost-effective.

Ref. European Pharmaceutical Review (U.K.)

WHO: 32 confirmed cases of yellow fever in Nigeria for second half of 2017

From a batch of 63 samples from Nigerian patients suspected of having yellow fever, 32 were positive, 24 turned out negative and seven were pending, according to an updated report from the World Health Organization covering the second half of the year. The country currently has 341 suspected cases, with 62.8% of those being in males.

Ref. Vanguard (Nigeria)

Despite shortage, India discards 1m blood units per year

India discards over a million units of blood collected every year, according to health ministry data. This is despite facing a severe blood shortage as only 9.9 million units are collected against the estimated annual requirement of 10-12 million units.

The reasons for collected blood having to be discarded include deterioration during storage and expiry due to outdating. The largest chunk of the wasted units is plasma, which could be used for various life-saving treatments. A unit of blood (450 ml) can potentially save at least three lives, according to the World Health Organisation. On an average, about six units of blood is needed for every open heart surgery, while a roadside accident victim could require up to 100 units. One out of every 10 people admitted to a hospital needs blood, according to WHO data.

The health ministry data was tabled in the Lok Sabha in response to a question. Reactivity for infections (malaria, syphilis, HIV, hepatitis B, hepatitis C) and expiry due to outdating, especially for platelets, which have a short shelf life of only 5 days, are among the reasons offered by the ministry. Others include deterioration during storage in the form of discolouration, haemolysis, bacterial contamination, not meeting quality parameters after collection and production and non-completion of blood collection in requisite quantities due to donor reactions.

The ministry added that though India does not have a National Blood Transfusion Service, since public health is a state subject, state blood transfusion councils are set up in every state to monitor proper functioning of blood transfusion services.

Patients need blood after major accidents or surgeries in which there is loss of blood. After a miscarriage or childbirth, the patient may need transfusion of a large amount of blood for saving her life or the child's. For patients with blood diseases like severe anaemias, leukaemias (blood cancer), haemophilia (bleeding disorder) and thalassemia, repeated blood transfusions are the only solution. In many other situations too, like poisoning, drug reactions, shock and burns, blood transfusion is the only way to save life.

WHO estimates that blood donation by 1% of a country's population is generally sufficient to meet its basic requirements for safe blood. Currently, an estimated 9.5 million Indians donate blood, which is 2.5 to 3 million less than the required number.

Globally, more than 287 000 women die each year during pregnancy, childbirth or in the postpartum period - 99% of them in developing countries; availability of safe blood can save many of them, according to the world health organisation.

Source:
https://health.economictimes.indiatimes.com

Drug Safety Alerts (October 2017-December 2017): The preliminary analysis of ADRs from the PvPI database reveals that the following drugs may be associated with the risks as given below.

Sr. No.	Suspected Drug	Indication	Adverse Drug Reaction
1	Amikacin	Short term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species, Escherichia coli, species of indole-positive and indole-negative proteus, providencia species, Klebsiella, Enterobacter, Serratia species and Acinetobacter species	Stevens Jhonson Syndrome
2	Allopurinol	Prophylaxis of gout; prophylaxis of hyperuricaemia associated with cancer chemotherapy	Uveitis
3	Quetiapine	For treatment of Schizophrenia and bipolar disorder	Gynaecomastia
4	Ceftriaxone	Serious infections due to sensitive bacteria, including septicaemia, pneumonia and meningitis; surgical prophylaxis; prophylaxsis of meningococcal meningitis; gonorrhoea; bone and joint infection	Palpitations
5	Fluoxetine	Fluoxetine is a SSRI antidepressant which is used in psychological disorders and also in premature ejaculation	Urinary Incontinence

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs. If such events are encountered please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/ Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

Reader's column:

Dear Dr. Subhash Mandal,
DIC Coordinator & Editor-DIC Bulletin.

Respected Sir,
Thank you very much for sending E-copy of Drug Information Bulletin published by IPA Bengal branch. The contents of the bulletin are good, informative and helpful for professionals in pharmacy and medical field.
I am running a retail pharmacy in rural area since last 35 years after working as pharmacist in Tata Memorial Hospital, Mumbai. Working as community pharmacist gives me pleasure and satisfaction while counseling to patients in Rural area, to whom our services are most needed.
In spite of doing pharmacy profession, I am working as an NGO in consumer awareness movement as the president of Akhil Bhartiya Grahak Panchayay, Satara District Branch in Maharashtra State since last 20 years.
I assure my full co operation if needed in your noble work.
Regards.
Dilip Patil, D.Pharm.,B.Sc.,MBA,