Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

Pharmacists Day
25th September 2019
Theme: Effective Medicines for all

Volume: 13 ***Number: 12*** ***8th September 2019***

Content

Editorial

It has been noticed that the Ministry of Health and Family Welfare, Government of India publishing advertisement seeking application for the "National Florence Nightingale Nurses Award" to recognize meritorious services of Nurses working in the State, Central, Autonomous Institutions, Private, Missionary and Voluntary organization in India. This award is being given on 12th May every year to recognize the service of a Nurse in India, which will in turn encourage other Nurses. Similar award is given to recognize doctors on 1st July every year, which will encourage doctors to serve better the society. Though two important health providers are being recognized, very unfortunately the third important health providers –"Pharnacists" are ignored till date.

A few years back Her Excellency Mrs. Prativa Patil, President of India, in a programme at New Delhi declared that similar award will be given to the Pharmacist to recognize their contribution to the health care system. Very unfortunately that has not happened till date. It may be due to bureaucratic delay or may be lack of persuasion by the pharmaceutical Organizations and Pharmacy Council of India.

It is high time that all pharmaceutical organizations be united and pursues the matter. The Pharmacy Council of India has extra responsibility in this matter being the highest authority of pharmacists. Hope we will see an similar advertisement seeking recommendation for such an award along with the next advertisement seeking recommendation for "Florence Nightingale Award" and "Dr. B.C.Roy Award".

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Clarification on manufacturing of new drug by a manufacturer in their own multiple manufacturing sites:CDSCO

F. No. 12-44/2019-DC (Pt- Misc)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, New Delhi
Dated: 30/8/2019

CIRCULAR

Subject: Clarification on manufacturing of new drug by a manufacturer in their own multiple manufacturing sites - reg.

Requirements for manufacturing of new drug by a manufacturer in its own additional site has been under discussion for quite some times now.

For generation of Chemistry, Manufacturing and Control (CMC) data, the manufacturer needs to obtain license/permission from concerned Authority.

The matter has been examined and it has been decided that if CMC data is generated by a manufacturer in one of its manufacturing facility and based on the data the approval/permission has been granted to the manufacturer for manufacturing of the new drug in that facility, the same data may be utilized by the same manufacturer for manufacturing of same product in its additional manufacturing sites with necessary permission/license provided that the manufacturer establishes the similarity by way of technology transfer with respect to manufacturing process, equipment, process parameters, process capability and bridging validation for technology transfer wherever required etc. between the proposed additional manufacturing sites and the approved manufacturing site.

V.G.S.

(Dr. V.G. Somani)
Drugs Controller General (India)

To: All Stakeholders through CDSCO website

New Drug: Levomilnacipran extended-release capsules, for oral use

levomilnacipran extended-release capsules, for oral use Initial U.S. Approval: 2009 under the Brandname "Fetzima".

WARNING: • Increased risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants (5.1). • Monitor for worsening and emergence of suicidal thoughts and behaviors • FETZIMA is not approved for use in pediatric patients.

INDICATIONS AND USAGE: FETZIMA is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of Major Depressive Disorder (MDD).
Limitation of Use: FETZIMA is not approved for the management of fibromyalgia. The efficacy and safety of FETZIMA for the management of fibromyalgia have not been established.
DOSAGE AND ADMINISTRATION: • Recommended dose: 40 mg to 120 mg once daily with or without food. • Initiate dose at 20 mg once daily for 2 days and then increase to 40 mg once daily. • Based on efficacy and tolerability, increase dose in increments of 40 mg at intervals of 2 or more days. • The maximum recommended dose is 120 mg once daily. • Take capsules whole; do not open, chew or crush (2.1) • Renal Impairment: Do not exceed 80 mg once daily for moderate impairment. Do not exceed 40 mg once daily for severe renal impairment. • Discontinuation: Reduce dose gradually whenever possible.
DOSAGE FORMS AND STRENGTHS: • Extended-release capsules: 20 mg, 40 mg, 80 mg and 120 mg.
CONTRAINDICATIONS: • Hypersensitivity to levomilnacipran, milnacipran HCl, or any excipient in the FETZIMA formulation. • Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with FETZIMA or within 7 days of stopping treatment with FETZIMA. Do not use FETZIMA within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start FETZIMA in a patient who is being treated with linezolid or intravenous methylene blue. • Suicidal Thoughts and Behaviors in Children, Adolescents, and Young Adults: Monitor patients for clinical worsening and suicidal thinking or behavior. • Serotonin Syndrome: Serotonin syndrome has been reported with SSRIs and SNRIs, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, amphetamines, and St. John's Wort). If such symptoms occur, discontinue FETZIMA and initiate supportive treatment. If concomitant use of FETZIMA with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. • Elevated Blood Pressure and Heart Rate: Measure heart rate and blood pressure prior to initiating treatment and periodically throughout treatment. Control pre-existing hypertension before initiating therapy with FETZIMA. • Abnormal Bleeding: Treatment can increase the risk of bleeding. Caution patients about the risk of bleeding associated with the use of NSAIDs, aspirin, or other drugs that affect coagulation. • Angle Closure Glaucoma: Angle closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. • Urinary Hesitation or Retention: Can occur. If such symptoms occur, discontinue FETZIMA or consider other appropriate medical intervention. • Activation of Mania/Hypomania: Screen patients for bipolar disorder, Caution patients about risk of activation of mania/hypomania. • Seizures: Can occur. Use with caution in patients with a seizure disorder. • Discontinuation Syndrome: Taper dose when possible and monitor for discontinuation symptoms (5.10). • Hyponatremia: Can occur in association with SIADH.
ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 5% and at least twice the rate of placebo) are: nausea, constipation, hyperhidrosis, heart rate increase, erectile dysfunction, tachycardia, vomiting, and palpitations.
DRUG INTERACTIONS: • Strong CYP3A4 inhibitors such as Ketoconazole: Do not exceed 80 mg once daily.
USE IN SPECIFIC POPULATIONS: • Pregnancy: Based on animal data, may cause fetal harm.

Status in India: CDSCO has approved Levomilnacipran ER capsules 20mg/40mg/80mg/120mg, for treatment of major depressive disorder 1 on 13.08.2019.

Zydus Cadila receives DCGI nod to market rabies drug in India

It has been reported that Zydus Cadila has received marketing authorisation for Twinrab, used for treating rabies, from the Drug Controller General of India (DCGI).

"The novel biologic which will be marketed under the brand name, Twinrab, is indicated in combination with rabies vaccine for rabies post-exposure prophylaxis," Zydus Cadila said in a statement.

Rabies, a viral disease which gets transmitted through the bite of a rabid animal, affects the central nervous system.

Zydus said in 2008, it had entered into an agreement with the World Health Organization (WHO) to explore opportunities in the development of a cocktail of monoclonal antibodies for the treatment of rabies.

"The use of rabies monoclonal antibodies could emerge as an innovative therapy and form a potent alternative to current blood derived rabies immunoglobulins (RIG's) produced by vaccinating horses (ERIG) or humans (HRIG)," the company added.

Zydus said it currently also manufactures and markets the rabies vaccine — VaxiRab which is a WHO pre-qualified vaccine.

Shares of Cadila Healthcare, the listed entity of the group, were trading 1.24 per cent higher at Rs 227.95 apiece on BSE.

Union Govt. sees Its SUGAM National Drugs Licensing System to Bolster E-Governance Initiatives

Union government sees its SUGAM National Drugs Licensing System to further strengthen the e-governance initiatives. The National Database of Manufacturers & Formulators along with the generation of unique ID for production sites will enable a smooth transition to the e-system. It will allow both operations agility and efficiency.

The data captured from the manufacturers provides hands-on information of the pharmaceutical production and marketing activity in the country, said by a representative of Centre for Development of Advanced Computing (CDAC).

From details of user registration, manufacturing site, formulations, production and production capacity of site will now empower the government with an effective real time platform, she added.

In a presentation titled SUGAM and National Drug Licensing System, at a workshop for providing training to pharma manufacturers on drug approval under the recent amendments to the Drugs & Cosmetics Rules in Bengaluru, she said that registration on SUGAM portal for adding manufacturing unit and formulation details allows ease of application submission for licensing, tracking its status, grant of permission and related approvals. Further, it creates live statistics of the registered pharma companies, number of submitted applications, processed applications and inspections conducted.

With the Digital India, the country is on the surge of change and revolution. The drug control officials in general see the need to create simple, automated and efficient processes for the pharma industry. Moreover, the convergence of cloud computing, mobile technology, social media and big data analytics is reshaping the future of e-governance. States like Karnataka, Gujarat among others are already way ahead in these initiatives which have facilitated transparency and efficiency in operations. The e-system of licensing and drug approvals has seen to enable maximising the network-level effectiveness. The streamlined structure leads to faster turnaround and better performance. For the long run, the e-system is seen as a cost-effective approach. Its implementation helps to achieve lower operational cost, improved access, reduced processing and dispatch of applications pending for approval of drugs and issue of licenses. Scope of work for national drug licensing system covers grant and renewal of licenses for manufacturing and sales of medicines, vaccines and blood products. Online system also issues certificates and no objection certificates (NOC). Further enforcement activities can be carried out by state drug controller officers. This is all enabled with the Management Information System (MIS) and Analytical platform.

The portal will also provide details of facility with regard to dosage, site, lab information and production capacity. There is also scope for queries to be posted on doubts about submission and cancellation of licenses.

Source: Pharmabiz

Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2019 invited

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3rd week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.

IPA, Bengal Branch Council select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy.

Any member of IPA can recommend name of the person with their detailed Bio-data & Two Page summary of the Bio data for 2019 award, which may be sent by 10th October 2019 to:

The Hony. Secretary,
Indian Pharmaceutical Association, Bengal Branch,
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Kolkata – 700029
e-mail: ipabengal@gmail.com

N.B.: Biodata should include the following points-

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
    a. Whether member of IPA? If yes, how many years?
    b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
    a. President/Vice President / Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
    b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.