Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Disposal of Bio-hazardous waste and drugs-that have expired / confiscated under law, pose a huge problem with respect to environmental pollution. The environment today is overloaded with myriad hazardous chemicals, drugs, excipients and biohazardous waste from different institutions pose a serious threat to the environment. It is a serious concern to the responsible citizens. Strict guidelines need to be framed and enforced with proper vigilance, so that they do not contaminate soil, water bodies / air and through these contaminate / damage human or animal bodies, crops, cattle, fishes etc. It is imperative to note that packaging materials used in the pharmaceutical industry is also another area, whose disposal poses a serious problem.

Guidelines for "Safe Disposal of unwanted pharmaceuticals in and after emergencies" have been framed by international agencies, but no such guidelines have been framed in India under any legislation. It is high time to prepare and enforce strict legislation for disposal of Pharmaceuticals and packaging materials to save the environment.

As pharmacists, we should be more conscious and cautious about disposal of drugs and other pharmaceutical and medical substances / aids, so as to reduce environmental hazards.

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Drug Safety Alerts

The preliminary analysis of Adverse Drugs Reactions from the PvPI database reveals that the following drug is associated with the risk as given below.

Name of the Drug: Fluoxetine

Indication: Bipolar disorder; Depressive Episode

Adverse Reaction: Hypoacusis (Hearing Impairement)

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above drug. If such reaction is 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.

Ref. PvPI

CDSCO Starts Inspecting drug companies to assess pharmacovigilance practices, regulatory compliance

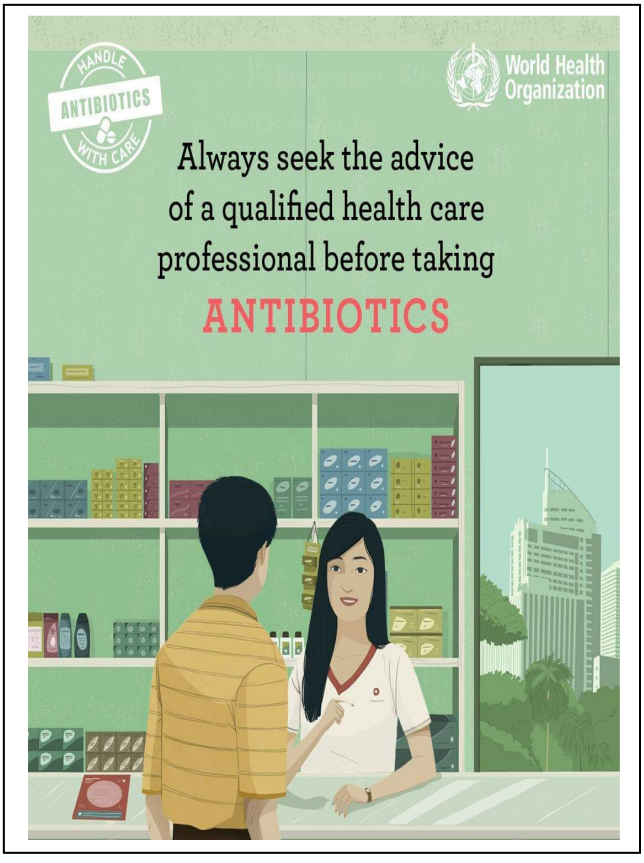
Almost a year after introducing the first pharmacovigilance (PV) guidance document, the Central Drugs Standard Control Organisation (CDSCO) has started inspecting sites of marketing authorisation holders (MAH) of pharmaceutical products to assess their PV practices and level of compliance, it is learnt. The inspections are being conducted on the basis of potential risk to public health and the results from across the country will be reviewed by a panel constituted at the CDSCO headquarters.

The move to scrutinise the PV practices of drug manufacturers and importers, under the National PV-inspection Programme (NPVIP), comes nearly two years after the government's decision to amend Schedule Y of the Drugs and Cosmetics Act of 1940 to make the mechanism mandatory. As per the amendment, any firm applying for a new drug licence should have a PV system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reaction (ADR). The apex drug regulator has prepared the roadmap for NPVIP after considering inputs from industry associations and pharmaceutical majors.

While welcoming efforts to establish an effective PV mechanism, industry sources say that the introduction of a new inspection regime won't enhance compliance, particularly in the absence of a clear regulatory mandate. "As per the guidance document that took effect in January this year, all drug manufacturers need to have a PV system in place for processing and forwarding the report to the licensing authority for information on ADR. The officer in-charge of data collection and processing should be a medical officer or a pharmacist trained in analysis of ADR reports. But only around 300 major drug manufacturers follow these regulations, chiefly due to the additional cost involved," an industry lobby group representative said on condition of anonymity.

According to statistics available in the public domain, India rates below 1 per cent in PV as against the world rate of 5 per cent, mainly due to ignorance of the subject and lack of training.

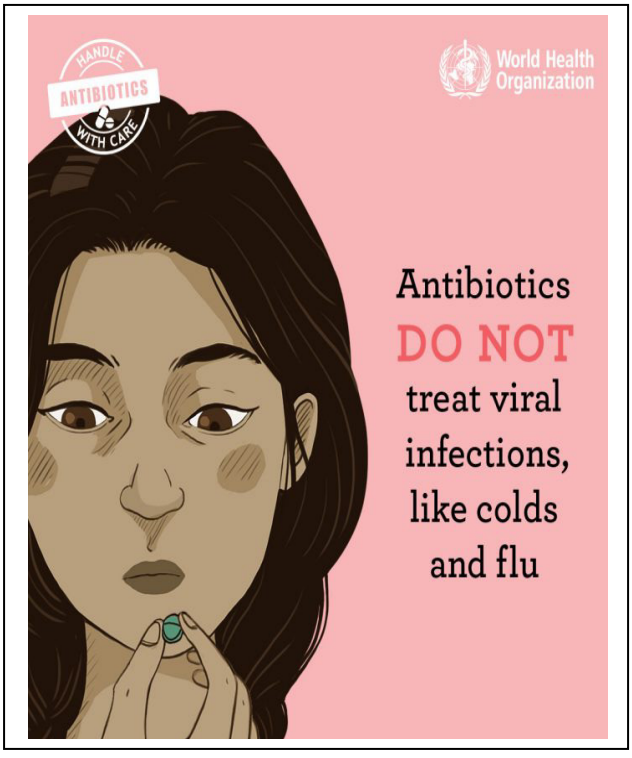
The industry representative also underscores the need for collective effort to improve compliance with PV regulations. "A company's individual case safety reports to the Pharmacovigilance Programme of India will go up only if clinicians notify ADRs," he added.



As per NPVIP rules, companies that place more new drugs in the market are prioritised for systemic PV inspection, depending on categories and frequencies of market launch. Re-inspection frequency will depend on changes to the system since the previous inspection. The regulator will prioritise a company if it comes to know about frequent post-approval changes on marketed medicinal products or gets ADR alerts from government bodies or procurement agencies.
Ref. Pharmabiz

New and updated revision Bulletins of USP-NF

- Bicalutamide Tablets (posted October 26, 2018; official November 1, 2018)
- Doxycycline Hyclate Tablets (posted October 26, 2018; official November 1, 2018)
- Fexofenadine Hydrochloride Tablets (posted October 26, 2018; official November 1, 2018)
- Morphine Sulfate Extended-Release Capsules (posted October 26, 2018; official November 1, 2018)
- Olmesartan Medoxomil Tablets (posted October 26, 2018; official November 1, 2018)
- Oxybutynin Chloride Extended-Release Tablets (updated October 26, 2018; official April 1, 2018)
- Telmisartan and Amlodipine Tablets (posted October 26, 2018; official November 1, 2018)



Stem cell-based Parkinson's therapy tested in Japan

Researchers at Kyoto University in Japan have transplanted 2.4 million induced pluripotent stem cells to the left brain of a male patient in his 50s with Parkinson's disease. The patient, who will be observed for two years, was stable post-transplant and will receive another implant of 2.4 million cells to the right side of the brain if he doesn't develop complications in the next six months.
Ref. Channel NewsAsia

USFDA Grants Non-Opioid Analgesic VVZ-149 Fast Track Status

The Food and Drug Administration (FDA) has fast-tracked VVZ-149 (Vivozon Inc), a non-opioid, non-NSAID analgesic for the treatment of pain.
According to Vivozon, *in vivo* tests have shown that the compound's pain suppressing efficacy is comparable to morphine. A Phase 2b clinical trial of VVZ-149 is ongoing in centers in Korea and the US. The trial is investigating the compound as an IV infusion treatment for postoperative pain following laparoscopic gastrectomy or laparoscopic colorectomy and lumbar radiculopathy. They are also investigating the potential for an oral formulation.
For details: https://www.empr.com

National-level Centre for snake bite antidote to be set up at Haffkine

Intending to save the lives of people from snake bites, an excellent quality anti-snake venom will be set up at the Haffkine Institute within the next two years. The Centre has sanctioned Rs 23 crores to set up a national-level centre for standardisation of antidote for snake poison at Haffkine Drugs Corporation (Haffkine Institute for Training, Research and Testing).
Haffkine Biopharmaceutical Medicines Corporation is a leading institute which has been producing antibiotics in the country. This institute has a major production centre at Pimpri in Pune district. The Haffkine Corporation had submitted a detailed project report to the Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Central Science

and Technology, to set up state-of-the-art centres for standardisation of snake venom in the institute, a state government official said.

According to project reports, which was prepared by Pradhan Mehta, the Managing Director of Haffkine Institute, BIRAC has sanctioned Rs 23 crore for this project. This project will be completed in different phases in the next two years and this will give the country the best quality of anti-venom. Minister of state for Food and Drugs Administration Madan Yeravar had sent a proposal to the Ministry of Biotechnology.

Source: Mumbai Mirror

Indian Eluting Stents reduce risk by half

A 29 to 50 per cent reduction in the risk of probable stent thrombosis has been reported with the use of the Indian Yukon Choice PC stent as compared to American stents.

The stent was earlier imported from Germany and the manufacturer set up its unit in Dehradun from where the stent is being produced for the last five years.

This drug eluting stent is used in the Aarogyasri scheme of the TS and AP governments. It is priced at Rs 20,000 per stent in India. The finding regarding the stent was reported at the scientific session of the American Heart Association.

Dr Syed Immamuddin, professor of cardiology at the Osmania Medical College, said that there were challenges presented with the stents earlier. "They these have now seen major improvements. Along with the improvements in the stents, there has also been increased operating experience by cardiologists which is adding to the benefit."

The randomised control trial presented data of 10 years to the scientific session. Yukon Choice PC is produced by an Indian manufacturer Translumina Therapeutics LLP and is approved for use in India.

The paper was presented in the American Heart Association so that it can be approved for use in America and Europe. The randomised control trial of the stent was carried out at the German Heart Centre, Munich, by Dr Sebastian Kufner.

This is for the first time that a decade-long research data has been presented for efficacy and safety of drug eluting stents. The data presented for stents earlier was only for five years.

Dr Sebastian Kufner in his presentation stated that Yukon Choice PC DES would give long-term success to the procedure of angioplasty. The risk of stent-related major cardiac events in terms of thrombosis has been recorded in the stents. Stent thrombosis is when a blood clot forms in the stent leading to adverse cardiac event and can be fatal too.

In the data comparison with the existing American stents in the market it was found that the adverse risk of cardiac arrest was reduced by 29 per cent in one stent and 50 per cent in another stent. Yukon Choice PC is using a combination of special surface modification and low polymeric load for optimal release of anti-proliferative drugs due to which there is durable performance of the device.

The success of this trial will increase the confidence of cardiologists in using new generation drug eluting stents and also reassure patients according to the research paper which was published in the journal Circulation.

Source: Deccan Chronicle

Congratulations!

Mrs. Manjiri Gharat

for receiving Ishidate Award of FAPA.