Drug Information Bulletin

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&
Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Regulatory Sciences and the profession of Regulatory Affairs is emerging as one of the most important discipline in the Pharmaceutical Profession.

A Pharmacy Graduate or Post Graduate in pharmacy may opt for different specializations like-Research, Manufacturing, Quality Control, Quality Assurance, Marketing etc. Generally they get exposure in the selected field only. A manufacturing Pharmacist generally gets opportunity to manufacture a single category, if not so fortunate to get exposure to all types of manufacturing. Similarly a QC Pharmacist gets hardly any exposure in other areas like -manufacturing, sales etc. But a Pharmacist opting for Regulatory Affairs requires handling of Manufacturing, Quality Control, Product Development, Clinical Trial, and Quality Assurance of medicines. He needs to handle not only Allopathic medicines, but also other systems like -Ayurvedic including Siddha, Unani and Homoeopathy also. A regulatory Pharmacist requires to be an expert on Blood Banks, Medical Devices, Cosmetics etc. as these are integral part of functioning under FDA. Being a regulatory personnel, a pharmacist needs to handle Import and export matters and thus must be an expert in this matter –requiring to be conversant with the regulatory mechanisms like-ICH, USFDA, EDQM, MCA, TGA, WHO certification etc. Regulatory personnel not only deal with Drugs and Cosmetics Acts, but also deal with other related laws like- IPR, Patenting, Copy Rights and Trade Marks, DPCO etc.. This is very important in case of introduction of a new product and even introduction of Generics in other countries. Therefore, RA covers a vast area in the pharmaceutical profession, providing immense opportunity of work. Additionally, there is tremendous scope for Regulatory personnel in Pharma Industry throughout the Globe.

Dr. Subhash C. Mandal
Editor

Nano-crystals improve absorption of drugs

India's National Institute of Pharmaceutical Education and Research has developed a way to convert drug actives into nano-crystals for improved bioavailability. The crystals' small size increases their surface area, enabling them to dissolve more quickly. The method allows for "a faster pharmacological action," said bioavailability expert Piera Di Martino, who cautioned it needs case-by-case evaluation, including stability tests.

Reference: In-PharmaTechnologist.com

EMA's Medical Literature Monitoring Service Goes Operational

The European Medicines Agency (EMA) launched its medical literature monitoring service to help identify suspected adverse reactions and reduce the duplication of such efforts by thousands of pharma and biotech companies.

The service, which aligns with guidance in Good Pharmacovigilance Practices (GVP) Module VI, will see EMA monitoring a total of 400 active substance groups, including 300 chemical active substance groups and 100 herbal active substance groups. The list of active substance groups and a reference to the journals covered by the monitoring service are available here.

The latest service comes after the previous system, where drug makers individually monitored medical literature to report cases of suspected adverse events, led to unnecessarily duplicative efforts tracking the active substances and duplicate reports entered into the EMA safety database known as EudraVigilance, as well as to national safety databases.

The European Union's pharmacovigilance legislation gave EMA the responsibility of monitoring portions of the medical literature for a defined set of active substances and for entering identified reports of suspected adverse reactions into EudraVigilance.

Literature reference databases that will be tracked by EMA include EMBASE, a large and daily-updated and indexed biomedical reference database covering literature from the European Economic Area (EEA) and non-EEA countries; EBSCO, which covers a wide variety of resources; International Pharmaceutical Abstracts (IPA) covering a spectrum of drug therapy and pharmaceutical information from over 800 journals; and the Allied and the Complementary Medicine Database (AMED) covering alternative treatments based on bibliographic records for articles from nearly 600 journals.

"By reducing duplication of reporting from multiple pharmaceutical companies, the initiative will improve the safety monitoring of medicines by enhancing the quality and consistency of data reported in EudraVigilance," EMA said in a statement.

Drug makers will no longer be obliged to enter information from the literature on suspected adverse reactions into EudraVigilance, and individual cases of suspected adverse reactions found in the literature will be made available to drug makers so they can include them in their safety databases and meet their reporting obligations outside the EEA.

EMA said the new service will benefit over 4,000 companies, though companies are advised to consult the list on whether their products are covered. Industry stakeholders previously offered comments on the proposed service back in May.

EMA also sent updates on the implementation of its monitoring service to the qualified persons for pharmacovigilance in pharma companies as well as to pharma industry groups, the agency said.
For details:
http://www.raps.org/Regulatory-Focus/News/2015/09/01/23107/EMAs-Medical-Literature-Monitoring-Service-Goes-Operational/#sthash.WRo4bQHD.dpuf

Monitoring System for Ayurveda Drugs Soon

A common system will be in place soon to keep a tab on 'patent medicines' in ayurveda that are licensed in various states, said sources in the Department of Ayurveda.

The system called Common Acceptable Software, being implemented by the Central Government across the country, is expected to facilitate standardisation of the ayurveda drug manufacturing business. "The new system is believed to be a part of introducing a new national policy for AYUSH, with revised rules/regulations and licensing system. At present, separate licences are granted for drugs manufactured using classical and textual preparation techniques and herbal drug combinations. The existing system will likely be annulled," said Ayurveda Medical Association of India general secretary Rejith Anand.

According to Rejith, the proposed tracking system will help identify drugs prepared using harmful ingredients. "Currently, there are no restrictions on drugs coming from the other states. Normally, drugs containing harmful ingredients are banned once they come to the notice of the Drug Controller for Ayurveda. The new system will keep a check on spurious ayurveda medicines produced in states that do not follow strict norms and regulations," he said.

Drug Controller (Ayurveda) N Vimala said the new monitoring system would help the authorities in checking violation of procedures like toxic study and clinical trail.

In some of the states, the governments do not mandate adherence to the set procedures while granting licence to ayurveda drugs. It is learnt that the authorities in some states even grant licence to drugs the same day on which the manufacturer submits application. The proposed system will standardise the ayurveda medicine manufacturing industry," added Vimala.

Meanwhile, officials at the Department of Ayurveda said that though a plan was mooted by the State Government earlier to set up a platform like the Common Acceptable Software, it did not take off.

Centre approves plan to strengthen drug regulatory system at Rs.1750 cr

The Central government has approved a proposal to spend Rs. 1750 crore for the next 3 years to strengthen the drug regulatory system in the country. In this regard, the Cabinet Committee on Economic Affairs, chaired by the Prime Minister Narendra Modi, has approved the proposal for strengthening the drug regulatory system both at the central and the state levels.

According to a report released by the government, the strengthening or up-gradation of the drug regulatory system will be spread over a period of three years and with a total of Rs.1750 crore. Of which, Rs.900 crore will be spent on strengthening central structures

and Rs.850 crore will be made available to the state governments, after signing a memorandum of understanding.

The up-gradation will include provision of additional equipment and manpower in existing drug testing laboratories; setting up of new laboratories for testing drugs, medical devices and cosmetics; making mobile drug testing laboratories available; creation of additional manpower for regulatory structures, including for new and emerging areas such as stem cell, regenerative medicine, biologicals and medical devices in addition to drugs. The upgradation will also introduce organisation wide e-governance and information technology enabled/online services, and setting up a training academy for regulatory and drug testing officials, of both the central and state governments.

Assistance will be provided to the states for strengthening their drug regulatory structures. The measure will help enhance quality, safety and efficacy of drugs and other medical products manufactured in the country, and thereby help mitigate the disease burden as also increase export of pharmaceutical products from India. Besides, it will also help trigger growth of the domestic medical devices sector.

According to regulatory sources, implementation of the said scheme will facilitate domestic manufacture of quality medical products and help establish a robust industry in the field of medical devices, biological and other areas. The common training programmes for regulatory and laboratory staff will also help in evolving uniform practices throughout the country. “Regular training to drug administrative staff and drug inspectors is very important. We have been demanding the government to strengthen the human resources and laboratory infrastructure. Sending drug inspectors to overseas will help gain knowledge about regulatory systems of other countries and implement the best practices to strengthen our own system,” says Ravi Uday Bhaskar, secretary general, AIDCOC.

Reference: Pharmabiz.com

Forthcoming Events

Seminar on Pharmacy Practice Regulation & Pharmacovigilance

Organizer:
IPA Bengal Branch & B.S.M.C Medical College
Venue: B.S.M.C, LT-1, Bankura
Date: 19.09.2015
Time: 12.30 pm

Pharmacists Day Celebration-2015 by IPA, Bengal Branch

Date: 25.09.2015

- *Pharmacist’s badges will be worn by Pharmacists in all sectors at their work place throughout the state.*
- *Get well soon cards will be distributed amongst the patients in Hospitals (Govt. & Private), clinics & community pharmacies throughout the state.*

Seminars:

- **IPA Auditorium, Kolkata:**
  Seminar on “Impact of Pharmacy Practice Regulation-2015”
  Speaker: Dr. V. Ravichandiran, Director, National Institute of Pharmaceutical Education &Research (NIPER), Kolkata
  Time: 6.00 pm
- **Institute of Pharmacy, Kalyani:**
- **Coochbehar:**
  Seminar on “Impact of Pharmacy Practice Regulation-2015”
  Seminar on “Impact of Pharmacy Practice Regulation-2015”.
  (Jointly with PAWB)