Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291
&
Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Recent notification of Pharmacy Practice Regulation 2015 is a landmark in the history of Pharmaceutical Profession in India, which will certainly help in giving proper shape to the unorganized state of Pharmacy Practice in India. In the present regulation the Pharmacy Practice is well defined and the same has set up certain regulation to regulate the same. The document is available at http://www.pci.nic.in/Circulars/Pharmacy%20Practice%20Regulations.pdf .

Some of our professional demands have got legal approval through this regulation, which are-

1. Pharmacists are require to submit Code of Pharmaceutical Ethics and Pharmacists oath with signature for registration
2. Now “Dispensing” is well defined, which will help to ensure dispensing of medicines through Pharmacists
3. Refresher course is mandatory for renewal of registration
4. Pharmacists can charge for his service, in certain cases
5. Name, qualification & photograph of pharmacist shall be displayed at a prominent place of the premises
6. Pharmacist require to comply with a dress code……..clean white overall with a badge displaying the name and registration number.
7. This regulation has given a structure of pharmacy cadres in different settings especially in case of hospital pharmacy, which will help in career growth
8. Punishment is well defined for misconduct by Pharmacists

It is felt that the Drugs and Cosmetics Act & Rule require to be amended suitably for proper implementation of this regulation. In spite of such a comprehensive regulation in place there are apprehensions from different quarters about proper implementation of the said regulation. It is expected that a consorted efforts of all professional organizations will help in implementation of this regulation and giving a proper shape to the profession.

Dr. Subhashl C. Mandal
Editor

Ministry of health launches Materiovigilance Programme of India (MvPI) to monitor safety of medical devices

In a strategic move to protect the health of the patients, the ministry of health & family welfare approved the commencement of the ambitious Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices in the country. The MvPI was formally launched on July 6 at Indian Pharmacopoeia Commission (IPC), Ghaziabad by Dr G N Singh, Drug Controller General of India (DCGI).

It is understood that while IPC will function as the national coordination centre for MvPI, Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST) will be functioning as National Collaborating Centre for the same. At the same time, the National Health Systems Resource Centre (NHSRC) under the ministry of health will collaborate and work as technical support and resource centre.

While stressing on the importance of this initiative, Dr Singh said this is an important step towards ensuring patient safety measures in the country as medical devices are as crucial and important aspect of healthcare as drugs.

"Considering the current healthcare needs of the country, MvPI is a necessity essential to safeguard the interest of the patients. Thus we would ask all the stakeholders to come forward and support us in this national cause," he added.

He further stressed that this will go a long way in generating India's safety data collection on the medical devices running in the market in a systematic manner so that regulatory decisions and recommendations on safe use of medical devices for India could be based on data generated here.

Dr V Kalaiselvan, Principal scientific officer, IPC informed that following the launch, the technical committee had a high level meeting in which the members of the steering committee and working group took important decisions on identifying the 10 adverse effect monitoring centres and data management system, along with finalising the other aspects relating to the modalities for the same.

Interestingly, this programme is meant to monitor medical device associated adverse events (MDAE), create awareness among health care professionals about the importance of MDAE reporting in India and to monitor the risk-benefit profile of medical devices. It will also play key role in generating independent, evidence-based recommendations on the safety of medical devices so as to communicate its results to the stakeholders.

At present, there is no mechanism to monitor or regulate the use of medical devices in the country against any possible adverse events. Thus experts from the industry strongly feel that this move will finally help in bringing some regulatory semblance to the sector. Especially since monitoring for possible adverse events pro-actively will not only help in ensuring better patient safety but also improve the standard of the industry as well.

Ref. Pharmabiz

Prescriptions in England rise 3.3% but average cost slips

The number of prescriptions dispensed in England in 2014 rose 3.3%, or 34.5 million items, from the prior year, driven by increases in the use of bloodthinners, antidepressants, diabetes drugs and Viagra.

According to the latest figures from the Health and Social Care Information Centre, the overall Net Ingredient Cost

(NIC) of prescriptions stood at £8.85 billion, marking an increase of 2.6% (£227.5 million) from 2013.

But the average NIC per item the item slipped to £8.32 from £8.37 in 2013, having continued its decline over the last decade, when the figure was nearly 30% higher.
Taking a closer look, the figures showed a strong rise - £44.8 million, or 47.8% - in the cost of medicines used to prevent blood clots, which was largely driven by the arrival of three new oral anticoagulants on the market.

In the same vein, atorvastatin, which helps to reduce the likelihood of heart attacks and strokes, also had the greatest increase in the number of items dispensed with 4.0 million more versus 2013.

Elsewhere, cash spent on diabetes drugs was up 7% at £849.1 million, but the HSCIC also noted that the number of prescription items dispensed also grew, by 2.1 million (4.8%), from 2013.

Also notable, there were 57.1 million antidepressant medicines dispensed in 2014, marking a 7.2% increase from 2013, and the number is now 97.1% higher than it was back in 2004. And prescriptions for erectile dysfunction sildenafil - the active ingredient in the Viagra brand - leapt 21.4% to 1.7 million, as cheaper generics entered the market.

The data also show that 89.9% (957.1 million) of prescriptions were issued free-of-charge, of which three in five were picked up by patients over the age of 60, accounting for 51.2% (£4.53 billion) of the overall NIC.
Ref. PharmaTimes (U.K.)

WHO finds violations in Quest Life Sciences' AIDS drugs clinical trial

The World Health Organization has released a notice of concern to Quest Life Sciences in India for mishandling data related to a clinical trial of various AIDS treatments. The WHO suggested the study be rejected after finding that trial paperwork was not completed when it should have been and that some had been backdated. WHO inspectors also found that patient data was altered to allow Quest staffers to use electrocardiograms from other participants in the same trial, and some ECGs were used more than once.
Ref. The Wall Street Journal (tiered subscription model)

Health ministry initiates sampling on spurious, NSQ drugs at 12 notified ports

Following completion of sampling of spurious and not-of-standard quality (NSQ) drugs as a part of a nationwide survey on spurious and NSQ drugs, the Central Drugs Standard Control Organisation (CDSCO) in association with National Institute of Biologicals (NIB) has initiated collection of all formulations and APIs imported into the country through 12 notified ports. The survey is being done in collaboration with Indian Statistical Institute (ISI) and National Sample Survey Organisation (NSSO).
It is a pan-India project in which drug samples were drawn from healthcare institutions and retail pharmacies across the country to assess the quality of drugs available to the common man. This will be followed by testing and analysis of the samples and drafting of the final report. As a part of the survey, samples have been collected from 665 of the total 676 districts of the country based on a statistical design.

Collection of 43000 samples have been done successfully encompassing all the retail drug stores including government medical stores, CHCs and PHCs as part of the pan-India survey. Around 36,000 samples have already been sent for testing at drug testing labs across the country. There are 6 central drug testing labs, 3 state drug testing labs at Maharashtra, Vadodara and Karnataka.

An official associated with the development explained that around 1000 drug inspectors from across the country were trained for the pan-India initiative.

Dr Surinder Singh, director, National Institute of Biologicals (NIB), Noida, is the chairman of the committee conducting the survey. This broad-based survey would help in identifying the geographical areas where spurious drugs are available so that a focused monitoring is done by the concerned authorities in these areas for eliminating the menace of spurious drugs.

Earlier, a survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the ministry of health, which revealed that the extent of drugs found spurious was 0.046 per cent only.

The NSSO had asked the state governments to provide information to arrive at a statistical design for the survey like information such as the number of retail outlets (district-wise); information regarding the maximum prescription of drugs under each of the 15 categories including their trade name district wise; number of civil hospital stores (district-wise); number of central medical store (state-wise); and number of Central Government Health Scheme (CGHS) dispensaries throughout the country.

The CDSCO formulated the survey plan in consultation with NIB for conducting a scientific study on the extent of problems of spurious drugs and drugs not of standard quality (NSQ). Through this initiative between the state and the centre, India will now be able to project a clear statistics on spurious drugs, thus clarifying India's stand on the same with scientific evidence.

Ref. Pharmabiz

Forthcoming Event

IPA-Pharmexcil Technical Conference-2015

Organized jointly:
IPA-RAD, IPA-IPD & IPA-Goa State Branch
Theme: USFDA-Steps for sustained compliance
Date: 26th July 2015
Venue: Hotel Fidalgo, Panjim

Registration & sponsoring the Event:
Mr. Ijaj Khalif,
e-mail:ijajkhalif@cipla.com
Mob. 91-9923757105
Dr. Subhash Rijwani,
e-mail:sbrijwani@gmail.com, Mob. 91-983036936
Dr. Subhash C. Mandal,
e-mail:subhash.mandaldr@gmail.com, Mob. 91-9830136291