Drug Information Bulletin

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Content

Editorial

The Ministry of Health and Family Welfare, Government of India conducted a "Survey of Extent of Problems of Spurious and Not of Standard Quality (NSQ) Drugs in the Country. Detailed report available at http://www.nib.gov.in/.

Programme was designed by an expert committee headed by Dr. Surinder Singh, Director I/C, National Institute of Biologicals, Noida. Statistical design of the training module was done by ISI, Kolkata, ISI, Hyderabad & NSSO, Kolkata. 28 Drug Control officers & 28 Civil Society members were appointed as trainers from different states who undergone Training for Trainers (TOT) at NIB during January 2012. These trainers provided training to the 899 Drug Control officers, Civil Society representatives & Pharmacy Council Members at 28 centres throughout the country.

A total of 47,954 samples were drawn under the survey by State and Central drug inspectors. Drug samples drawn were tested in the seven Central and three State Government Drug Testing Laboratories. All of these laboratories are accredited by NABL. The laboratory test/analysis data was analysed by Indian Statistical Institute, Hyderabad.

In case of Govt. sources state wise, NSQ percentage estimates varied from 0 to 17.39% percent (with the exception of Sikkim); States like Meghalaya, Mizoram, Arunachal Pradesh, Nagaland, Telangana, Uttarakhand, Uttar Pradesh and Punjab were on the higher side of NSQ (11.39 - 17.39%) whereas Chandigarh, Delhi, Orissa, Tamil Nadu and West Bengal were on the lower side of NSQ (0 - 7.93%).

In case of retail outlets state wise, NSQ percentage estimates for Retail Outlets varied from 0 to 8.82% (with the exception of Lakshadweep); States/UTs like Mizoram, Nagaland, Meghalaya, Manipur, Tripura, Puducherry, Gujarat, and Punjab were on the higher side of NSQ (4.20 – 8.82%) whereas, States/UTs like Andaman and Nicobar Islands, Dadra and Nagar Haveli, Goa, West Bengal, Delhi, Jharkhand and Kerala were on the lower side of NSQ (0 - 1.97%).

The extent of NSQ and Spurious Drugs for Retail Outlets and Government sources in the country was estimated to be 3.16% and 0.0245% respectively.

This is one of the largest scientific survey on determining extent of spurious and NSQ drug available in India, which will help to end the controversial data published by media in earlier occasions.

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NPPA has fixed/revised ceiling prices of 18 scheduled formulations of Schedule-I under Drugs (Price Control) Amendment Order, 2016 under DPCO, 2013

NPPA has fixed/revised ceiling prices of 18 scheduled formulations of Schedule-I under Drugs (Price Control) Amendment Order,2016 under DPCO, 2013 in related Notification /order dated 10.03.2017 vide nos. 787 (E) & 788(E). The formulations are- Griseofulvin 375 mg Tablet, Methyldopa -500mg, Human normal immunoglobulin, Vitamin A –50000 IU Tablet, Calamine (As per IP), Amphotericin B Powder for Injection-Conventional, Amphotericin BPowder for Injection-Lipid/ Liposomal, Acetylsalicylic acid Tablet -100mg, Verapamil Inj. -2.5mg/ml, Verapamil Tablet-80mg, Methyldopa Tablet -250mg, Vitamin A Inj. -50000 IU/ml, Furosemide Tablet-40mg, Furosemide Inj. -10mg/ml, Spironolactone Tablet -25mg, Bupivacaine Inj. -0.5% with 7.5% Glucose, Lignocaine Topical Form 2-5%, Verapamil Tablet -40mg. The details are available at http://nppaindia.nic.in/whatsnew.htm

22 medical devices have to carry Maximum Retail Price (MRP)

After controlling prices of stents, India's drug pricing regulator, National Pharmaceutical Pricing Authority (NPPA), has made it mandatory for the manufacturers and importers of "notified" medical devices to carry maximum retail price (MRP) on the packs. These devices include heart valves, catheters, bone cements, surgical dressings, condoms, stents, disposable hypodermic syringes, orthopaedic implants, intra ocular lenses, umbilical tapes, intra uterus devices among others.

"It has come to knowledge of the NPPA that several medical devices are available in the market and are also being used in healthcare facilities where no MRP is printed on the package by manufacturers/importers," the NPPA said in a notification. This is a blatant violation of law of the land, it added. The government has notified 22 medical devices as drugs under the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetic Rules, 1945, it said. In its tweet, the NPPA said: "Total 22 medical devices notified as 'drugs' must print MRP on the packs under DPCO, 2013; state govts/state drug controllers requested to enforce law."

Sources said the notification was issued following complaints from the patients being charged exorbitant prices on these medical devices. "All the manufactuers are advised to ensure compliance of provisions, otherwise they will be liable to deposit the overcharged amount with interest".

These devices are non-scheduled formulations and their sales are governed by the provisions of DPCO 2013, the notification said. The prices of non-scheduled formulations are monitored by the government. Manufacturers are not allowed to increase the price of these more than 10 per cent per annum, NPPA said.

Sources said that the move is expected to bring transparency and relief to consumers who could otherwise be taken for a ride as their prices are neither monitored nor controlled.

The NPPA had recently announced major price cuts for cancer drugs, up to 86 per cent in some cases and reduced cardiac stent prices by over 75%, capping the ceiling prices of drug eluting stents and bioresorbable vascular scaffolds (BVS) at Rs 29,600, and bare metal stents (BMS) at Rs 7,260, including VAT, these stents are expected to cost Rs 31,080 and Rs 7,623, respectively.

National Programme for prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke

with integration of Ayurveda, Homoeopathy and Unani

The ancient systems of medicine follow a holistic approach focused on of the individual (patient) while treating the patients for a specific disease whereas the Modern system of medicine focuses on the disease, thus, the two approaches are fundamentally different from each other.

The Ministry of AYUSH through its three research organizations. namely, Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Homoeopahty (CCRH) and Central Council for Research in Unani Medicine (CCRUM) have launched a programme to integrate Ayurveda, Homoeopathy and Unani with National Programme for prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS).

The major objective of the programme is prevention and early diagnosis of these diseases, reducing complications and reducing drug dependency through these systems.

This information was given by the Minister of State (Independent Charge) for AYUSH, Shri ShripadYesso Naik in reply to a question in Lok Sabha on 10th March 2017.

Phenylephrine and acetaminophen Drug-drug interaction, increased blood concentrations of phenylephrine: no significant risk to healthy consumers

Health Canada has helped raise awareness of a drug interaction between phenylephrine and acetaminophen among healthcare professionals and consumers. Although the interaction may lead to an increased amount of phenylephrine in the body; to date there is no evidence to show that this is a significant risk to healthy consumers. Phenylephrine and acetaminophen are drugs often found together in nonprescription health products used to relieve symptoms from the common cold, flu and allergies. Health Canada initiated a safety review following a report by the EMA about the potential drug-drug interaction between phenylephrine and acetaminophen. People who have high blood pressure or heart disease may be more vulnerable to the adverse effects of phenylephrine if taken together with acetaminophen due to an increase in concentrations of phenylephrine in the body (increased bioavailability). At the time of the review there was one Canadian report of increased blood pressure suspected to be due to a drug interaction between phenylephrine and acetaminophen. After further assessment, it was found that after adjusting pre-existing medication used for blood pressure the blood pressure returned to normal. There is one published report in the scientific literature of intracerebral haemorrhage in a person taking multiple cough and cold medicines containing phenylephrine over a 30-day period. It could not be confirmed that this event was due to an interaction between phenylephrine and acetaminophen. Overall, the safety data reviewed by Health Canada were lacking relevant information to determine if the drug-drug interaction between phenylephrine and acetaminophen causes adverse events.

Reference: *www.hc-sc.gc.ca*

Sodium bicarbonate Minimizing risk of intraventricular haemorrhage in pre-mature neonates

The Egyptian Pharmaceutical Vigilance Center (EPVC) has made recommendations to minimize the risk of intraventricular haemorrhage in premature neonates during administration of sodium bicarbonate injection. Sodium bicarbonate injection used in neonates is indicated for:

- correction of metabolic acidosis associated with cardiac arrest in patients with pre-existing metabolic acidosis;

- cardiac arrest associated with hyperkalaemia with pre-existing metabolic acidosis; and
- life threatening hyperkalaemia with preexisting metabolic acidosis.

The recommendations are:

4.2% solution or 8.4% solution should be diluted with 5% dextrose 1:1; clinical need should be carefully considered before administration because rapid administration at a high concentration may be associated with fluctuation in cerebral blood flow and possibly intracranial haemorrhage. The recommendations follow a report received at a regional centre in Egypt. A premature male neonate (26 weeks of gestation, 0.9 kg weight) received sodium bicarbonate 8.4 % to treat metabolic acidosis at a dose of dose 2mEq/kg and then developed intraventricular haemorrhage two days after drug administration. The patient died the following day.

Reference: EPVC Newsletter, EPVC, Volume 8, Issue 1, January 2017

Pics from Seminar on "Contemporary issues on Pharmaceutical Regulatory Affairs" organized by Regulatory Affairs Division (RAD) jointly with IPA-Jharkhand Branch

DISCLAIMER:

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.