Drug Information Bulletin

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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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New Drug: Cisatracurium besylate

2 mg/mL in 2.5 mL and 5 mL ampoules
5 mg/mL in 30 mL vials

Indication: muscle relaxation

Atracurium is a non-depolarising neuromuscular blocker. The molecule has several isom-ers, one of which is cisatracurium. This isomer also causes neuromuscular blockade, prob-ably by competing for cholinergic receptors on the motor end-plate. It is probably more potent than atracurium.

For tracheal intubation, cisatracurium is given as a bolus injection. During surgery or mechanical ventilation, neuromuscular blockade can be maintained by repeat injections or an infusion. After a bolus dose, the patient will be ready for intubation in 2-3 minutes. Higher doses shorten the time to onset of neuromuscular block, but this increases the time to spontaneous recovery. In general, cisatracurium has an intermediate duration. Depending on the dose given, spontaneous recovery is complete within an hour. Recovery can be speeded by giving an anticholinesterase.

As cisatracurium degrades in the body, its elimination is largely organ independent. No dose alterations are required in hepatic or renal failure.

Cisatracurium appears to be as safe as atracurium. Adverse effects include bronchospasm, bradycardia, hypotension, rashes and flushing. The risk of histamine release is unlikely to be greater than that of atracurium. The effect of cisatracurium is influenced by interactions with many commonly used drugs.

At present, it is uncertain if cisatracurium will have any significant clinical advantages over atracurium.

First published online 1 April 1997

Ref.: Aust Prescr 1997;20:45-51 | 1 April 1997

Status in India:

Cisatracurium Besylate Bulk & 2mg/ml injection has been approved by DCGI on 14.03.2016 as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery.

FDA approves Seqirus' Flucelvax Quadrivalent flu vaccine

The Food and Drug Administration has approved Seqirus' Flucelvax Quadrivalent, the first four-strain cell structure-derived inactivated influenza vaccine for adults and children over 4 years of age.

The quadrivalent vaccine covers two strains each of influenza A and influenza B and is derived from a cell culture — the same cell culture technology the company used in its first product Flucelvax.

"Flucelvax Quadrivalent will provide healthcare providers and their patients with an important option to further broaden their influenza coverage," Seqirus president Gordon Naylor said. "We are pleased to offer Flucelvax Quadrivalent, which is produced at our full-scale cell culture influenza vaccine manufacturing facility in North Carolina, to our valued customers during the 2016-2017 flu seasons."

Ref.:
http://www.drugstorenews.com/article/fda-approves-seqirus-flucelvax-quadrivalent-flu-vaccine

Drug Alert

The preliminary analysis of SUSARs from the PvPI database reveals that the following drugs are associated with the risks as given below.

1. Phenytoin: Angioedema
2. Osteoporosis
3. Risk of ulcer complication
4. Hyponatraemia
5. Risk of cardiac failure

Health care professionals, Patients/Consumers are advised to closely monitor the possibility of the above

adverse events while prescribing/consuming above suspected drugs and 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. 18001803024.

Piperacillin and tazobactam combination Risk of bronchospasm and hypokalaemia

The CDSCO has requested that bronchospasm and hypokalaemia are included as adverse reactions in the package insert for combination products of piperacillin and tazobactam. The request follows the recommendation received from the Pharmacovigilance Programme of India - Indian Pharmacopoeia Commission (PvPI-IPC). Piperacillin and tazobactam are used as antibiotics in combination. Based on available evidence and advice of the subject expert committee, CDSCO/PvPI have decided that it was necessary to revise the package insert to add hypokalaemia and bronchospasm as clinically significant adverse reactions.
Reference: Central Drugs Standard Control Organisation, February 2016 (www.cdsco.nic.in)

Piperacillin containing products (alone or in combination with tazobactam) Risk of Drug Reaction/Rash with Eosinophilia and Systemic Symptoms (DRESS)

Health Canada has updated the prescribing information for the drug combination piperacillintazobactam to include a warning statement for the risk of drug reaction/rash with eosinophilia and systemic symptoms (DRESS), and as a potential adverse effect for piperacillin alone. Piperacillin is an antibiotic that is available alone or in combination with a product that enhances piperacillin activity (tazobactam). Both products are administered into a vein (intravenously) or in a muscle (intramuscularly) and are used to treat different types of infections. Health Canada carried out a safety review to evaluate the potential link between the antibiotic drug combination piperacillin and tazobactam or piperacillin alone and DRESS. At the time of Health Canada's review, two cases of DRESS suspected of being linked with the drug combination piperacillin and tazobactam were reported in Canada. Both cases were considered to be linked to the piperacillintazobactam drug combination. In the published literature 17 cases of DRESS linked with the drug combination piperacillin and tazobactam were also identified. One case out of 17 resulted in death; however a direct association with the drug combination could not be established due to pre-existing health problems. In 10 cases, the patients recovered after stopping the combination treatment with or without additional treatment. The six remaining cases could not be assessed further because the information contained in the reports was incomplete. Additional investigation of a subset of the 17 cases suggests that the role played by piperacillin alone could not be excluded. Health Canada concluded that there is evidence of a link between the drug combination piperacillin and tazobactam and Drug Reaction/Rash with Eosinophilia and Systemic Symptoms (DRESS).
(See WHO Pharmaceuticals Newsletters No.1, 2016: Risk of acute generalised exanthematous pustulosis in Japan)
Reference: Summary Safety Review, Health Canada, 24 February 2016 (www.hc-sc.gc.ca)

Britain's Defense Ministry restricts use of Roche's anti-malarial drug for troops

Britain's Ministry of Defense has given a directive that Roche's anti-malarial drug Lariam be used only as a last resort for troops getting ready for deployment, due to the drug's adverse side effects. UK

service personnel should only be prescribed Lariam if all other alternative treatments prove intolerable, and after the patient has been individually assessed and made aware of the risks, the Defense Committee said.
Ref.: European Pharmaceutical Review (U.K.)

Parkinson's treatment introduced in UK

Zambon and Newron Pharmaceuticals launched Parkinson's treatment Xadago, or safinamide, in the UK. European regulators approved the drug more than a year ago, and it is already available in Germany, Switzerland, Spain, Italy, Belgium, Denmark and Sweden.
Ref.: PharmaTimes (U.K.)

Global health care wearable devices market to reach $18.9B in 2020

A Frost & Sullivan analysis predicts the global market for health care wearable devices will reach $18.9 billion in 2020, at a 29.9% compound annual growth rate. The clinical-grade wearables market is forecast to grow at a CAGR of 32.9%, and the report predicts that wearables that monitor patients with chronic conditions, as well as those that perform other clinical applications, will transform how health care is provided.
Ref.: HIT Consultant

Medical devices may need licenses to be sold soon

New Delhi, 3 June 2016: Medical devices such as stents, catheters, orthopaedic implants, heart valves and syringes are set to face stringent scrutiny as the government plans to make regulatory approval mandatory for all such products sold in the country, sources said.

Currently, only 22 medical devices are notified in the country, requiring registration and licence for selling in the market. The latest proposal would mean companies will have to seek regulatory approval prior to launching a product in the local market. Besides, the proposal, aimed at ensuring safety and affordability of medical devices, also suggests inclusion of all such products under the National List of Essential Medicines to bring them under government price control, a source said.

The proposal, once implemented, can be a major blow to the medical devices industry, pegged at over Rs 47,000 crore.

The government has already finalised a plan to set up a testing laboratory for medical devices in Vadodara (Gujarat). The laboratory-first of its kind in India-will also certify medical devices approved and sold in India. The government may also outsource part of the quality certification process to standardising bodies such as BIS or some global solution providers.

"Some devices are as important as life saving drugs. Many of these products are implanted into human body for critical care and therefore, it is very important to keep a check on their quality. If not regulated, patients may fall victim to poor quality medical devices," an official said. At present, only few reputed companies voluntarily get quality certification from standardising bodies like BIS.

For a long time, the health ministry has been trying to regulate the medical device industry. However, it has so far failed to do so given the government's simultaneous push for 'Make In India' drive and need for attracting FDI.

The Drugs and Cosmetics (Amendment) Bill, 2015, which is waiting to be tabled in Parliament, also proposes to introduce a separate chapter on medical devices, classifying them based on their risk parameters.
Ref. The Times of India.

Forthcoming Event

26th FAPA Congress 2016

Bangkok, Thailand 9-13 November 2016

"Integrating Asian Pharmacy Wisdom for Better Global Health."

Venue:

Bangkok International Trade and Exhibition Centre
88th Bangna - Trad Road,
Bangna, Bangkok 10260, Thailand
Tel.+66 2 749 3939
www.bitec.co.th

Registration

	Before 31 July 2016	After 31 July2016
Participant	USD 350	USD 400
Accompanying persons	USD 150	USD 200
Student	USD 150	USD 200

สำหรับคนไทย	ก่อนวันที 31 ก.ค. 2558	หลังวันที 31 ก.ค. 2558
ผู้เข้าประชุม	4,500 บาท	5,000 บาท
ผู้ติดตาม	2,500 บาท	3,000 บาท
นิสิต/นักศึกษา	2,500 บาท	3,000 บาท

http://www.fapa2016.com/15616273/details-of-payment

Abstracts

Abstract submission time line
FAPA 2016 Bangkok, 9-13 November 2016

Activities	Period
- Open abstract submission	1 January 2016
- Last day for abstract submission	15 June 2016
- Acceptance of submitted abstract	15 July 2016
- Oral and poster present day	10-13 November 2016