Drug Information Bulletin

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Content

Editorial

On its 78th meeting DTAB constituted a sub-committee under the Chairmanship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai. The supreme court in its order dated 15.12.2017 has directed that the matter of notification issued by the Govt. of India prohibiting 344 FDCs + 05 FDCs vide S.O. No. 705 (E) to 1048 (E) dtd. 10.03.2016 and S.O. No. 1851 (E) to 1855 (E) dtd. 08.06.2017 (www.cdsco.nic.in) should go to the DTAB and/or its sub-committee formed by the DTAB for the purpose of having a relook into these cases. The committee not only hear the petitioners / appellants before but they also hear submissions from All India Drugs Action Forum (AIDAN). The DTAB / sub-committee set up for the purpose will deliberate on the parameters set out in section 26 A of the Drugs & Cosmetics Act.

A few years back DCGI published a list of FDCs as irrational, but those were available in the market as a result of some litigation. Again DCGI has given a direction to submit Safety and Efficacy data of the FDCs available in the market without approval from the DCGI with a deadline on 30th August 2013. After 2013 there were several exercise by the DCGI and ultimately they have banned about 344 irrational combinations vide S.O. 705 (E) to 1048(E) dated 10.03.2016 and S.O. No. 1851 (E) to 1855 (E) dtd. 08.06.2017. Mainly FDCs of NSAIDs and FDCs of antibiotics are banned besides other therapeutic categories. This is a unique occasion that a huge number of drugs have been banned by the Indian regulators. Sources revealed that these moves made some of the pharmaceutical manufacturers in an uncomfortable position and they went to the court of law. However the Health activists who are fighting to eradicate irrational drugs/combinations since last few decades are quite satisfied. Experts feel that this step of DTAB may resolve this issue.

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A vertical structure has been created under CDSCO for regulation of AYUSH system of medicines

Ministry of Health & Family Welfare, Govt. of India created a vertical structure of AYUSH within CDSCO on and from 5th February 2018 for regulation of Ayurvedic, Siddha, Unani and Homoeopathy (AYUSH) drugs in terms of the Drugs & Cosmetics Act, 1940 and the Rules 1945.

For this purpose 9 posts have been created, which are-

Deputy Drugs Controller (Ayurveda)-01
Deputy Drugs Controller (Homoeopathy)-01
Assistant Drugs Controller (Ayurveda)-01
Assistant Drugs Controller (Unani)-01
Assistant Drugs Controller (Siddha)-01
Drugs Inspector (Ayurveda)-01
Drugs Inspector (Unani)-01
Drugs Inspector (Homoeopathy)-01
Drugs Inspector (Siddha)-01

In the mean time the Technical Officers of the Ministry of AYUSH will look matter the work of these posts in addition to their normal duties and will be responsible to carry out the regulatory work as assigned to them in accordance with the relevant provisions of the Drugs & Cosmetics Act 1940 and Rules 1945 till further order or till regular incumbents are appointed.

Source: Notification dated 05.02.2018

Intraocular injections of a compounded triamcinolone, moxifloxacin and vancomycin (TMV) formulation not recommended for use during cataract surgery

The US FDA has stated that the prophylactic use of intraocular vancomycin, alone or in a compounded drug combining multiple active ingredients such as triamcinolone, moxifloxacin, and vancomycin (TMV) formulation, is generally not recommended for use during cataract surgery because of the risk of haemorrhagic occlusive retinal vasculitis (HORV).

Intraocular vancomycin is used by many ophthalmologists during cataract surgery with the intent of preventing postoperative endophthalmitis. There is no FDA-approved vancomycin formulation for intraocular injection. The formulation is usually prepared at the surgical site or obtained in advance of surgery from a compounding pharmacy. The FDA received a report in August 2017 of bilateral HORV in a patient following injections of a compounded TMV formulation in each eye after cataract surgery procedures that were done two weeks apart. No cases of HORV were reported in a retrospective analysis of medical records of 922 patients (1541 eyes) who underwent cataract surgeries with intravitreal injections of compounded TMV formulations from November 2013 to December 2015. The adverse event being reported here serves as a reminder that intraocular administration of vancomycin, including when the vancomycin is one of multiple active ingredients in a compounded drug, can result in HORV.

Reference: Drug Safety Communication, US FDA, 3 October 2017 (www.fda.gov)

Hydroxyethyl-starch containing medicines new review of benefit-risk balance

The EMA has initiated a safety review of benefits and risks of medicines containing hydroxyethyl-starch (HES). HES containing products are used for the management of hypovolaemia (low blood volume) caused by acute (sudden) blood loss, where treatment with alternative infusion solutions known as 'crystalloids' alone is not considered to be sufficient. HES medicines are given by infusion into a vein and are used as blood volume expanders to prevent shock following acute bleeding. The review was after utilization studies indicated that HES containing medicines were being used outside their authorised uses, including in critically ill patients and those with sepsis and kidney injury, despite restrictions introduced in 2013 to reduce the risks of kidney problems and deaths. The drug utilization studies had been requested by EMA's PRAC in 2013 in order to verify adherence to restrictions. The PRAC will review the results of these studies and all other available data, and assess the impact on the benefit-risk balance of HEScontaining

medicines for infusion, and issue a recommendation on whether marketing authorizations should be maintained, varied, suspended or withdrawn across the EU.
Reference: News and press releases, EMA, 27 October 2017 (www.ema.europa.eu)

Amoxicillin containing products risk of thrombocytopenia

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package inserts for amoxicillin preparations have been updated to include the risk of thrombocytopenia as a clinically significant adverse reaction. Amoxicillin is an antibiotic used for the treatment of a number of bacterial infections. A total of nine cases of thrombocytopenia associated with use of amoxicillin have been reported in Japan. Of these, a causal relationship could not be excluded in five cases.
Reference: Revision of Precautions, MHLW/PMDA, 17 October 2017 (www.pmda.go.jp/english/)

Green tea extract containing natural health products Potential risk of liver injury

Health Canada has decided to strengthen the cautionary risk statement in the monograph for green tea extracts to include the advice on the potential risk of liver injury. Green tea extract-containing natural health products are used to help manage weight loss (along with diet and exercise) and as a source of antioxidants for the maintenance of good health. Health Canada reviewed the potential risk of liver injury associated with green tea extract because of ongoing reports of serious liver injuries worldwide, including a recent report in Canada. Health Canada's review concluded that there may be a link between the use of green tea extract and the risk of rare and unpredictable liver injury. While this risk is already identified in Health Canada's green tea extract's monograph, warnings will be strengthened. The safety review also recommended that green tea extract products should be used by adults only.
Reference: Summary Safety Review, Health Canada, 15 November 2017 (www.hc-sc.gc.ca)

US FDA Alert: Clarithromycin risky in patients with heart disease

Healthcare providers should exercise caution when prescribing the macrolide antibiotic Clarithromycin (Biaxin, generics) to patients with coronary heart disease because of a potential increased risk for heart problems or death that can occur years later, the US Food and Drug Administration (FDA) said in a safety communication.
The FDA's recommendation is based on 10-year follow-up results of the CLARICOR study, which found an "unexpected" increase in deaths among patients with coronary heart disease who received a 2-week course of Clarithromycin that became apparent after patients had been followed for at least 1 year, the agency said.
The FDA first issued an alert on Clarithromycin in 2005, before the 10-year follow-up results from CLARICOR were available, but did not recommend any specific changes to the use of Clarithromycin at that time.
On the basis of the new data, the FDA has added a new warning about the increased risk for death in patients with heart disease and advised prescribers to consider using other antibiotics in such patients. The study results have also been added to the Clarithromycin label.
Clarithromycin is used to treat a variety of infections affecting the skin, ears, sinuses, lungs, and other parts of the body, including Mycobacterium aviumcomplex (MAC) infection, a lung infection that often affects people with HIV, the FDA alert notes. It is not approved to treat heart disease.
The FDA said there is "no clear explanation" for how Clarithromycin would lead to more deaths than placebo. Of the six observational studies published to date in patients with or without coronary artery disease, two found evidence of long-term risks from Clarithromycin and four did not.

"Overall, results from the prospective, placebo-controlled CLARICOR trial provide the strongest evidence of the increase in risk compared to the observational study results," the FDA said.

They said it was unclear at present whether results of the CLARICOR trial can be applied to patients who do not have heart disease.

The FDA advises healthcare professionals to be aware of these "significant risks and weigh the benefits and risks of Clarithromycin before prescribing it to any patient, particularly in patients with heart disease and even for short periods, and consider using other available antibiotics."

The FDA is continuing to monitor safety reports in patients taking Clarithromycin. The agency encourages healthcare providers to report adverse events or side effects related to Clarithromycin to MedWatch, the FDA's safety information and adverse event reporting program.

Source: Medscape

Curbs on Oxytocin production and trade to check misuse

The Union government has decided to restrict the manufacture of Oxytocin, known as the "cuddle hormone", in the country and ban its import and export to stop the widespread misuse of the drug in the dairy industry.

The curbs are being introduced after attempts to regulate the supply of Oxytocin failed. All private manufacturers— about 130 companies have the licence to make the hormone—will be "slowly phased out", a top government official said.

Only a Bengaluru-based state-owned pharmaceutical company will manufacture the hormone in the quantity required for medical purposes, said another government official.

Oxytocin will be made available only to hospitals and sale of the hormone by private entities will be banned, the official said. To ensure there is no misuse, Oxytocin will be supplied in barcoded packages.

The hormone released by the pituitary gland is responsible for human behaviour associated with relationships and bonding. It causes uterine contractions during labour and helps new mothers lactate.

However, the hormone is misused to increase the size of some vegetables.

In the dairy industry, livestock are often injected with the hormone to spur the release of milk. The drug in the milk can eventually reach humans and cause medical problems such as nausea, early puberty and foetal damage.

The drug booster has also been reportedly misused among trafficked children to accelerate puberty among girls.

The Central Drugs Standard Control Organization ordered drug controllers last year to crack down on the misuse of the controversial growth drug. "Several steps to regulate the supply of Oxytocin have remained unsuccessful.

It was the need of the hour to ban the import and export of the hormone so that no further damage is caused," said a senior government official on condition of anonymity

SOURCE: ET HEALTH WORLD

Forthcoming Event

Refresher course for registered pharmacists

Organized by: IPA Bengal Branch

Schedule:

25.02.2018: IPA Auditorium, Kolkata

03.03.2018 & 04.03.2018: Bankura Medical College, Bankura

17.03.2018: DSP Main Hospital

25.03.2018: Tamluk, Purba Medinipur