Drug Information Bulletin

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Content

Editorial

WHO is publishing Model List of Essential Medicines since 1977 which is being updated every 2 years and the latest one is 19th edition published 1n the year of 2015. They also publishing Model List of Essential Medicines for the Children since 2002 and the latest one being the 5th version published in 2015. The list presents a list of minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost–effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. WHO is publishing Model Formulary of the medicines included in the Model List of Essential Medicines to provide independent information on essential medicines for pharmaceutical policy-makers and prescribers worldwide. For each medicine the Formulary provides information on use, dosage, adverse effects, contraindications and warnings, supplemented by guidance on selecting the right medicine for a range of conditions. WHO has adopted a specific structure and sections like Model List of Essential Medicines, but **any country or organization** can adopt any other structure for their own purpose. As a result like several countries round the globe Government of India has published 4th edition of National Formulary of India in 2011. Govt. of India has earlier published three versions in the year of 1960, 1966 and 1979. There are several other Formularies published by several organizations to meet their specific need which is not always common with other Like- Essential Drug Formulary 2006 published by Delhi Society for Promotion of Rational Use of Drug, Hospital Formulary of SRM University, India. Adoption of formularies at the National, Regional & Institutional level is useful for providing independent information on medicines used by the concerned health facilities.

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Aspirin-containing over-the-counter antacid products serious bleeding risk

The US FDA has warned consumers about the risk of serious bleeding when using over-the-counter (OTC) aspirin-containing antacid products to treat heartburn, sour stomach, acid indigestion, or upset stomach. In 2009, a warning about the risk of serious bleeding was added to the labels of all OTC aspirin-containing antacid products. However, a search of the FDA Adverse Event Reporting System (FAERS) database identified eight cases of serious bleeding events associated with these products after the warning was added. All of these patients were hospitalized. As a result, the FDA will continue to evaluate this safety concern and plan to convene an advisory committee of external experts to provide input regarding whether additional actions are needed.

Reference: Drug Safety Communication, US FDA, 6 June 2016 (www.fda.gov)

Metformin Precaution during administration of contrast media

The Egyptian Pharmaceutical Vigilance Center (EPVC) has reminded health-care professionals of precautionary measures needed during the administration of contrast media, in patients taking metformin. Metformin is an oral medicine used to control blood sugar levels in type 2 diabetes. The EPVC has advised that metformin should be temporarily stopped in patients who undergo an X-ray or CT scan using contrast dye, because such interventions with iodinated materials may result in acute alteration of renal function. This Precaution is already mentioned in Egyptian labels of metformin-containing products. The EPVC has stated that metformin must be withheld after the administration of the contrast agent for 48 hours to avoid this complication. If renal function is normal at 48 hours, metformin can be restarted.

Reference: Newsletter, EPVC, Volume 7, Issue 6, June 2016

Loperamide Serious heart problems with high doses

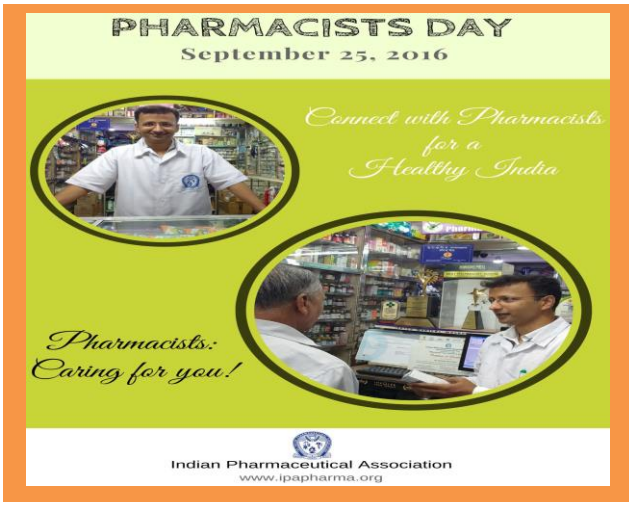
The US FDA has warned that taking higher than recommended doses of loperamide (Imodium®), can cause serious heart problems that can lead to death. The risk of these serious heart problems, including abnormal heart rhythms, may also be increased when high doses of loperamide are taken with several kinds of medicines that interact with loperamide. Loperamide is approved to help control symptoms of diarrhoea, including travellers' diarrhoea. Loperamide can be obtained over the counter (OTC) and the maximum approved daily dose for adults is 8 mg per day for OTC use and 16 mg per day for prescription use. The majority of reported serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide in attempts to selftreat opioid withdrawal symptoms or to achieve a feeling of euphoria. The FDA continues to evaluate this safety issue and will determine if additional FDA actions are needed. The FDA has advised that health-care professionals should be aware that use of higher than recommended doses of loperamide can result in serious cardiac adverse events. Loperamide should be considered as a possible cause of unexplained cardiac events including; QT interval prolongation, torsades de pointes or other ventricular arrhythmias, syncope, and cardiac arrest.

Reference: Drug Safety Communication, US FDA, 7 June 2016 (www.fda.gov)

Miconazole (topical use including oral gel) Potential for serious drugdrug interactions with warfarin

The MHRA is considering the use of further measures to minimize the risk of potentially serious interactions between miconazole and warfarin, to prevent bleeding. Miconazole (Daktarin® and Daktacort®) is an antifungal indicated for prevention and treatment of various infections of the mouth, throat, skin, nails, or genitals. Warfarin is an oral anticoagulant that has been widely used for prophylaxis of thromboembolic events. Up until 13 April 2016, the MHRA has received 146 reports of possible drug interactions between miconazole and warfarin. Most reports concerned the oral gel form of miconazole. The potential for drug interactions between miconazole and warfarin is well established. The mechanism is understood to be inhibition by miconazole of one of the main cytochrome P450 isozymes involved in warfarin metabolism (CYP2C9), resulting in reduced warfarin clearance and an enhanced anticoagulant effect. The MHRA is currently reviewing available data for this interaction. This review follows a coroner's report of a death, which may have been partly due to the coadministration of miconazole oral gel and warfarin. Further advice will be communicated as appropriate when the review is complete.

Reference: Drug Safety Update, MHRA, Volume 9, issue 11:3, June 2016 (www.gov.uk/mhra)



TB patients in India could be much higher: Study published in Lancet

Number of patients suffering from tuberculosis in India could be much more than those previously estimated by the Government of India, according to a new study published in Lancet Infectious Diseases Journal. The study, based on sale of TB cure medicines during 2013-14, estimates the number of patients seeking treatment with private physicians could be two to three times higher.

The study claims that up to 22 lakh patients may have sought treatment with private doctors in 2014, spending upto Rs 395 crore as out-of-pocket expenses. These patients would have escaped the purview of the National TB Control Programme, run by the GoI and went unaccounted for. Only over a lakh TB cases were reported by private doctors to the government during that year, though it is mandatory for them to report cases.

In 2014, as per GoI records, 14 lakh TB patients had approached public hospitals to seek care under Revised National Tuberculosis Programme (RNTCP).

The study took into consideration the nation-wide drug sales data of 189 branded anti-TB medicines, containing components such as Isoniazid, Rifampacin, Ethambutol and Pyrazinamide, among others. The researchers then arrived at an estimate of how many patients may have been put on such treatments by private physicians during the year, by analysing the volume of drugs sold.

"An average of 22 lakh patients sought medication from private sector doctors that year. Our estimate was 8 lakh patients, and the new numbers - close to three times higher - are glaring. The under-reporting occurs as private physicians fail to report cases to the government," said Dr Sunil Khaparde, deputy director general (TB), Ministry of Health and Family Welfare.

"These patients also ended up spending over Rs 395 crore as out-of-pocket expenses for drugs alone in 2014, when the government was offering free treatment in public sector.

The annual budget of RNTCP is Rs 640 crore, which is spent on patient care as well as on drugs," said Dr Khaparde.

Uttar Pradesh is the worst hit, with 2.45 lakh patients getting treated under RNTCP and almost a double around 5.6 lakh receiving treatment in the private sector under the 9-month TB drug regimen. Maharashtra is a close second with 1.33 lakh patients getting treated under RNTCP, and 1.8 lakh patients seeking private care.

"In terms of volume of TB care given by public and private sectors, Bihar recorded 3.5 times more patients approaching the private sector than the government's RNTCP. Uttaranchal comes a close second with 3.4 times receiving treatment in private sector," said Dr Nimalan Arinaminpathy, lead author of the research, from the School of Public Health at Imperial College London.

The study further reveals that in 2014 private physicians procured nearly double the volume of drugs as compared to the government under the RNTCP.

It was estimated that in 2014, 96 lakh people fell ill with TB across the globe and 15 lakh died. The actual numbers could be much higher as there could be under-reporting in many countries, thanks to poor systems. India has the highest number of TB cases in the world.

The study on TB - a bacterial infection, spread through inhaling of tiny droplets from the coughs or sneezes of an infected person has been jointly conducted by GoI's Central TB Division, World Health Organisation (WHO), School of Public Health at Imperial College, London, IMS Health and Bill and Melinda Gates Foundation.

Reference: Daily News & Analysis

Combined sitagliptin, metformin is effective diabetes treatment, study finds

metformin 50/1,000 mg twice daily for 30 weeks had a -1.49% reduction in their A1C levels, compared with a -0.71% reduction among those on glimepiride therapy. The findings in the Journal of Diabetes, based on 292 diabetes patients, revealed that 81.2% of those in the combined therapy group achieved the target A1C of 7% or less, compared with 40.1% in the glimepiride therapy group, and the combined therapy group also had a greater reduction in fasting plasma glucose.

Ref.: Healio