Editorial

Greetings from Drug Information Bulletin!

The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India released Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for Pharmaceutical companies to restrict unethical promotion of Drugs with effect from 12th March 2024 replacing the earlier version released in the year 2014. Details are available at https://pharmaceuticals.gov.in/sites/default/files/UCPMP%202024%20for%20website_0.pdf

There are some changes in its provisions like- prohibition to offer gifts, travel facilities (inside or outside the country), paid vacations, or any other pecuniary advantage or benefit in kind to healthcare professionals or their family members. It also prohibited organization of CME/CPE in foreign locations. Limit of free samples distribution by a company is restricted to 2 percent of its domestic sales per year. Through this document all Pharmaceutical associations are requested to constitute an Ethics Committee for Pharmaceutical Marketing Practices (ECPMP) and set up a dedicated UCPMP portal on their website linked to the UCPMP portal of the Department of Pharmaceuticals for lodging complaints. Pharmaceutical associations are also instructed to take steps against offenders as per the provisions of this code.

Though there are some improvements in terms of conditions to be complied by the marketing companies, there are hardly any effort for its proper implementation as it is still an "advisory" but not mandatory. The penal provisions are unchanged and the stakeholders are apprehensive of its effectiveness.

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WHO publishes the **WHO Medically Important Antimicrobials List for Human Medicine**

The responsible and prudent use of antimicrobials needs to be improved in all sectors - human, animal, plant/crop, and environment - to preserve their public health benefits. In particular, antimicrobials that are medically important for human medicine need to be preserved by reducing their use in the non-human sectors. The WHO list of medically important antimicrobials for human medicine (WHO MIA List) is a risk management tool that can be used to support decision-making to minimize the impact of antimicrobial use in non-human sectors on antimicrobial resistance (AMR) in humans. The WHO MIA List is created to guide international, national, and subnational (local, state, provincial) antimicrobial stewardship efforts. It complements the WHO AWaRe (Access, Watch, Reserve) framework and antibiotic book which provide guidance on appropriate use of essential antibiotics within the human health sector.

The list categorizes antimicrobial classes based on their importance for human medicine and according to the AMR risk and potential human health implications of their use in non-human sectors: critically important, highly important, and important to human medicine. The publication is intended to serve as a reference tool to support decision-making by national regulators and policymakers in ministries of health and agriculture, authorities responsible for regulating, monitoring, and assuring the responsible and prudent use of antimicrobials, and professional prescribers in different sectors.
The WHO MIA List was developed in close collaboration with the Food and Agriculture Organization (FAO), the United Nations Environmental Programme (UNEP) and the World Organisation for Animal Health (WOAH) as a joint effort to harmonize and align related guidance and lists developed by the four organizations. Best practice statements included in the document are aligned with the position of the Quadripartite organizations (FAO, UNEP, WHO, and WOAH) and are critical to preserving the effectiveness of the agents in the WHO MIA List. Further work is ongoing to harmonize guidance on the prudent use of antimicrobials across all four organizations and this WHO antimicrobial list and the WOAH List of antimicrobial agents of veterinary importance.

AMR remains one of the top global public health threats facing humanity and was associated with the death of close to 5 million people globally in 2019. AMR occurs when bacteria, viruses, fungi, and parasites change over time and no longer respond to antimicrobial medicines making infections harder to treat and increasing the risk of disease spread, severe illness, and death. As a result, antimicrobial medicines become ineffective and infections persist in the body, increasing the risk of transmission to others. The WHO MIA List supports the optimized use of antimicrobial medicines in human and animal health.

Ref. WHO

Pregabalin and gabapentin in non-opioid poisoning deaths

Post-mortem findings of gabapentinoids have often been connected to drug abuse and especially opioid use. We aimed to investigate whether gabapentinoids have been implicated in the cause of death without the presence of opioids. In a three-year study period from 2016 to 2018, a total of 907 Finnish post-mortem cases positive for pregabalin or gabapentin were found. In nearly half of the pregabalin cases and in a third of the gabapentin cases, the blood concentration was above the typical therapeutic range of the drug. Of the cases in which pregabalin was detected, in 35% the drug was implicated in a fatal poisoning with or without other drugs or alcohol. For gabapentin, the percentage was 22%. In most of the fatal gabapentinoid poisonings, opioids or other central nervous system depressants were additionally detected in relevant concentrations. There were eight non-opioid gabapentinoid poisonings, in which no relevant other drugs were detected. Many of these cases were unintentional poisonings with a relatively high gabapentinoid concentration in the blood. In all but one, the manner of death was accidental, or the intent was undetermined. This study confirmed the previous findings that gabapentinoids are mostly implicated in fatal poisoning together with opioids. Half of the non-opioid cases were related to drug abuse but in the other half the death was presumably caused by overuse of a prescribed drug or suicide. While the use of gabapentinoids is a well-known problem among people who use drugs, it is important to note other groups of users who may be at risk of overdose by gabapentinoids.


Drug overdoses reach another record with almost 108,000 Americans death in 2022

CDC reported recently that nearly 108,000 Americans died of drug overdoses in 2022. Over the last two decades, the number of U.S. overdose deaths has risen almost every year and continued to break annual records — making it the worst overdose epidemic in American history. The official number for 2022 was 107,941, the U.S. Centers for Disease Control and Prevention said, which is about 1% higher than the nearly 107,000 overdose deaths in 2021. Earlier provisional data estimated more than 109,000 overdose deaths in 2022, but provisional data includes all overdose deaths, while the final numbers are limited to U.S. residents. The female overdose death rate declined for the first time in five years, although the male overdose death rate continued to inch up, the report said. Males account for about 70% of U.S. overdose deaths. The overall drug overdose death rate rose from 2021 to 2022, but the increase was so small it was not considered statistically significant.

Ref. Washington Post
Medicines containing turmeric or curcumin Risk of liver injury

The Therapeutic Goods Administration (TGA) has advised consumers and health professionals that medicines and herbal supplements containing the herb Curcuma longa (turmeric) and/or curcumin may cause liver injury in rare cases. This risk also relates to other ingredients from the Curcuma species as they contain naturally occurring curcumin: Curcuma aromatica, Curcuma zanthorrhiza and Curcuma zedoaria. Curcuma longa (turmeric) is a plant that has been used as a food spice for over 4,000 years, as well for medicinal purposes in traditional Indian (Ayurvedic) and Chinese medicines. Curcumin is a naturally occurring component in Curcuma longa (turmeric) and can be isolated and used as an active ingredient in medicines. Medicines and herbal supplements containing these Curcuma species and/or curcumin can be bought in supermarkets, health food shops and pharmacies without a prescription and without the advice of a health professional. There are over 600 listed medicines included in the Australian Register of Therapeutic Goods (ARTG) that contain these Curcuma species and/or curcumin. The TGA has received 18 reports of liver problems experienced by consumers taking products containing Curcuma longa (turmeric) and/or curcumin up to 29 June 2023. Nine of these reports had enough information to suggest a liver injury that may have been caused by the Curcuma longa (turmeric) or curcumin product. Of these, in 4 cases there were no other ingredients likely to have contributed to the liver injury. Two of these cases were severe, including one that had a fatal outcome. The other 5 cases involved products that contained other ingredients that may have contributed to liver injury. In addition to these cases, there have been several Australian and overseas case reports in the scientific literature, and multiple cases reported to regulators in other countries. The TGA has completed a safety investigation of the ingredients Curcuma longa (turmeric) and curcumin and the risk of liver injury. Available evidence shows that there is a rare risk of liver injury from taking Curcuma longa (turmeric) and curcumin in medicinal dosage forms. The risk may be higher for products with enhanced absorption or bioavailability and/or higher doses. People with existing or previous liver problems may be more likely to develop this rare adverse event. However, there is not enough information at this time to conclusively identify which medicines are higher risk. The TGA will continue to monitor this issue and is currently considering further regulatory action.

Reference: Safety updates, TGA, 15 August 2023 (link to the source within www.tga.gov.au)