Greetings from Drug Information Bulletin!

One recent estimate showed that about 700000 people are dying of drug resistant infection due to overuse in humans, livestock and agriculture globally. It is also predicted that this number could skyrocket and may reach 10 million deaths annually by 2050 resulting in a deep financial crisis. The widespread irrational use of antimicrobial medications needed to combat such diseases as tuberculosis, malaria and MRSA has made these infections more resistant to traditional treatment. A few examples of misuse include cold or flu sufferers taking antibiotics without realizing that such drugs are incapable of killing viruses and farmers using antibiotics to promote growth or prevent the spread of disease among animals such as chickens, pigs and cows. When microbes come into unnecessary contact with antimicrobials, they have more chances to adapt to specific strains, increasing the likelihood of genetic mutations that undercut the medications' effectiveness. In order to combat AMR several steps have already been taken which are-1. National Policy for combating AMR. 2. Steps for restricting irrational use of Antimicrobials 3. Framing legislation for restricting self-medication. 4. Guidelines for rational prescribing. Scattered steps were taken to resolve these health problems, but recently it has been suggested to adopt "one health approach"- human health, animal health and environmental health. COVID pandemic has already proved that concerted effort from the highest level is effective to manage pandemic. Recently WHO has published the “WHO implementation hand book for national action plan on AMR: guidance for the human health sector” with the purpose of proper implementation of NAP. It will be of great help to the national government for implementation of NAP. In order to combat AMR IPA has taken multipronged efforts-one of those are promoting concept of Antibiotic Gurdian. My request to all pharmacists to become an Antibiotic Gurdian.

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Order Issued by National Medical Commission for Enrolment of Medical Colleges as Adverse Drug Reactions (ADR) Monitoring Centres under PvPI

PUBLIC NOTICE

Subject: Enrollment of Medical Colleges as Adverse Drug Reactions (ADR) Monitoring Centers under PvPI – regarding.

All the recognized Medical colleges and Standalone PG institutions are informed that Indian Pharmacopoeia Commission (IPC) is functioning as the National Co-ordination Centre, Pharmacovigilance Programme of India (PvPI) to collect, analyze and monitor the adverse drug reactions (ADRs) from Indian population to promote patient safety & safe guard the health of patients by ensuring that the benefits of use of medicines outweigh the risk associated with its use. The collected ADRs data serves as a major source of evidence for recommendations of regulatory interventions regarding safety of medicines to the Central Drugs Standard Control Organization (CDSCO).

2. In order to achieve the above objective, IPC has so far enrolled 652 Adverse Drug Monitoring Centres (AMCs). In the 22nd Meeting of the Governing Body of India Pharmacopoeia Commission held on 14.10.2022 under the chairmanship of the Secretary (HFW) it has been decided that all Medical colleges/ hospitals under the National Medical Commission should also be enrolled as AMCs with IPC.

3. Accordingly, all Medical colleges/hospitals under the National Medical Commission are directed to get themselves enrolled with Indian Pharmacopoeia Commission (IPC) as AMCs at the earliest.

4. This issues with the approval of Chairman, NMC.

(Dr. Pukhraj Kumar)
Secretary (I/C), NMC

NPPA fixes retail price of 74 FDCs and 82 drugs under EML

National Pharmaceutical authority recently revised retail price of 74 drug formulations vide S.O. 878(E) dt 24-02-2023 of several drugs used to treat diabetes including Dapagliflozin, Metformin, sitagliptin and drugs for treating hypertension like Telmisartan and Bisoprolol etc. They also fixed price of 80 drugs under EML vide S. O. 879(E) dated 24.02.2023 several categories of drugs like antiepileptic - Sodium Valproate tablet, Antimicrobials- Cyclosporin capsule, Ciprofloxacin ointment, Gentamycin injection, Rifampicin oral liquid etc., Erythropoietin injection.

They also fixed two more drugs vide S.O. 880(E) dt 24-02-2023, S.O. 881(E) dt 24-02-2023. These revisions will have direct impact on the retail price of the drugs in Indian market.

The NPPA is mandated to fix or revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. The regulator implements and enforces the provisions of the Drugs (Prices Control) Order. It is also entrusted with the task
of recovering amounts overcharged by manufacturers for controlled drugs from consumers.

**11 minutes of brisk walking daily could early death**

According to a study that was just published in the *British Journal of Sports Medicine*, just 11 minutes of moderate-intensity exercise per day (or 75 minutes per week) is enough to reduce your risk of developing conditions including heart disease, stroke, and several types of cancer.

The researchers conducted the broadest analysis to date of the relationship between physical activity levels and risk of heart disease, cancer, and early mortality by reviewing 196 peer-reviewed studies that included more than 30 million individuals from 94 major study cohorts.

They discovered that benefits in terms of lowered risk of disease or early death increased marginally above 150 minutes per week, but that benefits even at half this amount were significant, such as a 23% lower risk of early death.

The findings indicated that 75 minutes per week of moderate activity was sufficient to lower the chance of acquiring cancer by 7% and cardiovascular disease by 17%. The risk decrease was higher for some specific cancers; it was between 14 and 26% lower for head and neck, myeloid leukemia, myeloma, and gastric cardia cancers. A 3–11% decreased risk was seen for other malignancies like lung, liver, endometrial, colon, and breast cancer.

Researchers further said that one in ten (10%) early deaths could be avoided, even if everyone performed at least 75 minutes per week of moderate-intensity physical activity. Cardiovascular disease would be prevented in one in twenty (5%) occurrences, and cancer would be prevented in almost one in thirty (3%) cases.

Source: [https://www.sciencedaily.com/releases/2023/02/230228205249.htm](https://www.sciencedaily.com/releases/2023/02/230228205249.htm)

**FDA panel wraps up back-to-back RSV AdComs with nod to GSK jab**

An FDA advisory committee voted unanimously on Wednesday that GSK's data support the effectiveness of its respiratory syncytial virus (RSV) vaccine RSVPreF3-AS01 at preventing disease in people 60 years and older. The committee also voted by a margin of 10-2 that company data show the shot, which will be marketed as Arexvy if approved, is also safe.

GSK has been vying with Pfizer over which will become the first to reach the US market with vaccines for the lung illness. The endorsement comes a day after the same panel voted 7-4 with one abstention that data presented by Pfizer demonstrate both the safety and efficacy of its RSV candidate RSVpreF in older adults. Pfizer is proposing to sell its vaccine under the name Abrysvo if it gets approved.

Phil Dormitzer, global head of vaccines R&D at GSK, said Wednesday's AdCom "brings us an important step closer to delivering one of the world's first vaccines for RSV." He added "we're delighted that the advisory committee recognised the strength of our vaccine's data...with a unanimous vote on [its] effectiveness." GSK's filing is supported by results from the Phase III AReSVi 006 study, recently published in the NEJM, in which RSVPreF3-AS01 demonstrated overall efficacy of 82.6% against RSV-lower respiratory tract disease in adults aged 60 years and above, while it was 94.1% effective in preventing severe disease.

However, as was the case with Pfizer, the FDA advisors expressed concern that GSK's shot could be associated with risks of rare nervous system disorders such as Guillain-Barré syndrome (GBS). A 78-year-old woman in Japan was diagnosed with GBS nine days after receiving the UK drugmaker's vaccine, and was discharged from the hospital six months after vaccination. She was the only case of GBS out of 15,000 recipients. GSK has said there was not sufficient evidence to confirm a diagnosis, although FDA scientists consider the case to be related to the vaccine.

Meanwhile, there were two cases of GBS diagnosed during Pfizer's RSV vaccine testing out of close to 20,000 vaccine recipients. The
company suggested there were confounding factors in both instances, and it had not identified any safety concerns during the trial. Still, Pfizer said it would conduct a safety study to further assess GBS after a potential approval. For its part, GSK said it is also closely monitoring safety concerns during its trials and will continue to do so after a potential approval. Marie Griffin, who sits on the FDA advisory panel, said the fact that such a rare disorder occurred in both companies' trials is troubling.

Committee chair Hana El Sahly indicated that more safety data are needed before approval. Aside from the GBS case, two people developed acute disseminated encephalomyelitis after receiving both RSVPreF3-AS01 and the influenza vaccine, one of whom died. Griffin agreed that more data is needed, adding "I just don't see why the rush on getting this vaccine approved now."

The FDA is expected to make its decision on GSK's vaccine by May 3, with a decision on Pfizer's shot expected to come that month as well.

Ref: Bloomberg

**Beneficial Efficacy of Escitalopram: A Step towards Development**

Major depression is described as a debilitating, occasionally fatal disorder that may worsen the quality of life and well-being.

Escitalopram has established a highly selective and dose-dependent inhibitory activity on human serotonin transport. Selective serotonin reuptake inhibitors (SSRIs) are approved to be the first-line drugs for managing major depressive disorder (MDD).

A recent study explored the therapeutic potential of escitalopram in managing MDD and panic disorders by exploring the data of many reputed databases.

The results underscored the clinical efficacy, safety, recent development, increased bioavailability profile and stable formulation of escitalopram. Clinical and pharmacoeconomic data proved escitalopram to be an effective first-line treatment option for MDD patients. These results regarding escitalopram are encouraging for further research perspectives.

Source: CNS & Neurological Disorders - Drug Targets, April 8, 2022.

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