Editorial

Warm Greetings from Drug Information Bulletin!

Approval or Emergency Use Approval (EUA) of new drugs during Covid pandemic raised controversy in several cases throughout the globe. Repurposed medicines were approved for the treatment of Covid-19 which was developed for entirely different purpose is at the centre stage. There were allegations that the data generated from clinical trials are not proper and adequate. The recent approval of a new drug by USFDA for the treatment of Alzheimers attracted several criticisms from the scientific community. Some of them alleged that the approval was made on the basis of inappropriate and inadequate data submitted for approval. Though a majority of the relevant expert committee was not recommended for approval, the USFDA has accorded approval to it.

Profile of the first drug for the treatment of Alzheimers - Aducanumab-avwa injection (Aduhelm), for intravenous use approved by USFDA was published received several critical comments and one of those is reproduced below. This shows that the approval process by regulatory agencies should be on proper scientific basis and the process should be more transparent.

Dr. Subhash C. Mandal
Editor
E-mail: subhash.mandaldr@gmail.com
Mob. 9830136291
Critical comments on approval process of Aducanumab:
Aducanumab (Brand name Aduhelm) is the first new Alzheimer’s treatment drug approved by USFDA on 21st June 2021 and was published in “The final responsibility for the approval of a medicine rests with the Minister of Health or equivalent. The Minister represents the people (population) that elected the government; decisions are made on behalf of the people. The Medicines Regulatory Authority is a Technical Body that works under the Minister of Health but has a complex relationship with the Minister. Usually the Minister agrees with the Medicines Authority and merely formally (nominally) approves the decisions. Where the Minister disagrees with the Medicines Authority and makes a different decision, reasons must be given publicly for reasons of accountability, and the Minister accepts the responsibility.
In this case there has been a series of failures - first, the USFDA approved the medicine despite the vast majority of the Expert Committee NOT recommending approval. No reasons/justification was given by the USFDA for ignoring the recommendation of the Expert Committee. Secondly the Secretary of Health and Human Services (=Minister) appears to have ignored publicly for reasons of accountability, and the Minister accepts the responsibility.
With a price of US 50,000+/year it appears the major effect would be financial toxicity of the patient and his/her carers.
All this demonstrates that the process of medicines approval can be seriously flawed in High Income Countries that have the technical capability to do an adequate job but apparently lack the will. Further those who are given the responsibility of safeguarding the health of the people seem unable to do their duties.
There are many accusations that Medicines Regulatory Authorities in Low and Middle Income countries do not carry out their functions properly. This is true in many cases but there are limitations - human resources, financial etc; many Authorities however do their best and serve the people even with the limited resources.

Pregnant Women are safe to take Covid-19 Vaccine: Health Secretary, GOI
The Health Secretary, Govt. of India communicated that pregnant women are safe to take Covid-19 vaccines in addition to the lactating mother through a letter dated 2nd July 2021.
As per the recommendation of the Expert committee and wider stakeholders support the Ministry of Health & Family Welfare has approved vaccination of pregnant women against Covid-19: stated Health Secretary.
National Technical Advisory Group on Immunization (NTAGI) has deliberated in a series of meeting in this matter and recommended for vaccination of pregnant women. Then in a national consultation held on 21st June 2021 involving representatives of State Govts, Medical Colleges, FOGSI, NGOs and partner organizations the NTAGI recommendation was welcomed.

Misuse of Antibiotics Soared In India during Covid Pandemic: Study
Covid-19 likely contributed to 216.4 million excess doses of antibiotics for adults, suggesting that the drug was used by almost everyone to treat mild and moderate cases of coronavirus infection in the country, claims a research pointing out Covid guidelines were not followed.
The study led by researchers at the Barnes-Jewish Hospital in Missouri, US, showed a total of 16.29 billion doses of antibiotics were sold in India in 2020.
Adult dose usage increased from 72.6 per cent in 2018 and 72.5 per cent in 2019 to 76.8 per cent in 2020. In addition, sales of azithromycin, used for treating typhoid fever, non-typhoidal Salmonella and traveller's diarrhoea, for adults in India increased from 4 per cent in 2018 and 4.5 per cent in 2019 to 5.9 per cent in 2020.

The study, published in the journal PLOS Medicine, also showed notable increases in the sales of doxycycline and faropenem, two antibiotics commonly used to treat respiratory infections.

"Antibiotic resistance is one of the greatest threats to global public health. Overuse of antibiotics lessens their ability to effectively treat minor injuries and common infections such as pneumonia, which means that these conditions can become serious and deadly. Bacteria that have become resistant to antibiotics don't have boundaries.

"They can spread to any person in any country," said infectious diseases specialist Sumanth Gandra, Associate Professor of medicine and an associate hospital epidemiologist at the Barnes-Jewish Hospital.

"Our results indicate that almost everybody who was diagnosed with Covid-19 received an antibiotic in India," he added.

On the other hand, in high-income countries such as the US, UK and Canada, overall antibiotic use plunged in 2020, even during Covid-19 peaks, revealed the study.

"This is because physicians in high-income countries generally did not prescribe antibiotics for mild and moderate Covid-19 cases. The uptick in India indicates that Covid-19 guidelines were not followed," Gandra said.

In India, an unregulated private sector accounts for 75 per cent of healthcare and 90 per cent of antibiotic sales, allowing for antibiotic over prescription.

Antibiotics should only be given to patients who develop secondary bacterial illnesses, but Gandra said that "this was not the case, indicating the need for policy changes in India, especially in light of the current crisis and the possibility of a devastating third wave".

Source: Business Standard

**NPPA Allows 50% Price Hike for Ibuprofen, Ranitidine, Carbamazepine**

India’s pharmaceutical pricing regulator has allowed a one-time price hike of 50 per cent for three key drugs -- ibuprofen, ranitidine, and carbamazepine -- that are used as the first line of treatment.

These are scheduled drugs (or ones that are under price control) and low priced. After the latest increase, the price of carbamazepine would range from Rs 1 to Rs 4.61 per tablet, depending on the dosage; for ranitidine, the new price would be in the range of Rs 1-2.43 per tablet or per ml of liquid; for ibuprofen, it would be 59 paise to Rs 1.04 per tablet. These prices are exclusive of goods and services tax.

Some of the companies that stand to benefit by the move are Torrent Pharmaceuticals, Cadila Pharmaceuticals, Zydus Cadila, and J B Chemicals as they have top-selling ranitidine brands. GSK Pharma had stopped selling this molecule globally after the controversy around ranitidine containing a carcinogenic element in its bulk drug. Sun Pharmaceuticals, Torrent Pharmaceuticals, Intas, and Abbott have leading carbamazepine brands, while Cipla and Abbott have popular ibuprofen brands.

The National Pharmaceutical Pricing Authority (NPPA), in its meeting held on June 28, allowed the price hike, noting that these were essential medicines for public health management, and pricing shouldn’t be the reason for their shortage, discontinuation or unavailability.

The NPPA said its mandate is to ensure the availability of drugs at affordable prices. “While ensuring affordability, access cannot be jeopardised, and life-saving essential drugs should remain available to the general public at all times,” it said. The Authority added that “unviability” of these formulations should not lead to a situation where these drugs become unavailable in the market and the “public is forced to switch to costly alternatives”.

In the past few months, prices of active pharmaceutical ingredients (APIs) have shot up, thanks to a sudden surge in demand for some key drugs (especially those used in Covid-19 treatment) and slower supplies from China. Thus, the prices of drugs like paracetamol,
azithromycin, doxycycline, and ivermectin, which are antibiotics or analgesics, and other drugs used to treat Covid-19, have gone up. For example, the price of APIs for paracetamol, a fever and pain medication, has jumped about 25 per cent from Rs 450-480 per kg in December 2020 to Rs 580-600 per kg in April. When compared to the pre-Covid prices of December 2019, the price surge is steeper at around 140 per cent.

The industry, which has been making representations to the government in this regard, welcomed the move. “The government has started recognising the role of increased API prices in the overall cost. Production of price-controlled drugs becomes unviable when the API prices go up. One cannot stop manufacturing these, but pharma players start reducing the production step by step, and eventually cut down entirely,” a senior executive at a pharma firm said.

Earlier, in December 2019, the NPPA had allowed a one-time increase in prices of 21 formulations, including common antibiotics, leprosy and malaria drugs, vitamin C, and anti-allergy medicines, by 50 per cent. The API prices of some of those drugs had gone up by over 80 per cent. This time, an upward price revision of 13 drugs comprising 27 formulations was discussed, of which the NPPA felt only three could be allowed to increase prices.

The NPPA has granted exemption to Torrent Pharmaceutical’s Tapentadol nasal spray for five years as it is covered under the Indian Patent Act. A patent has been granted to the Ahmedabad-based pharma major for 20 years. The patent was granted in January 2021, following which the company had applied to the NPPA in May. Tapentadol is exempted from price control for five years from the date of commencement of commercial marketing.

Source: Business Standard

**Reader’s Column………………..**

Hi Dr. Subhash,

Congrats for the IPA DI Bulletin which I have been receiving since those days when I was in FAPA, and as President visiting India and still read with interest the on goings in India although I have just stepped down as elected Council member of MPS after 26 elections! It certainly needs strong interest and dedication to keep on going, and you with the publication. I believe we have met before, and also with your many colleagues including Dr Rao, Sad, the pandemic has disrupted most of our normal activities, and we are now using IT to conduct AGM, Convention, etc., perhaps a positive outcome to adopt technology in pharmacy, from education to practice as patient social behaviour is changing. Late delivery and logistics slowed our vaccination programme as we are in wave 3 lockdown and talking a toll on social and economy.

Hope things worked out well for India and us in coming months. Stay healthy and safe.

Warm regards,

John

(John Chang)

Former President, FAPA

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