Editorial

Greetings from Drug Information Bulletin!

Recent report in the media regarding the increase of drug price since 1st April 2022 created a ripple among the general people. They believe that increase of drug price may be an additional burden on general public as they have to pay from their pocket when the country is going through inflation. This has happened due to a provision that manufacturers are allowed to increase the drug price under scheduled formulations as per the wholesale price index (WPI) with respect to the previous year as made in the Drugs Price Control Order (DPCO)-2013. People believe that this provision should not be there as this is helping in escalation of price of essential medicines. Experts believe it is the responsibility of the country to reach essential medicines to the general people and strongly believe this provision should be deleted from the DPCO-2013. Experts are raising the question is that whose benefit are protecting by this provision?

Hope the Government will consider this issue for the sake of public health.

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**New Drug: Rifapentine**

Priftin (rifapentine) Tablets  
Initial U.S. Approval: 1998

**INDICATIONS AND USAGE:**  
- Rifapentine is a rifamycin antimycobacterial indicated for the treatment of pulmonary tuberculosis caused by *Mycobacterium tuberculosis* in combination with one or more antituberculosis drugs.  

**DOSAGE AND ADMINISTRATION:**  
- **PRIFTIN** has been studied for the treatment of tuberculosis caused by drug-susceptible organisms as part of regimens consisting of an initial 2 month phase followed by a 4 month continuation phase.  
- **PRIFTIN** should not be used alone in either the initial or the continuation phases of antituberculosis treatment.

- **Initial Phase (2 Months):** 600 mg twice weekly for two months by direct observation of therapy, with an interval of no less than 3 consecutive days (72 hours) between doses, in combination with other antituberculosis drugs.  
- **Continuation Phase (4 Months):** 600 mg once weekly for 4 months by direct observation therapy with isoniazid or another appropriate antituberculosis agent.  
- Concomitant administration of pyridoxine (Vitamin B6) is recommended in order to avoid INH-associated peripheral neuropathy. Take with food.

**CONTRAINDICATIONS:** Known hypersensitivity to any rifamycin.

**WARNINGS AND PRECAUTIONS:**  
- Do not use as a once weekly Continuation Phase regimen with isoniazid in HIV seropositive patients due to the risk of failure and/or relapse with rifampin-resistant organisms.  
- Co-administration with Protease Inhibitors and Reverse Transcriptase Inhibitors.  
- Higher relapse rates occur in patients with cavitary pulmonary lesions and/or positive sputum cultures after the initial phase of treatment or those with evidence of bilateral pulmonary disease: Use cautiously.  
- Hepatotoxicity: In patients with abnormal liver tests/disease monitor liver tests prior to therapy and every 2-4 weeks during therapy. If signs of disease occur or worsen, discontinue therapy. Hyperbilirubinemia: Repeat testing and reassess patient.  
- Discoloration of body fluids: May permanently stain contact lenses or dentures red-orange. Porphyria: Avoid use in these patients.  
- Clostridium difficile-associated colitis: Evaluate if diarrhea occurs.

**ADVERSE REACTIONS:** The most common adverse reactions (≥10%) are hyperuricemia, pyuria, hematuria, urinary tract infection, proteinuria, lymphopenia, neutropenia, anemia, and hypoglycemia.  

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**DRUG INTERACTIONS:** Protease Inhibitors and Reverse Transcriptase Inhibitors.  
- Hormonal Contraceptives: Use another means of birth control.  
- May increase metabolism and decrease the activity of drugs metabolized by cytochrome P450 3A4 and 2C8/9. Dosage adjustments may be necessary if given concomitantly.

**USE IN SPECIFIC POPULATIONS:**  
- Pediatrics: The safety and effectiveness under the age of 12 has not been established.


**Status in India:**

1. Rifapentine 150mg film coated tablet “For the treatment of latent tuberculosis infection caused by *Mycobacterium tuberculosis* in adults and children 2 years and older who are at high risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph). Active tuberculosis disease should be ruled out before initiating treatment for latent tuberculosis infection. Rifapentine Tablets 150mg must always be used in combination with isoniazid as a 12-week once-weekly regimen for the treatment of latent tuberculosis infection” approved by CDSCO on 08.08.2019.

2. Rifapentine bulk and FDC of Isoniazid and Rifapntine (300mg/300mg Indicated for treatment of latent tuberculosis, caused by *Mycobacterium tuberculosis* (For use in
NTEP only approved by CDSCO on 28.06.2021.

Both the products are available in India. Rifapentine and Isoniazide combination has been recommended by WHO and this product is also included in the WHO Model List Essential Medicines-2021

WHO Director-General's opening remarks at the WHO press conference – 30 March 2022
(Relevant to Covid-19 reproduced)

Today, WHO is releasing our updated Strategic Preparedness, Readiness and Response Plan for COVID-19. This is our third strategic plan for COVID-19, and it could and should be our last. It lays out three possible scenarios for how the pandemic could evolve this year. Based on what we know now, the most likely scenario is that the virus continues to evolve, but the severity of disease it causes reduces over time as immunity increases due to vaccination and infection. Periodic spikes in cases and deaths may occur as immunity wanes, which may require periodic boosting for vulnerable populations. In the best-case scenario, we may see less severe variants emerge, and boosters or new formulations of vaccines won’t be necessary. In the worst-case scenario, a more virulent and highly transmissible variant emerges. Against this new threat, people’s protection against severe disease and death, either from prior vaccination or infection, will wane rapidly.

Addressing this situation would require significantly altering the current vaccines and making sure they get to the people who are most vulnerable to severe disease. So how do we move forward, and end the acute phase of the pandemic this year? It requires countries to invest in five core components:

First, surveillance, laboratories, and public health intelligence;
Second, vaccination, public health and social measures, and engaged communities;
Third, clinical care for COVID-19 and resilient health systems;
Fourth, research and development, and equitable access to tools and supplies;
And fifth, coordination, as the response transitions from an emergency mode to long-term respiratory disease management.

We have all the tools we need to bring this pandemic under control: we can prevent transmission with masks, distancing, hand hygiene and ventilation; And we can save lives by ensuring everyone has access to tests, treatments and vaccines. Equitable vaccination remains the single most powerful tool we have to save lives. Striving to vaccinate 70% of the population of every country remains essential for bringing the pandemic under control, with priority given to health workers, older people and other at-risk groups. I’m surprised that there are some in the global health community who see the 70% target as no longer relevant. Many high- and middle-income countries have reached this target, and have seen a decoupling between cases and deaths. Even as some high-income countries now roll out fourth doses for their populations, one third of the world’s population is yet to receive a single dose, including 83% of the population of Africa. This is not acceptable to me, and it should not be acceptable to anyone. If the world’s rich are enjoying the benefits of high vaccine coverage, why shouldn’t the world’s poor? Are some lives worth more than others? Even as we continue to respond to the pandemic, WHO is also putting in place new measures to help keep the world safe against future epidemics.

India saw a sharp rise in TB during the covid-19 pandemic

As per the India TB report 2022 and National TB Prevalence Survey, India saw a sharp 19% rise in tuberculosis cases in 2021 over the previous year even as 64% of the surveyed symptomatic population did not seek healthcare services...
between 2019 and 2021. As per the India TB report 2022, the total number of incident TB patients (new and relapse) notified during 2021 were 19,33,381 as opposed to that of 16,28,161 in 2020. The prevalence of all forms of TB for all ages in India was 312 per lakh population for the year 2021 and the highest prevalence for all forms of TB was 747 per lakh in Delhi and the lowest was 137 per lakh population in Gujarat.

In 2021, the vision of the National Strategic Plan for Elimination of Tuberculosis (NSP 2017- 25) permeated to state and district levels yet again to encompass more objectives. Eighteen States have committed to Ending TB by 2025 by formally implementing Statespecific Strategic Plans and have gone a step ahead to devise a District-specific Strategic Plan, which shall serve as a guiding tool for the programme managers and staff at the district and sub-district level towards the elimination of Tuberculosis.

According to the Global TB Report 2021, the estimated incidence of all forms of TB in India for 2020 was 188 per 1 lakh population. In India, childhood TB remains a staggering problem, contributing to approximately 31 per cent of the global burden. Over the last decade, consistently, children constitute 6-7 per cent of all the patients treated under National Tuberculosis Elimination Programme (NTEP) annually, pointing to a gap of 4-5 per cent in total notification against the estimated incidence. Comorbidities like malnutrition, diabetes, HIV, tobacco smoking, and alcohol impact a person with TB in predisposition and severity. Around Rs 1,488 crore were paid to 57.33 lakh TB patients under the Nikshay Poshan Yojana (NPY) as direct benefit transfer (DBT) from April 2018 to February 2022.

**Cefuroxime Potential risk of Kounis syndrome**
The SFDA has released a potential safety signal concerning Kounis syndrome associated with the use of cefuroxime. Cefuroxime is cephalosporin antibacterial drug indicated for the treatment of infectious diseases caused by sensitive bacteria. The SFDA reviewed 11 case reports, three of which supported the association, and the literature. Reference: Safety Alerts, SFDA, 21 June 2021

**Bevacizumab Potential risk of Fournier’s gangrene**
The SFDA has released a potential safety signal concerning Fournier’s gangrene associated with the use of bevacizumab. Bevacizumab is a monoclonal antibody inhibiting VEGF-A and indicated for the treatment of non-small cell lung cancer and other cancers. The SFDA reviewed 35 case reports, nine of which supported the association, and the literature. Reference: Safety Alerts, SFDA, 9 August 2021 (link to the source within www.sfda.gov.sa)

**Finasteride Potential risk of diabetes mellitus**
The SFDA has released a potential safety signal concerning diabetes mellitus associated with the use of finasteride. Finasteride is a 5α-reductase inhibitor and indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate. The SFDA reviewed 62 case reports, two of which supported the association, and the literature. Reference: Safety Alerts, SFDA, 17 August 2021 (link to the source within www.sfda.gov.sa)

**Atezolizumab Potential risk of keratitis**
The SFDA has released a potential safety signal concerning keratitis associated with the use of atezolizumab. Atezolizumab is a monoclonal antibody inhibiting PD-L1 and indicated for the treatment of locally advanced or metastatic urothelial carcinoma after prior chemotherapy or that are considered cisplatin ineligible. The SFDA reviewed four case reports, one of which supported the association, and the literature. Reference: Safety Alerts, SFDA, 9 August 2021 (link to the source within www.sfda.gov.sa)

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