



Drug Information Bulletin

Drug Information Centre (DIC)

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Editorial

Recently US FDA has approved new oral three-drug regimen for the extensively-drug resistant tuberculosis (XDR-TB), estimated to have a mortality rate of 60 per cent. The treatment involves pretomanid tablets in combination with Bedaquiline and Linezolid, collectively referred to as the BPaL regimen, according to FDA's statement on August 14, 2019. It has an efficacy rate of 90 per cent. Pretomanid was developed by TB Alliance, a not-for-profit organisation, funded by governments of Australia, Germany, the United Kingdom and the US, as well as philanthropic sources. US pharmaceutical corporation Mylan has been granted licence for manufacturing of the drug. MSF has asked Mylan to make the price public. According to the World Health Organization (WHO) previously available drugs had a success rate of only 34 per cent for XDR-TB and 55 per cent for multi-drug resistant TB (MDR-TB) cases. They also had severe side-effects like deafness, numbness, joint pain, renal failure hormonal imbalance, vertigo, among others. The new regime was tested on 109 patients with XDR-TB and MDR-TB from South Africa in 2015-2017. After a six-month trial, 95 patients were successfully treated. A follow-up of six months was also done.

There are 1,14,237 MDR-TB patients globally, of which more than 8,000 are XDR-TB, according to [2018 WHO TB update](#). India has 26,966 MDR-TB patients, the highest in the world, while there are 2,130 XDR-TB patients in the country. Of the total MDR-TB patients worldwide, 6.2 per cent are likely to become XDR-TB, thereby meaning the number of XDR-TB cases may very well be more than 9,000 in our country. The [success rate](#) of treatment for XDR-TB in India is merely 23 per cent while for MDR-TB it is 46 per cent. Thus, the new drug regimen is important for countries like India, which has the second-highest burden to XDR-TB patients in the world, after Russia –as per the experts. Health experts are expecting its availability in India at an affordable price.



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Announcements

1. Extract of the minutes of the 107th/Central Council meeting of PCI held in August, 2019.

<p><u>01.107.1205</u>: Sub: Amendment in Pharmacy Practice Regulations, 2015 for –</p> <p>a) inclusion of the post of Clinical Pharmacist with qualification, duties and responsibilities.</p> <p>b) creation of Drug Information Centres in Hospitals.</p> <p>-----</p> <p>(14-126/2019-PCI)</p> <p>1205.1 The latest information on record was placed.</p> <p>1205.2 It was decided to approve the proposed amendments in the Pharmacy Practice Regulations, 2015 for -</p> <p>a) inclusion of the post of Clinical Pharmacist with qualification, duties and responsibilities.</p> <p>b) creation of Drug Information Centres in Hospitals.</p> <p>1205.3 It was further decided to -</p> <p>a) forward the amendments to Health Ministry.</p> <p>b) simultaneously initiate action u/s 10(3) of Pharmacy Act, 1948 for seeking comments of the State Govts. / Union Territories.</p>
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2. Comments on the proposed amendments in the Pharmacy Practice Regulations, 2015 are invited so as to reach the Pharmacy Council of India on or before 13.11.2019.

***PCI already circulated the draft of proposed amendment for having opinion of the States and UTs
For details: www.pci.nic.in

Hygiene Products like Sanitary Napkins, Disinfectants and Adult Diapers could soon come under Price Control

Essential hygiene products such as sanitary napkins, hand wash, disinfectants and adult diapers may soon come under price control. The government is finalising a list of essential hygiene products, which is likely to form the basis for expansion of price control from medicines and medical devices to other important health products.

At present, there is only a National List of Essential Medicines (NLEM), which also includes some critical medical devices. While the government is revisiting NLEM to make relevant additions and omissions, it is also preparing separate lists for medical devices, disposables and hygiene products.

While a price-control regime for hygiene products is in the works, for medicines the government currently regulates prices of around 384 essential medicines, including medical devices such as stents, by imposing a cap on their maximum retail price. For all other drugs, companies are allowed to hike prices by up to 10% annually (on a 12-month moving average basis). Besides, the government has also imposed a cap of 30% on trade margins for 42 cancer drugs.

“The list of essential hygiene products is in its final stages and is likely to be released over the next two months,” an official involved with the process told TOI. The list will be divided into two categories — primary and secondary. While products in the primary category will be price-controlled, the government will ensure availability of even those categorised as secondary at reasonable prices.

Once the list is notified, a Niti Aayog committee will take a call on whether there will be an overarching ceiling price or a cap on trade margins. An official indicated it could be a mix of the two — while there can be a price cap for items on the primary list, trade margin limits may be prescribed for those on the secondary list.

According to the official, many of these products are commonly used and contribute substantially to household expenditure on health. Though these products are not categorized as pharmaceuticals, they are healthcare products that play a significant role in maintaining a healthy lifestyle and are often also used in various medical purposes.

However, many of these products, including sanitary napkins, sanitizers and diapers, are exorbitantly priced with soaring trade margins.

The practice of using pieces of cloth and rags is still highly common among rural and urban poor. Apart from inadequate awareness, absence of low-cost sanitary napkins is another problem.

“The idea is to ensure that all these products are available and affordable to the common people as they play a crucial role in disease control and maintaining health and hygiene. Some of these products will be available for free at primary and community health centres,” the official said.

The list is being drafted by a sub-committee formed under the standing national committee on medicine and health under the secretary, department of health research, and Indian Council of Medical Research director general Balram Bhargava.

The standing committee on affordable medicine, under the chairmanship of Niti Aayog member V K Paul, will take a final call on price rationalisation of any medicine and healthcare product. However, the list of essential products will form the basis of price rationalisation by this committee.

Source: The times of India

FDA approves new drug for treatment-resistant forms of tuberculosis that affects the lungs

The U.S. Food and Drug Administration today approved Pretomanid Tablets in combination with bedaquiline and linezolid for the treatment of a specific type of highly treatment-resistant tuberculosis (TB) of the lungs.

“The threat of antimicrobial-resistant infections is a key challenge we face as a public health agency,” said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. “The bacterium that causes tuberculosis can develop resistance to the antibiotics used to treat it. Multidrug-resistant TB and extensively drug-resistant TB are public health threats due to limited treatment options. New treatments are important to meet patient national and global health needs. That’s why, among our other efforts to address antimicrobial resistance, we’re focused on facilitating the development of safe and effective new treatments to give patients more options to fight life-threatening infections. This approval also marks the second time a drug is being approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs, a pathway, advanced by Congress, to spur development of drugs targeting infections that lack effective therapies. We hope we continue to see more development of antibacterial drugs for treating serious or life-threatening infections in limited populations of patients with unmet medical needs.”

Pretomanid in combination with bedaquiline and linezolid is approved for treating a limited and specific population of adult patients with extensively drug resistant, treatment-intolerant or nonresponsive

multidrug resistant pulmonary TB. Multidrug-resistant TB and extensively drug-resistant TB are difficult to treat due to resistance to available therapies. According to the World Health Organization, in 2016, there were an estimated 490,000 new cases of multidrug-resistant TB worldwide, with a smaller portion of cases of extensively drug-resistant TB.

The safety and effectiveness of Pretomanid, taken orally in combination with bedaquiline and linezolid, was primarily demonstrated in a study of 109 patients with extensively drug-resistant, treatment intolerant or non-responsive multidrug-resistant pulmonary TB (of the lungs). Of the 107 patients who were evaluated six months after the end of therapy, 95 (89%) were successes, which significantly exceeded the historical success rates for treatment of extensively drug resistant TB.

The most common adverse reactions observed in patients treated with Pretomanid in combination with bedaquiline and linezolid included damage to the nerves (peripheral neuropathy), acne, anemia, nausea, vomiting, headache, increased liver enzymes (transaminases and gamma-glutamyltransferase), indigestion (dyspepsia), rash, increased pancreatic enzymes (hyperamylasemia), visual impairment, low blood sugar (hypoglycemia), and diarrhea.

Pretomanid used in combination with bedaquiline and linezolid should not be used in patients with hypersensitivity to bedaquiline or linezolid.

Pretomanid is the second drug to be approved under the [Limited Population Pathway for Antibacterial and Antifungal Drugs](#), or LPAD pathway, established by Congress under the 21st Century Cures Act to advance development and approval of antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need. Approval under the LPAD pathway may be supported by a streamlined clinical development program. These programs may involve smaller, shorter or fewer clinical trials. As required for drugs approved under the LPAD pathway, labeling for Pretomanid includes certain statements to convey that the drug has been shown to be safe and effective only for use in a limited population.

Pretomanid also received the FDA's [Qualified Infectious Disease Product \(QIDP\)](#) designation. The QIDP designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.

The FDA granted Pretomanid Tablets [Priority Review](#), under which the FDA's goal is to take action on an application within an expedited time frame, and [Orphan Drug](#) designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Pretomanid Tablets to The Global Alliance for TB Drug Development (TB Alliance). With this approval, The Global Alliance for TB Drug Development is awarded a [Tropical Disease Priority Review Voucher](#) in accordance with a provision included in the Food and Drug Administration Amendments Act of 2007 that aims to encourage development of new drugs and biological products for the prevention and treatment of certain tropical diseases.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Ref.: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-resistant-forms-tuberculosis-affects-lungs>

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