



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Editorial

Govt. of India has notified in the month of March 2018 directing all Pharmacy, Chemist and Druggist dispensing anti-tubercular medicines, shall notify respective tuberculosis patients along with details of medicines to local Public Health Authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies in whatever way they are known; or their designated District Tuberculosis Officers.

Pharmacy, Chemist and Druggist, failing to notify may attract the provisions of sections 269 and 270 of the Indian Penal Code (45 of 1860), as the case may be, which are reproduced below: "269. Negligent act likely to spread infection of disease dangerous to life. - Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both. 270. Malignant act likely to spread infection of disease dangerous to life. - Whoever malignantly does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both." This is an appropriate step to ensure proper tuberculosis diagnosis and its management in patients and their contacts and to reduce tuberculosis transmission and further to address the problems of emergence and spread of Drug Resistant-Tuberculosis, it is essential to collect complete information of all tuberculosis patients.

This direction is also applicable for Medical Practitioners and Medical Laboratories as notified vide F.No. Z-28015/2/2012-TB dtd. 16th March 2018 (available at: <http://www.cdsc.nic.in/writereaddata/management%20in%20patients.pdf>).

This is a golden opportunity for the pharmacists engaged in community pharmacy to establish them as one of the important health care provider.

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Price announced for new lifesaving TB drug Pretomanid still too high: MSF

The Global Drug Facility has just announced <https://www.reuters.com/article/us-tb-alliance-tuberculosis/new-tuberculosis-treatment-for-developing-countries-to-cost-1040-idUSKBN1X713X> a price of US\$364 for a six-month treatment course of pretomanid, only the third new drug developed for TB in half a century. Pretomanid was approved for use by the US Food and Drug Administration in August 2019. Médecins Sans Frontières (MSF) is calling on the TB Alliance (TBA), a non-profit TB drug development organisation, and its commercial partner pharmaceutical corporation Mylan, to further lower the price of this drug, as it is just one part of a regimen of multiple drugs that people need. MSF has been calling for the price of a complete DR-TB treatment course to be no higher than \$500 per person. Pretomanid was developed by the TB Alliance, a not-for-profit organisation, funded by governments (e.g. Australia, Germany, the UK and the US) and philanthropic sources. It is the first TB drug to be developed and approved as part of a ready-to-use treatment regimen (BPAL: bedaquiline + pretomanid + high-dose linezolid) for people with extensively drug resistant (XDR)-TB, treatment-intolerant, or nonresponsive multidrug-resistant pulmonary TB. This new regimen has the potential to dramatically shorten treatment length to six months, greatly reduce the number of pills required, and helps increase XDR-TB cure rates from the abysmal 39%. In light of recent price announcement, the lowest global price for a 6-month course of BPAL regimen is US\$1,040, which is double what MSF is calling for.

Researchers from the University of Liverpool have estimated that generic versions of pretomanid could be produced and sold at a profit for less than \$1.35 a day, or less than \$35 a month. The high price of one of the other newer TB drugs, bedaquiline, at \$400 for a six-month treatment course will also impede the uptake of the BPAL regimen in high TB burden countries. MSF has launched a global campaign <https://nomoretears.msfacecess.org>

calling on pharmaceutical corporation Johnson & Johnson (J&J) to lower the price of bedaquiline to no more than US\$1 per day (\$200 for six months, or half of what J&J currently charges).

Furthermore, the TB Alliance must also support or carry out research to address outstanding medical questions concerning the safety and efficacy of its drug independent of the BPAL regimen and in comparison to another drug in the same class, as well its suitability for different populations including children, pregnant women, and people living with HIV receiving the antiretroviral dolutegravir.

Response from Sharonann Lynch, HIV & TB Policy Advisor, MSF Access Campaign.

"Newer TB drugs, including pretomanid, may have tremendous potential for tackling difficult-to-treat drug-resistant forms of TB, but only if they are affordable. The high price of this drug could have a chilling effect on its uptake in high TB burden countries.

We are calling on Mylan and the TB Alliance to bring the price of pretomanid down much further, so that the TB Alliance can hold true to its stated mission of developing and making improved TB medicines accessible to people who need them.

After half a century, we finally have new TB drugs that can offer a better chance of survival for people who otherwise continue to die from the world's leading infectious disease killer. The public helped pay for the development of this drug, and therefore, this drug should be affordable and accessible to anyone who needs it. What good is a lifesaving drug if the people who need it can't afford it?"

Ref.: E-Drugs

Industry-Govt. partnership may help bring down TB drug price

While India contributes 27% to the global burden of Tuberculosis (TB), its diagnosis and drug price continues to be a concern. In an interview with *The Hindu*, Director of National Institute for Tuberculosis and Respiratory Diseases (NITRD), Rohit Sarin spoke on the issues that lead to delayed diagnosis, methods to prevent the disease, and other aspects. He was in Hyderabad

on Friday to participate in the 50th Union World Conference on Lung Health.

Scores of TB patients in India, who are from poor background, have difficulty in accessing medicine owing to its high price? Is there a way to make pharma companies bring down the prices?

There has to be partnership between industry and the government. They have to reach consensus on what should be the most appropriate price. It's easy to ask industries to sell drugs at a particular price, but it may not be viable for the industry. Efforts have to be put in to manufacture drugs in India. It will at least cut down the cost to a large extent. If volumes (demand) are more, drugs could be available at a reasonable price.

What kind of effort does the NITRD puts in to bring down the TB drug price?

When we hold discussions with the Drug Controller General of India (DCGI), we put forward the point that prices should not be prohibitive. We also ensure that there is competition in manufacturing drugs, and more and more companies are permitted to manufacture drugs.

What are the reasons for delay in diagnosing TB?

We have the technology for rapid diagnosis of TB. But what we lack is access. A large number of patients who develop TB belong to poor socio-economic strata. For them, loss of time and wages is important. If they have to travel long distances and spend money on it, wait in line and lose wages for a day, they would like to go to a practitioner who lives close to their home to get checked for cough.

Are medicines the only way to prevent TB, or are there any other methods?

Medicines do have their role. But wider interventions are required. Patients with active TB have to be educated about using a handkerchief or cloth when coughing so that it will not infect others. One way of cutting the chain of transmission is by ensuring that the individual does not allow bacterial transmission from him/her.

Besides, the sooner a patient with active TB starts treatment, the less infectious he/she becomes.

Early diagnosis and treatment of a patient would also prevent the spread of the disease to rest of the community. Whenever a patient is in a healthcare setting, the environment should be in a manner that it reduces the transmission.

Among people of different age groups and sex, in whom is the TB diagnosis slow?

It is difficult to diagnose TB in children as even if they cough, there will be no sputum.

The current tests for TB are sputum based. So we miss out on the diagnosis. Also, there are challenges in diagnosing extra pulmonary TB. The disease can affect any part or organ of the body like bones, skin and lymph nodes for which ready diagnosis is not available.

Source: The Hindu

NIHR, MRC invested over 6 million pound on tackling diabetes and hypertension in low- and middle-income countries (LMICs)

The National Institute for Health Research (NIHR) has announced a new collaboration with the Medical Research Council (MRC), detailing plans to invest over £6 million in five implementation science projects focused on tackling diabetes and hypertension in low- and middle-income countries (LMICs).

The projects will allegedly unite with over 25 international research projects from across 40 different countries in landmark collaboration under the Global Alliance for Chronic Diseases (GACD) - a unique collaboration of fifteen of the world's largest health research funding agencies.

Through the multi-million-pound investment, the GACD is "making an important contribution to global research in low and middle-income countries and to indigenous communities and vulnerable populations in high-income settings," explained Mark Palmer, MRC director of international relations and chair elect of the GACD.

He continued, "Each project has a unique collaboration with a research centre in a high- and low-income country. Through this alliance, funders are making a significant impact in the fight against chronic diseases at country level."

Projects include the Bangladesh D:CLARE (Diabetes: Community-Led Awareness, Response and Evaluation) Project, a mission evaluating the

role of pharmacists and m-Health strategies in the management of hypertension in General Pueyrredon and a project dubbed “CHARMING - Control of Hypertension and diabetes in Minas Gerais”.

Every year 15 million people die from a non-communicable disease, such as cardiovascular diseases, cancers, respiratory diseases, and diabetes. This is the equivalent of 71% of all deaths globally, most of which occur in LMICs. Unhealthy diets, physical inactivity, exposure to tobacco smoke, the harmful use of alcohol, as well as rapid unplanned urbanisation and an ageing population, all contribute to the increase in the number of people affected.

Source: The Pharmatimes

Niti Aayog proposes separate regulator for medical devices in India

Government think tank Niti Aayog has rejected the health ministry’s proposal to bring medical devices under the Central Drugs Standard Control Organisation (CDSCO), saying the body does not have the required expertise. People aware of the matter said the Aayog has instead moved a draft Bill proposing that medical devices be governed by a separate regulator.

Earlier this month, the ministry had issued a draft notification saying that all medical devices would come under the category of drugs from December 1 and would be regulated under the Drugs & Cosmetics Act. A senior official confirmed to ET that there is some support for Niti Aayog’s view in the government that it is inappropriate to allow CDSCO to regulate medical devices as they have expertise in pharmacy/chemicals and not in devices. People familiar with the development told ET that the Aayog has floated a draft Bill to

regulate over 6,000 bio medical devices in the country.

“The Bill proposes a separate regulator for medical devices on the lines of the Food Safety and Standards Authority of India (FSSAI), an autonomous body under the health ministry,” one of the persons cited earlier said, requesting not to be named.

In India, only 23 categories of medical devices are regulated under the Drugs and Cosmetics (D&C) Act. The ministry’s notification said all medical devices will be brought under regulation in a phased manner.

It has proposed seven categories of devices intended for use in human beings or animals as drugs with effect from December 1, 2019, while ultrasound equipment would be treated as drugs from November 1, 2020.

India’s medical devices market is the fourth largest in Asia—after Japan, China and South Korea—at over \$10 billion and is projected to grow to \$50 billion by 2025.

Source: The Economic Times

Forthcoming Events

58th National Pharmacy Week Celebration by IPA Bengal Branch

PROGRAMME	
17.11.2019 (Sunday)	Inauguration Programme Venue: Gandhi Bhavan, Jadavpur University 9.30 a.m. Registration 10.00 a.m. Inauguration 1.00 p.m. Lunch
18.11.2019 (Monday)	Seminar at Calcutta Institute of Pharmaceutical Technology and Allied Health Science
19.11.2019 (Tuesday)	Seminar at BCDA College of Pharmaceutical Technology Seminar at Eminent College of Pharmacy & Technology
20.11.2019 (Wednesday)	Students Day: Venue- Bengal School of Technology, Sugandha, Chinsurah, Dist. Hooghly
21.11.2019 (Thursday)	Seminar and NPW celebration at Institute of Pharmacy, Kalyani
22.11.2019 (Friday)	Blood Donation Camp at Institute of Pharmacy, Kalyani
23.11.2019 (Saturday)	● Scientific Day Celebration National Workshop on “Pharmacists in improving therapeutic outcome” at H.L. Roy Auditorium, Jadavpur University (Participation on registration)
24.11.2019 (Sunday)	● Rally at Siliguri
24.11.2019 (Sunday)	● Hospital Pharmacy Day celebration at North Bengal Medical College
24.11.2019 (Sunday)	● Scientific Seminar at DSP Main Hospital Conference Hall, Durgapur, Burdwan
	● Cultural Programme at IPA Auditorium, Kolkata

**WAAW 2019: 18-24
November**

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The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.