

Date: 21/10/2022

To, Dr. Mansukh Mandaviya Minister of Health and Family Welfare Ministry of Health and Family Welfare Government of India and Chair, Stop TB Board, Stop TB Partnership Secretariat Global Health Campus, Chemin du Pommier 40 1218 Le Grand-Saconnex, Geneva, Switzerland

Cc:

Dr. Rajendra P Joshi, DDG, Central TB division Ministry of Health and Family Welfare Government of India

Subject: Updates required to the National tuberculosis guidelines to support access to shorter regimens as a human right in India.

Dear

Sir,

We write this letter on behalf of the Global Tuberculosis Community Advisory Board (TB CAB), a group of research-literate activists from around the world that advise research and product sponsors and advocate for the expeditious translation of research to policies that benefit the health and well-being of people at risk of and living with TB. We write to you in close collaboration with the civil society organizations listed below and in solidarity with communities affected by TB in India. Many of the representatives that make up the signatories to this letter have direct lived experience with TB and the outdated, longer, more toxic regimens that have historically been used to treat it.

After over two decades of investments in research and development, TB can be finally treated and cured in as little as one month and most forms of drug-sensitive and drug-resistant TB in four and six months, respectively. Yet few people anywhere in the world have access to these shorter regimens. According to international human rights law, governments have "a duty to make available and accessible to all persons, without discrimination, especially to the most vulnerable, all the best available applications of scientific progress necessary to enjoy the highest attainable standard of health." The standard of care set by World Health Organization Guidelines should serve as the minimum framework of care guaranteed to people affected by TB everywhere in the world including the National TB Elimination Program, in India.

Thus we appeal upon you to:

1. Align national and global guidelines: by making urgent updates to the national guidelines for the prevention, treatment, care and control of TB in the country, by fully aligning with the recommendations issued in the latest consolidated guidelines of the World Health Organization (WHO);¹⁻⁶. The WHO recommendation's endorsing these regimens are evidence-based and the result of an exhaustive review of

the science and best practices. These updates should include the following shortcourse treatment regimens referred to by a global civil society as the "1/4/6x24" campaign.

- The one-month (28-day) or once-weekly (12 weeks) TB preventive treatment regimens, "1HP" and "3HP" one month of daily rifapentine and isoniazid, and three months of once-weekly rifapentine and isoniazid.
- The four-month rifapentine- and moxifloxacin-containing regimen from Tuberculosis Trials Consortium Study 31 / AIDS Clinical Trials Group Study 5439 (HPMZ) and the four-month regimen from the SHINE trial for children with non-severe TB (HRZ[E]).
- The six-month bedaquiline- and pretomanid-based regimens for drug-resistant TB (BPaL[M]) from the TB-PRACTECAL and ZeNix studies.

Further to this, we also reiterate on our earlier demand for Bedaquiline access under the letter "*TB Activists Demand Government Action to Expand Access to Bedaquiline*" submitted on the 2nd July 2022. The letter called upon the Government of India to respond to the petition filed before the High Court of Bombay (Meera Yadav & Anr. v Union of India & Ors. PIL (L) No. 495 of 2021) and issue a compulsory license to enable local developers to manufacture bedaquiline both for domestic use and for export to countries to ensure access to generic versions of bedaquiline and the scale up of government procurement and implementation of the medicine.

- 2. To advocate for financial and other resources necessary to by the end of 2024 get in place the "staff, stuff, space, systems, and support" needed to implement the updated national guidelines in place by 2024:
 - To follow through on the commitments articulated by the Ministers of Health in Moscow in 2017 and by Heads of State in New York during the United Nations High-Level Meeting on TB in 2018 toward achieving the 2030 Sustainable Development Goals, the 1/4/6 regimens offer a new unified framework around which to rally the energy, political will, and funding necessary to correct the course of the global fight to end TB.
 - We understand that the implementation of national guidelines that are fully • aligned with the WHO consolidated guidelines entails not only the effort of the Ministry of Health and the National TB Program but also cooperation across sectors and the provision of sufficient funds from the government and other sources. For this reason, we ask your offices to make the necessary efforts with the competent authorities to ensure adequate resources to ensure the full healthcare infrastructure necessary for delivering patient-centered care-what the late Dr Paul Farmer referred to as the "5 Ss": staff, stuff, space, systems, and support. Staff being all care providers, including doctors, nurses, and community health workers (e.g., public, private, informal, community-based, etc); Stuff being diagnostic tests and corresponding consumables, imaging technologies, medications and other equipment; Space being appropriate, dignified care facilities for patients within a clinic, hospital, or community care setting; Systems being policymaking and regulatory mechanisms, active case finding outreach programs, referral services; and Support being accompaniments for patients to get better, such as food, housing, counseling, and other psychosocial services. This approach requires a multi-sector and fully financed TB response.

It is only with this type of comprehensive and patient-centered approach that we stand a chance of addressing the ravages of stigma and social inequality that TB leaves across patients and their families. We remind you that every dollar invested in tuberculosis programs returns 40 dollars in investment in health. And the cost of inaction is inevitably higher – according to one analysis, the failure to adopt and scale up the full range of innovations available to us would result in 6.6 million additional TB deaths and economic loss of US \$1 trillion by 2030. We stand ready as allies to support the health program to advocate for sufficient resources.

3. To include civil society and affected community voices in these efforts, as the participation of civil society and TB-affected communities is of crucial importance. Public health must be a sustained commitment of all, the most vulnerable communities have been the most affected by tuberculosis throughout history, so attending to their needs and controlling the disease impacts not only the health but also the economy of the most disadvantaged. As such an equal seat and consideration in the processes of preparing policies and frameworks that determine standards of care for people and communities affected by TB in the country, needs to be included.

We invite you to join us in rejecting the inertia and mediocrity that has too long plagued the response to TB globally and in the country, and to meet the call to action issued by the 1/4/6x24 Campaign by taking urgent action to ensure that every eligible person with TB infection or TB disease will have access to evidence-based, short-course treatment regimens; this is their human right and your responsibility.

Respectfully submitted,

Global Tuberculosis Community Advisory Board (TB CAB)

On behalf of:

- 1) Access to Rights and Knowledge (ARK) Foundation, Nagaland
- 2) Survivors Against TB, Delhi
- 3) Diptendu Bhattacharya, TB Survivor, West Bengal
- 4) Ketho Angami, Health Activist, Nagaland
- 5) Alok Mohan Agarwal, President, Delhi Drug User's Network
- 6) Delhi Drug User Network
- 7) Karthik Krishnan, Chennai, Tamil Nadu
- 8) Sagar Karmakar, Convenor, BFPUD, West Bengal
- 9) Bengal Forum of People who Use Drugs (BFPUD), West Bengal
- 10) Ganesh Acharya, TB survivor, Mumbai India
- 11) Shabab Alam, General Secretary, Misbah NGO
- 12) Misbah NGO, Delhi
- 13) Alex Lunminthang, Freelance Health Activist, Churachandpur Manipur.
- 14) Community Network for Empowerment (CoNE), Manipur
- 15) Rajkumar Nalinikanta, Health activist, Manipur
- 16) Komaljit Singh, Manipur
- 17) Prashant Sharma, Health activist, Sikkim
- 18) Sikkim Drug Users' Forum (SDUF)
- 19) Jahnabi Goswami, President, Assam Network of Positive People

- 20) Assam Network of Positive People (ANP +)
- 21) NK Lian Guite, Twice TB survivor, Manipur
- 22) Molun Hrangbung, President, MSNP+, Meghalaya State network of positive people.
- 23) Meghalaya State Network of Positive People, MSNP+
- 24) Agui Daimei, Co-Founder, MSNP+
- 25) Sutirtha, Drug User, West Bengal
- 26) Nagaraju Valaparla, Andhra Pradesh
- 27) Andhra Pradesh Drug Users' Forum (APDUF)
- 28) Haryana Drug Users' Forum (HDUF)
- 29) Wendy K.Zodinpuii, Asst. Secy MDUF, Twice TB survivor
- 30) O. Harikumar Singh, Executive Member, ADUM, MANIPUR
- 31) ADUM, Manipur
- 32) Sasang, TB survivor, Churachandpur, Manipur
- 33) Sashimeren, Secretary, Evergreen Welfare Society & General Secretary, Mon Users' Network
- 34) Evergreen Welfare Society, Mon, Nagaland
- 35) Mon Users' Network, Nagaland
- 36) Tsewang Gyatso Sherpa, Sikkim
- 37) Mizoram State Network of Positive People (MiSNoPP)
- 38) Daisy David, Network for Chennai PLHIV network (NCP+), Tamil Nadu
- 39) Surjeet Singh, Kaithal, Haryana
- 40) ActionTBIndia
- 41) Delhi Network of Positive People (DNP+), India
- 42) International Treatment Preparedness Coalition -South Asia
- 43) Positive Network of Dimapur (PND+), Nagaland.
- 44) Indian Network For People Living with HIV/AIDS(INP+), Chennai, India.
- 45) Hari Shanker Singh, Delhi
- 46) Henry Zohmingthanga, Aizawl, Mizoram.
- 47) Positive Women Network of Mizoram (PWNM)
- 48) Shansham Organization, Mon, Nagaland
- 49) Prayas Network of Ppositive People Welfare Society, Punjab
- 50) Network of Naga People Living with HIV and AIDS (NNP+), Nagaland
- 51) Ashique Ahmed
- 52) Charan, IDUF, harm reduction activist
- 53) Moses Pachuau, Mizoram
- 54) Ajai Sahani, Uttar Pradesh
- 55) Amrita, MDRTB survivor.
- 56) Surjeet Singh, TB survivor
- 57) Paulraj, President, Tamil Nadu Network for People living with HIV and AIDS (TNNP+)
- 58) Karunanithi, Secretary, Tamil Nadu Network for People living with HIV and AIDS (TNNP+)
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