

To

10 July 2018

Mr. Jagat Prakash Nadda

Honorable Minister of Health, Ministry of Health & Family Welfare, Government of India

Cc

The Prime Minister's Office, Government of India

Mr. Piyush Goyal, Minister of Finance, Ministry of Finance, Government of India

Ms. Preeti Sudan, Secretary, Ministry of Health & Family Welfare, Government of India

Dr. S. Venkatesh, DGHS, Ministry of Health & Family Welfare, Government of India

Mr. Sanjeeva Kumar, Addl. Secretary (Health), Ministry of Health & Family Welfare, Government of India

Dr. Sunil D. Khaparde, Deputy Director General, Head, Central TB Division, Ministry of Health & Family Welfare, Government of India

**Subject: Injection-free MDR TB treatment**

Dear Hon. Minister Mr. Nadda,

We write to you as members of the TB affected community and Civil Society in India and globally commend the Government of India for the recent advances in addressing Tuberculosis in India and the bold steps taken so far to end TB by 2025.

However Tuberculosis continues to be a major health emergency in India. According to WHO Global TB Report 2017, our country is the highest burden TB country in the world and had an estimated **27,90,000** people fall ill with TB in 2016, with **4,23,000** deaths the same year. To make matters worse, **1,47,000** new cases of TB in India were drug-resistant.

One of the biggest challenges with TB is diagnosis of people affected by TB and ensuring that they are put on the right treatment. According to the Global TB Report 2017, only one in five persons with MDR-TB was started on treatment. India and China accounted for 39% of the global gap. Treatment success remains low at a bleak 54% globally.

Last week, the global medical community woke up to the welcoming news that South Africa had become the first country to recommend an injection-free, bedaquiline-based regimen for ALL patients with rifampicin-resistant tuberculosis. We sincerely hope that India follows suit immediately.

We request the Health Ministry to take necessary steps to ensure that bedaquiline replaces the injectable medicines that currently form part of India's standard treatment regimen for rifampicin-resistant tuberculosis (RR-TB). Bedaquiline should be used in children 12 and older as they metabolize drug similarly to adults. As paediatric studies of bedaquiline are ongoing in children under 12, we request the Health Ministry to ensure an appropriate injectable-free regimen for children under 12, who are particularly vulnerable to hearing

loss. For children under 12 years old with less severe disease, the Health Ministry should drop the injectable without replacement in line with 2016 World Health Organization recommendations for children<sup>1</sup>. For children under 12 years with more severe forms of disease, the Health Ministry should replace the injectable with delamanid—which has been shown to be very safe, and its paediatric use is recommended by the World Health Organization<sup>2</sup>.

The injectables are associated with a number of serious side effects, including causing permanent damage such as irreversible hearing loss in as many as 50 percent of patients<sup>3</sup>, and their efficacy against drug-resistant TB has not been validated in a clinical trial. Streptomycin is not recommended by the World Health Organization as part of standard treatment of rifampicin-resistant TB, and its use in India especially under the Category II regimen should be stopped immediately in accordance with World Health Organization guidance<sup>4</sup>.

Bedaquiline, on the other hand, has had several clinical trials and has already been approved by stringent regulatory authorities since 2012 and in India since 2015. It has been seen with recent studies that regimens containing bedaquiline were associated with a 41% increase in treatment success and a 3-fold reduction in mortality<sup>5</sup>.

Quoting from a study<sup>6</sup> that was published last year, the authors conclude: "There is limited evidence of the efficacy of IAs [injectable agents], clear evidence of the risks of these drugs, and that persons living with MDR-TB should be informed about these risks and provided with access to alternative therapeutic options" namely, bedaquiline and delamanid.

Patients with MDR-TB are suffering from painful injectables and permanent hearing loss from injectables, when there are more effective evidence-based treatment options available like bedaquiline.

We hope that the Indian Government takes the necessary action keeping in mind that every person who is affected by TB has the right to access drugs that will cure them and not leave them with permanent disability.

We look forward to your response by the end of this month and are committed to supporting the ministry and the TB programme in providing the highest quality care and ending TB in India.

For further information, kindly contact Ms. Rhea Lobo, Global Coalition of TB Activists, on +919930687886, or email [communication@gctacommunity.org](mailto:communication@gctacommunity.org)

Respectfully submitted by,

Affected Communities and Civil Society

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<sup>1</sup> <http://apps.who.int/iris/bitstream/handle/10665/250125/9789241549639-eng.pdf?sequence=1>

<sup>2</sup> [http://www.who.int/tb/publications/Delamanid\\_interim\\_policy/en/](http://www.who.int/tb/publications/Delamanid_interim_policy/en/)

<sup>3</sup> [http://www.tbonline.info/media/uploads/documents/who\\_must\\_recommend\\_bedaquiline\\_for\\_all\\_patients\\_with\\_mdr\\_t  
b.pdf](http://www.tbonline.info/media/uploads/documents/who_must_recommend_bedaquiline_for_all_patients_with_mdr_tb.pdf)

<sup>4</sup> <http://apps.who.int/iris/bitstream/handle/10665/255052/9789241550000-eng.pdf?sequence=1>

<sup>5</sup> [https://www.ghdonline.org/drtb/discussion/global-tb-cab-welcomes-introduction-of-safer-drug-/](https://www.ghdonline.org/drtb/discussion/global-tb-cab-welcomes-introduction-of-safer-drug/)

<sup>6</sup> [http://www.ingentaconnect.com/content/iuatld/ijtld/2017/00000021/00000011/art00006;jsessionid=199yqjqho10jr.x-  
ic-live-02](http://www.ingentaconnect.com/content/iuatld/ijtld/2017/00000021/00000011/art00006;jsessionid=199yqjqho10jr.x-ic-live-02)

- 1 Aarti Kumar, Advocate, Supreme Court of India
- 2 Alberto Colorado, Americas TB Coalition
- 3 Aleksandre Tarkhnishvili, Georgia
- 4 Alex P. Margery, TB Proof, South Africa
- 5 Alma Ram, Jagriti Bhalai Kendra Society, India
- 6 Ani Amashukeli, Georgia
- 7 Ankesh Grover, India
- 8 Anuvinda Varkey, Advocate, India
- 9 Arjun Maharaj, India
- 10 Arne Von Delft, TB Proof, South Africa
- 11 Arumugam Sankar, Empower India
- 12 Austin Arinze Obiefuna, Afro Global Alliance, Ghana
- 13 Bella Akhagba, Bella Foundation for Child and Maternal Care, Nigeria
- 14 Blessina Kumar, Global Coalition of TB Activists, India
- 15 Carlos Basilia, Observatório Tuberculose Brasil
- 16 Cedric Fernandes, Sahara Aalhad Centre for Residential Care & Rehabilitation, India
- 17 Chanel Rossouw, TB Proof, South Africa
- 18 Choub Sok Chamreun, KHANA, Cambodia
- 19 Colleen Daniels, CD Global Consulting
- 20 D. Roshan Kumar, SEEDS, India
- 21 Dalene Von Delft, TB Proof, South Africa
- 22 David Tevzadze, Georgia
- 23 Donato Santos Bruno, Movimento População De Rua, Brazil
- 24 Dra. Doris Saldaña Pinedo, Lawyers Human Rights and Health Institute, INSADEH, Perú
- 25 Edwina Pereira, Bangalore, India
- 26 Eldrid Tellis, Sankalp Rehabilitation Trust, India
- 27 Elene Khmiadashvili, Georgia
- 28 Elvi Solita Siahaan, Yayasan Menara Agung Pengharapan Internasional, Indonesia
- 29 Emmanuel R. Chidong'oi, Tanzania Organization for Agricultural Development (TOFAD)
- 30 Erekle Lashkhi, Georgia

- 31 Erica Lessem, Treatment Action Group, USA
- 32 Eva Limachi Salgueiro, Survivor of TB RAFA (Adverse Reaction to the Antituberculosis Drug), Bolivia
- 33 Faiz Anwar, Jharkhand, India
- 34 Ganesh Acharya, TB survivor, India
- 35 Giorgi Lashkhi, Georgia
- 36 Giorgi Meishvili, Georgia
- 37 Gopa Kumar, Touched by TB, India
- 38 Harold Kachepatsonga, Malawi Network of Religious Leaders living with HIV/AIDS (MANERELA+), Malawi
- 39 Hna. María Vander Linde, Instituto de Salud "Cristoforus Deneken" ISDEN, Perú
- 40 Jaime Ernesto Argueta Medina, National Association of Positive People Vida Nueva, El Salvador
- 41 Jennifer Furin, Harvard Medical School, USA
- 42 Jerry Amoah-Larbi, Ghana National TB Voice Network
- 43 Ketevan Gordeladze, Georgia Red Cross Society
- 44 Ketevan Mindeli, Georgia Red Cross Society
- 45 Ketho Angami, ARK Foundation, Nagaland
- 46 Khatuna Mindeli, Georgia
- 47 Khumanthem Jayanta Kumar Singh (Bobby), Delhi
- 48 Leonid Lecca, Socios En Salud, Peru
- 49 Lourdes Mercedes Cruzado Castro, REDTBLAC, Latin American & Carribean
- 50 Maia Kukava, Georgia
- 51 Marcus Low, South Africa
- 52 Mary E Miller, TB Proof, South Africa
- 53 Mathew Titus, Economist, India
- 54 Md Saiful Islam, Associate Scientist, International Centre for Diarrheal Diseases Research, Bangladesh
- 55 Md. Sanwar Hossain, program Manager, Ashar Alo Society (AAS), Bangladesh
- 56 Mercy Annapoorni, Rainbow TB forum, India
- 57 Michelle Galloway, TB Proof, South Africa
- 58 Mohammad Khakerah Rashid, MSH Afghanistan
- 59 Mona Balani, Touched by TB, India

- 60 Nana Burduli, Georgia Red Cross Society
- 61 Nino Barbaqadze, Georgia
- 62 Nino Didberidze, Georgia Red Cross Society
- 63 Nino Osepaishvili, Georgia Red Cross Society
- 64 Nino Siradze, Georgia Red Cross Society
- 65 Nutsa Chapidze, Georgia
- 66 Pedro Quiñones Figueroa, Human Rights and Health Institute, INSADEH Perú
- 67 Peter Ngo'la Owiti, Wote Youth Development Projects, Kenya
- 68 Prabha Mahesh, Touched by TB, India
- 69 Priyanka Kumari, Global Coalition of TB Activists, India
- 70 Prof. Brian Citro, Northwestern Pritzker School of Law, USA
- 71 Pubudu Pathirana, Shanrhi Maargam, Sri Lanka
- 72 Raja Mohamed, Meera Foundation, India
- 73 Rajesh Singh, Founder Director INFIMAS and STA-WBG, India
- 74 Raphael Godlove Ahenu, Global Media foundation, Ghana
- 75 Rhea Lobo, Touched by TB, India
- 76 Salome Atim, Engendering Gender International, Uganda
- 77 Sasi Kumar, Delhi
- 78 Soumita Basu, Bone TB Survivor, India
- 79 Subrat Mohanty, The Union, India
- 80 Sunitha Varghese, Public Health Physician, India
- 81 Swarna Kodagoda. Executive Director, Alliance Lanka, Sri Lanka
- 82 Tea Chikviladze, Georgia Red Cross Society
- 83 Thua Aung, Radanar Ayar Rural Development Association, Myanmar
- 84 Timpiyan Leseni, Talaku Community, Kenya
- 85 Uchenna Ebenezer, Annabelles Bogi Development Initiative, Nigeria
- 86 Vanessa Gutierrez, USA
- 87 Vikas Panibatla, TB Alert, India
- 88 Wieda Human, TB Proof, South Africa
  
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- 87 Vikas Panibatla, TB Alert India
- 88 Wieda Human, TB Proof, SA

**Organisations:**

- 1 Activists Coalition for TB Asia Pacific (ACT! AP)
- 2 Alliance Lanka
- 3 Americas TB Coalition
- 4 Annabelles Bogi Development Initiative, Nigeria
- 5 ARK Foundation



- 6 Bella Foundation for Child and Maternal Care
- 7 Blossom Trust
- 8 Center for Change and Community Development
- 9 CNS (Citizen News Service)
- 10 Drug Resistant TB Scale-Up Treatment Action Team (DR-TB STAT), Stop TB Partnership, Geneva
- 11 Empower India
- 12 Engendering Gender International Uganda
- 13 Georgia Red Cross Society
- 14 Ghana National TB Voice Network
- 15 Global Coalition of TB Activists
- 16 Global Media foundation
- 17 Global TB CAB
- 18 Hepatitis Foundation of Ghana
- 19 Human Rights and Health Institute, INSADEH, Perú
- 20 Infimas
- 21 Jagriti Bhalai Kendra Society
- 22 KHANA
- 23 MANERELA+
- 24 Meera Foundation
- 25 Movimento População De Rua
- 26 MSH Afghanistan
- 27 National Association of Positive People Vida Nueva, El Salvador
- 28 National Coalition of People living with HIV in India (NCPI+)
- 29 Observatório Tuberculose Brasil
- 30 Radanar Ayar Rural Development Association
- 31 Rainbow TB forum
- 32 Sahayog
- 33 Sankalp Rehabilitation Trust
- 34 SEEDS
- 35 Shanthi Maargam
- 36 Socios En Salud

- 37 South Indian Harm Reduction Network
- 38 Talaku Community
- 39 TB Alert India
- 40 TB Proof, South Africa
- 41 TEST foundation
- 42 The Association for Supporting MDR-TB Patients from Romania
- 43 The Drug-Resistant TB Scale Up Treatment Action Team, Boston, USA
- 44 The Sentinel Project on Pediatric Drug-Resistant Tuberculosis, Boston, USA
- 45 Touched by TB, India
- 46 Treatment Action Group
- 47 Western Harm Reduction Network
- 48 Widows Fountain of Life (WFoL)
- 49 Wote Youth Development Projects
- 50 Yayasan Menara Agung Pengharapan Internasional, Indonesia