Open Letter by the Special Rapporteur on the right of everyone to the highest attainable standard of mental and physical health, Dainius Pūras, in the context of the preparations for the United Nations High-Level Meeting on Tuberculosis, which will take place in New York in September 2018

18 June 2018

Excellencies,

I am honoured to address you regarding the United Nations High-Level Meeting on Tuberculosis and respectfully request that this letter may be shared with UN Member States to inform the negotiations.

Tuberculosis (TB) is a preventable and curable disease, yet killed 1.7 million people in 2016—more than any other infectious disease, including HIV and AIDS. This paradox is explained by the inequality, poverty, and human rights violations that drive the TB epidemic. Indeed, TB tracks inequality globally and within communities; 70% of the global TB burden is in South-East Asia and Africa, with a disproportionate impact everywhere on those who are poor, marginalized and vulnerable.[1] TB is one of the top five killers of women aged 20-59 years old.[2]

If TB is a disease of poverty and marginalization, drug-resistant TB is doubly so, and often the result of compounding human rights violations. The TB response will not be successful if it fails to address the underlying drivers of the epidemic.

This open letter draws attention to a few of the key human rights issues that this meeting must address if it is to mark a turning point in the global struggle to end TB.

OBLIGATIONS UNDER INTERNATIONAL LAW

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) establishes the right to the highest attainable standard of physical and mental health, which is further developed by the Committee on Economic, Social and Cultural Rights (CESCR) in its General Comment 14. According to this international legal framework States Parties are under the obligation to immediately comply with core obligations, including non-discriminatory and equitable provision of health services that

[1] People living with HIV accounted for 10 % of the total global TB burden. In 2016, 1.7 million people died from TB, i**ncluding 0.4 million among** people with HIV (WHO). This is close to 24%.
[2] WHO, Tuberculosis in Women, http://www.who.int/tb/publications/tb_women_factsheet_251013.pdf (2015).

are necessary for a successful TB response.[3] Yet compliance among many States is weak,[4] and some have even regressed in their compliance.[5] Most States are also yet to meet their "obligations of comparable priority," whose scope encompasses measures to prevent, treat and control the TB epidemic; provide education and information to communities regarding how to prevent and treat TB; and provide appropriate training for health personnel, including on health and human rights.[6]

States Parties are obligated to take immediate steps to progressively realise the right to health

The International Covenant on Economic, Social and Cultural Rights obligates States Parties to "progressively realize" the right to the enjoyment of the highest attainable standard of health.[7]

If the current rate of decline of TB incidence continues, it will take until 2182 to reach the End TB targets for 2030 established by the World Health Organization (WHO).[8] It is not rational to target 2030 yet act toward 2182. The End TB Strategy benchmarks reflect what is achievable if States meet their legal obligation to "move as expeditiously and effectively as possible" toward realizing the right to the highest attainable standard of health.[9][10] Progressive realisation is not perpetually deferrable but rather requires action toward measurable advancement in the TB response.[11]

The lack of adequate progress in the TB response can largely be attributed to the failure of States to adopt and implement effective, rights-based, and cost-effective strategies, including universal access to good quality prevention, testing and treatment, including rapid diagnostic tests, new drugs and community-based care, legal protections against discrimination and for privacy and confidentiality, access to information about the disease, its symptoms and prevention and treatment options, and intensified efforts to address stigma and the underlying determinants of health, such as water, sanitation, the environment, housing, and food.

[3] CESCR General Comment No. 14, para. 44(A, E). See also other core obligations of primary relevance, including those in GC14, 43(B-D, F).
[4] WHO. World Health Statistics 2018 (2018), http://apps.who.int/iris/bitstream/handle/10665/272596/9789241565585-eng.pdf. WHO. State of inequity: Reproductive, mother, newborn and child health (2015). http://www.who.int/gho/health_equity/report_2015/en/.
[5] There is, moreover, evidence of regression in key areas; for example, it is estimated that the number of undernourished people in the world increased to 815 million people in 2016 from 777 million in 2015. (FAO, IFAD, UNICEF, WFP and WHO. 2017. The State of Food Security and Nutrition in the World 2017. Building resilience for peace and food security, Rome, FAO at ii).
[6] CESCR, General Comment 14, para. 44(c-e). WHO. Global Tuberculosis Report 2017 (2017). http://www.who.int/tb/publications/global_report/en/.
[7] ICESCR article 2(1) and CESCR, General Comment No 14, para. 31.
[8] Global Plan to End TB for 2016-2020.
[9] Stop TB, End TB Strategy, http://www.who.int/tb/post2015_TBstrategy.pdf?ua=1; Global Plan to End TB for 2016-2020, http://www.stoptb.org/assets/documents/global/plan/GlobalPlanToEndTB_TheParadigmShift_2016-2020_StopTBPartnership.pdf.
[10] ICESCR article 2(1) and CESCR, General Comment No 3, para. 9.
[11] ICESCR article 2(1) and CESCR, General Comment No 3, para. 2.

States in a position to assist must fund the TB response at levels sufficient to meet sustainable development goals

Many States "in a position to assist" in the TB response have not adequately met their duty to provide economic and technical assistance and cooperation,"[12] necessary to meet global targets.[13] In 2017, $6.9 billion in TB funding was available in the countries that carry 97% of the global TB burden. To implement TB care and prevention activities in line with WHO End TB Strategy and the Stop TB Partnership's Global Plan to End TB 2016-2020, States should double current funding to at least $13 billion annually, working together through the Global Fund, bilateral efforts, and domestic resources.[14]

At the High-Level Meeting on Tuberculosis, States should commit to:

- Set concrete, deliberate, and specific targets and timelines that fulfil human rights obligations arising from domestic, regional, and international law. These targets must include the full participation of civil society and affected communities, including people affected by drug-resistant TB (DR-TB), be fully resourced and implemented, and be aligned to the WHO End TB Strategy, the Stop TB Partnership Global Plan to End TB, and the Sustainable Development Goals.
- Prohibit in law and policy all forms of discrimination against people affected by TB, including in employment, education, housing, and health care settings, and repeal or amend any laws or policies that discriminate against people based on TB or other health status. Further, establish legal protections for the rights to privacy and confidentiality for people affected by TB, and establish accessible remedies for discrimination or violations of the rights to privacy or confidentiality.
- Fulfil the right of all people to access high quality, people-centred prevention, testing, treatment and care services for TB (including drug-resistant forms), including counselling, new drugs and technologies, such as bedaquiline, delamanid, and rapid diagnostic tests.
- Implement community-based services that are accessible to all people and take all measures necessary to reach all people in need of such services, including through the deployment of community health workers employed under dignified conditions.
- States in a position to assist should commit to:
  - Doubling current funding to US$13 billion annually.
  - Holding a donor conference in 2019 to develop a funding strategy and specific commitments on TB funding.

[12] ICESCR article 2(1) and CESCR, General Comment No 14, para. 45
[13] Global Plan to End TB for 2016-2020, at 101.
[14] United to End Tuberculosis: An Urgent Global Response to A Global Epidemic, Key Asks from TB Stakeholders and Communities.

RESEARCH AND DEVELOPMENT GAPS AND OTHER ACCESS BARRIERS

More than fifty years of inadequate research and development (R&D) funding for TB have contributed to the rise of drug-resistant TB strains and, at the same time, left us with few tools to adequately combat them.[15] The only two new drugs for TB, bedaquiline and delamanid (the first in more than 40 years) are not available to most people who need them. In fact, only 16,639 courses of bedaquiline (10,429 of those by South Africa) and 1,429 courses of delamanid have been procured by national TB programs. [16] This, despite the fact that that nearly 500,000 people fell ill with DR-TB in 2016 alone. [17] The lack of access to effective diagnostics and treatment, accelerates the process by which even newer drugs become ineffective against emerging forms of TB. [18] Moreover, while largely funded by public research and development sources,[19] newer and better quality medicines and technologies remain unavailable and unaffordable to most of those who need them.[20] It is essential to ensure that TB innovations produced by public investment are considered public goods, with affordable and equitable access for all.

The Global Plan to Stop TB estimates that approximately $2 billion in TB R&D is needed annually; yet annual global investment in TB R&D only exceeded $700 million for the first time in 2016, still leaving a $1.3 billion annual funding gap.[21] This funding gap is a public health and human rights serious issue. States acting alone could close the $1.3 billion annual funding gap by committing 0.1% of their current annual expenditure on R&D to TB.[22]

The 2016 UN Secretary General's High-Level Panel on Access to Medicines made a number of recommendations to address structural R&D barriers for TB and other neglected illnesses including, among others: (i) public funders of research should require knowledge generated from such research to be freely and widely available, including positive, negative and inconclusive clinical trials data; (ii) Universities and research institutions must prioritize public health objectives in patent & licensing practices and (ii) UN Member States and funders should implement new models for financing and

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[15] *See*, Low M. *The Tuberculosis Treatment Pipeline: A Breakthrough Year for the Treatment of XDR-TB.* In: Frick, Gaudino A, Harrington M, Horn T, et al.; *Treatment Action Group. 2017 Pipeline Report.* New York: Treatment Action Group; 2017. http://www.pipelinereport.org/2017/tbtx.

[16] DR-TB STAT, *Country Updates: Cumulative Program Numbers.* Most reported data through Quarter 1 (end March) 2018. Available at http://drtb-stat.org/country-updates/

[17] WHO, *Global Tuberculosis Report, 2017*, p. 1 (2017). Available at http://www.who.int/tb/publications/global_report/en/

[18] Thi Van Anh Nguyen, Richard M Anthony, Anne-Laure Bañuls, Thi Van Anh Nguyen, Dinh Hoa Vu, Jan-Willem C Alffenaar; Bedaquiline Resistance: Its Emergence, Mechanism, and Prevention, Clinical Infectious Diseases, Volume 66, Issue 10, 2 May 2018, https://academic.oup.com/cid/article/66/10/1625/4602986.

[19] In 2016, only 11% of R&D funding came from private sources, with 66% coming from public sources, 20% from philanthropic sources and 3% from multilateral sources.

[20] Médecins Sans Frontières Access Campaign, *Issue Brief, Four Years and Counting: Slow Scale-Up of Newer Mdr-Tb Drugs Covers Less Than 5% in Need* (2017) at 2.

[21] Stop TB Partnership, *Global plan to end TB, 2016–2020: the paradigm shift*, http://www.stoptb.org/global/ plan/plan2/; *The Ascent Begins: Tuberculosis Research Funding Trends*, Treatment Action Group.
2017 at 3.

[22] As measured by Gross Domestic Expenditure on Research and Development (GERD). Treatment Action Group, *Investing in R&D to end TB: a global priority* (2017) at 2.

rewarding research on unmet public health needs that delink costs of research and development from end prices.[23]

At the High-Level Meeting on Tuberculosis, States should commit to:

- Close the $1.3 billion annual R&D funding gap, including by dedicating at minimum 0.1% of their total national R&D expenditure to funding innovations for the TB response.
- Commit to funding models that delink the costs of R&D from drug and diagnostic prices.
- Ensure universal access to all new medicines and diagnostic technologies, including bedaquiline, delamanid and rapid diagnostic tests, for all people and in all countries where they are needed.
- Implement all recommendations of the High-Level Panel on Access to Medicines.

Reform of Law, Policy, and Practice Is Needed to Ensure Access to Diagnostics & Medicines

The right to health requires essential medicines and relevant technologies to be available and accessible to all.[24] In 2016, only 6.3 million of the estimated 10.4 million TB cases were reported due to barriers including insufficient access to health facilities and diagnostic tools.[25] In addition, only 5% of people who need them have access to newer TB medicines.[26] These conditions do not indicate adequate "progressive realization" of the right to health and directly lead to further rights violations.

While the use of flexibilities included in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other access strategies has expanded access to some essential medicines and technologies, especially for HIV/AIDS, significant gaps remain where TRIPS flexibilities are under-utilized in tuberculosis and other diseases and implementation of TRIPS-plus measures are making effective use more difficult and delaying competition.

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[23] United Nations Secretary-General's High-Level Panel on Access to Medicines, Promoting Innovation and Access to Health Technologies, 2016, https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf. Some successful delinkage models include the Life Prize and the Drugs for Neglected Disease initiative (DNDi). To accelerate innovation and collaboration to achieve accessible and affordable TB medicines, the Life Prize pools funding to incentivize R&D, pools intellectual property and data and finances R&D activities up front through grants. https://www.msfaccess.org/3Ps-project. *See also*, Lessons Learned: 10 Years of DNDi, https://www.dndi.org/about-dndi/business-model/lessons-learned/.

[24] CESCR, General Comment No 14, para. 12.

[25] WHO, Global TB Report (2017).

[26] Médecins Sans Frontières Access Campaign, *Issue Brief, Four Years and Counting: Slow Scale-Up of Newer Mdr-Tb Drugs Covers Less Than 5% in Need* (2017).

At the High-Level Meeting on Tuberculosis, States should commit to:

- Update national TB guidelines and essential medicine lists to align to WHO guidelines and issue humanitarian waivers and rapid registration programs where MDR-TB medicines are not registered.
- Establish rigorous, substantive patent examination guidelines aligned to the right to health in order to prevent unwarranted patents and foster local and generic pharmaceutical production.
- Make full use of TRIPS flexibilities, including by incorporating them into domestic legal frameworks.
- Halt use of undue political and economic pressures with regard to implementing TRIPS-plus measures in developing countries that may restrict access to essential medicines and technologies.
- Conduct Legal Environment Assessments, using the Stop TB Partnership's Operational Guide, to ensure an enabling, rights-respecting legal and policy environment for TB.[27]

THE OVER AND INAPPROPRIATE USE OF PUNITIVE LAWS, DEPRIVATION OF LIBERTY AND PRISON CONDITIONS FUEL TUBERCULOSIS

Persons deprived of liberty are at exceptionally high risk of TB, in both high and lower burden countries alike. These high rates of transmission result directly from rights violations in custodial settings such as poor nutrition, unhygienic conditions, and poor access to medical care, inadequate ventilation and significant overcrowding.[28] These and other conditions drive the TB pandemic both within and beyond the walls of prisons and other places of confinement.

International standards, including the UN Revised Standard Minimum Rules for the Treatment of Prisoners (the "Mandela Rules"), set forth minimal human rights protections in prisons.[29] Yet, few States have put in place legal frameworks that provide adequate TB services in prisons and address the apex problem of overcrowding. Furthermore, inadequate accountability and transparency in prison and other custodial settings impede change.[30]

[27] http://www.stoptb.org/assets/documents/communities/StopTB_TB LEA DRAFT_FINAL_Sept 27.pdf
[28] WHO, Tuberculosis in Prisons, http://www.who.int/tb/areas-of-work/population-groups/prisons-facts/en/; Stop TB Partnership, Prisoners Key Populations Brief.
[29] United Nations Standard Minimum Rules for the Treatment of Prisoners (Mandela Standards), A/Res/70/175.
[30] *E.g.* Judicial Inspectorate for Correctional Services South Africa Annual Report for the period 1 April 2015 to 31 March 2016, at 12 and 32.

At the High-Level Meeting on Tuberculosis, States should commit to:

- Initiate or accelerate penal reform towards the radical reduction of incarceration decriminalisation of illicit drugs, expand alternatives to incarceration, and rehabilitation, with a strategy, timelines, and targets, developed in collaboration with civil society and other stakeholders.
- Provide good quality TB prevention, testing, treatment and care services to all persons deprived of their liberty and living with TB and those at risk of infection or disease, including isoniazid preventive therapy, drug susceptibility testing, new drugs, and counselling.
- Ensure a continuity of TB services upon a person's release from detention, including through effective and timely communication between prison administrators and national TB programs.
- Align legal frameworks relevant to detention to international best practice and human rights, including the Mandela Rules.

COERCIVE LAWS AND MEASURES AND OVERUSE OF CONFINEMENT DRIVE TUBERCULOSIS

WHO emphasizes that community-based care should always be considered before the use of isolation[31] that involuntary isolation is unethical and in the extremely rare circumstances in which involuntary isolation might be considered, it should be a last resort measure and conducted in a medically appropriate setting.[32] Placing people in prison because there are inadequate facilities and services is not compatible with the right to health. People with TB should never be detained or imprisoned for stopping or interrupting their treatment, and prison cells should not be used for involuntary isolation. Rather than relying on confinement, a rights-based approach requires States to develop well-resourced community care options, ensure TB patients have adequate information and support. Rights-protecting, community-based treatment models have been shown to be extremely effective, with high treatment completion and cure rates.[33]

At the High-Level Meeting on Tuberculosis, States should commit to:

- Align law and policy on the use of coercive measures and notification of communicable diseases to international human rights standards, including the rights to liberty and freedom of movement, and the WHO Ethics guidance for the implementation of the End TB Strategy.

[31] WHO, Ethical Guidance (2017), at 37.
[32] WHO, Ethical Guidance (2017) at 37. Involuntary isolation must also be implemented in an ethical and non-discriminatory manner, with the least restrictive means, in an appropriate medical setting and with legal safeguards. Id.
[33] Partners in Health, PIH Achieves High Treatment Success Rate among Children with MDR-TB, https://www.pih.org/article/pih-achieves-high-treatment-success-rate-among-children-with-mdr-tb.

- Provide the financial and technical resources required to implement such legal frameworks, alongside the scaling up of community-based, ethical, and available treatment and support models
- Eradicate the practice of criminalizing or imprisoning people on the basis of TB status, including for stopping or interrupting treatment or for TB transmission.

LAW AND POLICY MUST ENSURE THE PROVISION OF TB SERVICES FOR MIGRANT AND MOBILE POPULATIONS

Some groups of migrants are at disproportionately high risk of TB infection, yet face many barriers accessing TB prevention, treatment and care. Many countries link access to health care services to residency status, denying or limiting services to non-citizens.[34] Some countries require x-rays and deport or prevent entry of migrants who do not have TB but only have scars on their lungs from earlier TB.[35] Undocumented people may also avoid seeking TB or other health care services out of fear of adverse immigration consequences.[36] Denying or discouraging access to health care for migrants violates the core obligation of non-discrimination in provision of health services[37] and facilitates TB transmission within States and across borders.

At the High-Level Meeting on Tuberculosis, States should commit to:

- Provide TB prevention, testing, treatment and support to migrants and mobile populations with legal protections against negative immigration or other consequences.
- Repeal or amend laws, policies and practices that discriminate against migrants in regards to access to health care; including laws that allow for travel and work restrictions, deportation, or confinement on the basis of TB status.
- Ensure that laws and policies clearly provide for migrants' access to TB services in detention and confinement settings.
- Immediately implement the commitments from World Health Assembly Resolution 61.17, including promoting bilateral and multilateral cooperation on migrants' health among countries involved in the entire migratory process to ensure the portability of health benefits and harmonization of treatment protocols.[38]
- Create binding regional agreements to guarantee comprehensive TB care for all migrants across borders.

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[34] Stop TB Partnership, Key Populations Brief Mobile Populations.
[35] Farida I. Al Hosani and Ghada A. Yahia, *Prevalence of pulmonary tuberculosis among expatriates subjected to medical visa screening in Abu Dhabi, United Arab Emirates*, Journal of Epidemiology and Global Health, 2013-03-01, Volume 3, Issue 1, Pages 23-30; Asma Ali Zain, *People with old tuberculosis scars can get UAE visa*, Khaleej Times (February 26, 2016). Available at https://www.khaleejtimes.com/nation/shaikh-mohammed-amends-medical-exam-system-for-expats
[36] The effect of fear on access to care among undocumented Latino immigrants. J Immigr. Health. 2001;3(3):151–6.
[37] CESCR, General Comment No 14, para 43(a).
[38] World Health Organization, Resolution WHA 61.17: Health of Migrants (2008); World Health Organisation, Tuberculosis Control in Migrant Populations Guiding Principles and Proposed Actions, http://apps.who.int/iris/bitstream/handle/10665/246423/9789290617754-eng.pdf?sequence=1.

RIGHTS-BASED AND INCLUSIVE ACCOUNTABILITY

Accountability of States and healthcare systems to those they serve is a precondition for effective implementation of all other measures needed to end TB. It is incumbent on States to take concrete measures to ensure that healthcare users and civil society are empowered to make their healthcare systems work, including by protecting the rights to freedom of assembly, of expression and of the press.[39]

Accountability in healthcare also requires improved data systems to monitor progress and identify obstacles, including disaggregated data across key populations. Accountability in the TB response requires genuine accountability for the commitments made at this High-Level Meeting.

At the High-Level Meeting, States should commit to:

- Fund and facilitate, through legislation and policy, proactive measures that enable people affected by TB and DR-TB to lead in the formulation, implementation, monitoring and evaluation of the TB response at all levels. Keeping in mind the social and economic conditions that often impede their full engagement, such measures must include providing financial and technical support to TB community groups and civil society, and allowing for freedom of expression.
- Fund and otherwise support local accountability structures, such as clinic and village health committees, including by adopting legal and policy frameworks that govern and foster their operations and ensure their independence.
- Review and reform laws and policies that impede civil society access to foreign funding.[40]
- Develop metrics in collaboration with civil society and key and affected populations, nationally and as part of monitoring the commitments at this High-Level Meeting, that incorporate human rights obligations and community concerns.
- Maintain a Global TB Cabinet through which Heads of State convene at least every two years to assess the implementation of all commitments made at this High-Level Meeting.
- Convene a second High-Level Meeting on TB within five years, by which time progress on agreed targets must be assessed according to measurable indicators.

CONCLUSION

I thank you for taking the time to consider these issues alongside the many other inputs for the High-Level Meeting on Tuberculosis. I remain at your disposal and should

[39] *See, e.g.* Report of the Special Rapporteur on the rights to freedom of peaceful assembly and of association, A/68/299 (7/08/2013) paras. 57 and 94.
[40] Report of the Special Rapporteur on the rights to freedom of peaceful assembly and of association, A/HRC/23/39 (24/04/2013) para. 79.

further information or clarifications be required with respect to this letter, I can be contacted through the Office of the High Commissioner for Human Rights (srhealth@ohchr.org, ldelasierra@ohchr.org; Tel: +41 22 917 9741;).

Please accept, Excellencies, the assurances of my highest consideration.

Dainius Pūras
Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health