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## ARTICLES

### ACTIVATING LAW AND HUMAN RIGHTS TO END TUBERCULOSIS: AN EMPIRICAL ASSESSMENT OF TEN COUNTRIES' FULFILLMENT OF UNITED NATIONS COMMITMENTS

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#### ABSTRACT

The United Nations General Assembly held the first-ever High-Level Meeting on Tuberculosis in 2018 (the TB UNLHM). In the Political Declaration that followed, Heads of State made ambitious pledges to end TB and drug-resistant TB by 2030. Among these were pioneering legal and human rights commitments on the right to health, non-discrimination, and access to medicines. In 2020 and 2023, the UN Secretary-General and World Health Organization released reports examining countries' progress toward the UN pledges. The reports discuss some human rights initiatives and contain data for key targets, such as reductions in TB incidence and deaths, but they do not empirically evaluate progress toward the legal and human rights commitments. This paper fills this gap by reviewing law and policy in ten countries with high burdens of drug-resistant TB. It develops the TB UNHLM Legal Rights Index modeled on the Human Development Index, comprising quantitative indicators for the legal and human rights pledges. Using this empirical framework, this paper evaluates over 150 legal instruments from the ten countries and finds that each has failed to meet all three commitments. The results nonetheless demonstrate significant variation among the countries and highlight challenges and opportunities as they work to fulfill their pledges in the new Political Declaration from the second TB UNHLM held in September 2023.

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## TABLE OF CONTENTS

I.	INTRODUCTION
II.	GLOBAL CONTEXT
A.	<i>Drug-Resistant Tuberculosis</i>
III.	ASSESSMENT SCOPE, METHODOLOGY, AND LIMITATIONS
A.	<i>Scope</i>
1.	<i>TB UNHLM Commitments</i>
2.	<i>Legal Jurisdictions</i>
3.	<i>Sources of Law</i>
B.	<i>Methodology: TB UNHLM Legal Rights Index</i>
1.	<i>Right to Health Indicator</i>
2.	<i>Non-Discrimination Indicator</i>
3.	<i>Access to Medicines Indicator</i>
C.	<i>Limitations</i>
IV.	ASSESSMENT RESULTS: FULFILLING TB UNHLM LEGAL AND HUMAN RIGHTS COMMITMENTS
A.	<i>TB UNHLM Legal Rights Index</i>
B.	<i>Right to Health</i>
C.	<i>Non-Discrimination</i>
D.	<i>Access to Medicines</i>
V.	CONCLUSION
	APPENDIX

## I. INTRODUCTION

In September 2018, the United Nations (UN) General Assembly held the first-ever High-Level Meeting on the Fight against Tuberculosis (the TB UNHLM).<sup>1</sup> The theme was: “United to end tuberculosis: an urgent global response to a global epidemic.”<sup>2</sup> During the meeting, the heads of UN Member States acknowledged that tuberculosis (TB) was the top infectious disease killer at the time and a major cause of death related to antimicrobial resistance. They agreed to accelerate efforts to end TB and reach all affected people with prevention, diagnosis, treatment, and care.

The TB UNHLM produced a Political Declaration on the Fight against Tuberculosis in the form of a UN General Assembly resolution.<sup>3</sup> In the Declaration, UN Member States affirmed that:

tuberculosis, including its drug-resistant forms, is a critical challenge

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1. *United Nations High-Level Meeting on the Fight to End Tuberculosis*, GEN. ASSEMB. OF THE UNITED NATIONS, (Sept. 26, 2018), <https://www.un.org/pga/73/event/fight-to-end-tuberculosis> [<https://perma.cc/X284-JLPE>].

2. *Id.*

3. G.A. Res. 73/3 (Oct. 18, 2018).

and the leading cause of death from infectious disease, the most common form of antimicrobial resistance globally and the leading cause of death of people living with HIV, and that poverty, gender inequality, vulnerability, discrimination and marginalization exacerbate the risks of contracting tuberculosis and its devastating impacts, including stigma and discrimination at all ages . . .<sup>4</sup>

Member States committed to meeting ambitious targets in the four years from 2019 to 2022, during which the Political Declaration runs. These targets include reaching forty-million people with TB treatment, including 1.5 million with drug-resistant TB (DR-TB) and thirty million with preventive treatment.<sup>5</sup> In addition to public health targets, countries made three pioneering legal and human rights commitments to “protect and promote” the right to health, “promote and support an end to stigma and . . . discrimination” against people affected by TB, and “[promote] access to affordable medicines.”<sup>6</sup> Member States also requested the UN Secretary-General to submit a report in 2020 and conduct a “comprehensive review” in 2023 with the World Health Organization’s (WHO) support on “the progress and implementation of the [Political Declaration] towards agreed tuberculosis goals at the national, regional and global levels.”<sup>7</sup>

In 2020, the UN Secretary-General and WHO released reports highlighting global progress toward the TB UNHLM targets and documents containing data on TB funding pledges and public health targets, such as reductions in TB incidence and deaths and increases in treatment access.<sup>8</sup> However, the 2020 progress reports do not empirically evaluate progress toward fulfilling the three legal and human rights commitments. Instead, the Secretary-General’s report discusses a few human rights initiatives, noting that legislators in some “high-burden countries have been working . . . to promote laws that protect the rights of people with TB.”<sup>9</sup> In their recommendations, the reports call on Member States to “[r]eview and update laws, policies and programmers to combat inequalities and eliminate stigma and discriminatory practices in the TB response, working together with civil society and affected communities.”<sup>10</sup>

In 2023, the UN Secretary-General and WHO released their final,

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4. *Id.* at 1.

5. *Id.* ¶¶ 24-25.

6. *Id.* ¶¶ 19, 37.

7. *Id.* ¶ 53.

8. U.N. Secretary-General, *Progress Towards the Achievement of Global Tuberculosis Targets and Implementation of the Political Declaration of the High-Level Meeting of the General Assembly on the Fight Against Tuberculosis*, A/75/236 (Sept. 16, 2020); World Health Org., *Overview: Progress Towards Achieving Global Tuberculosis Targets and Implementation of the UN Political Declaration on Tuberculosis* (Sept. 23, 2020).

9. U.N. Secretary-General, *id.* ¶ 62(b).

10. *Id.* ¶ 103(a); World Health Org., *supra* note 8, at 5.

comprehensive review of global progress towards the TB UNHLM targets.<sup>11</sup> The 2023 reviews contain detailed analyses of global progress in meeting public health targets, including reductions in TB incidence and mortality and the number of people treated for TB.<sup>12</sup> The reviews also contain socio-economic indicators, such as the number of people with TB who experienced financial hardship because of the disease and global funding levels for TB services.<sup>13</sup> However, like the 2020 reports, the 2023 reviews do not empirically evaluate progress toward the TB UNHLM legal and human rights commitments. The Secretary-General's report includes a section titled "Transforming the tuberculosis response with a focus on human rights, equity, multisectoral engagement and accountability," but it only briefly mentions some human rights-related initiatives and highlights the engagement of civil society and affected communities in the TB response.<sup>14</sup> The report also includes a recommendation calling on Member States to "Enforce laws, policies and programmes that protect human rights, and eliminate inequalities, stigma and discriminatory practices in the TB response."<sup>15</sup>

Notably, neither the 2020 nor 2023 progress reports discuss intellectual property or patent policy, despite Member States' commitment in the Political Declaration to use so-called "flexibilities" from the World Trade Organization's TRIPS Agreement to address intellectual property and patent-related barriers to TB drugs.<sup>16</sup> Instead, the Secretary-General's 2020 report highlights global mechanisms and claims that "[b]ilateral and multilateral agreements are helping to make new drugs and diagnostics more affordable."<sup>17</sup> The document only refers to intellectual property barriers in relation to research and development, noting that the "complexity and variability of regulatory processes related to sharing scientific data, patent information, the review of new health products and research protocols also constrain the pace of research" for TB.<sup>18</sup> The Secretary-General's 2023 report does not mention intellectual property and only refers to patents once in a sentence asserting that "[e]asily accessible databases on research and development investment, patents and the pricing of medicines can help ensure that investments in innovation lead to equitable access."<sup>19</sup> The Secretary-General's 2023 report does not mention intellectual property and only

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11. U.N. Secretary-General, *Comprehensive review of progress towards the achievement of global tuberculosis targets and implementation of the political declaration of the United Nations high-level meeting of the General Assembly on the fight against tuberculosis*, A/78/88 (May 18, 2023); World Health Org. *Status Update: Reaching the Targets in the Political Declaration of the United Nations General Assembly High-Level Meeting on the Fight Against Tuberculosis* (Sept. 2023).

12. U.N. Secretary-General, *id.* ¶¶ 8-15, 18-21; World Health Org., *id.* at 3.

13. U.N. Secretary-General, *id.* ¶¶ 16-17, 25-30; World Health Org., *id.* at 5.

14. U.N. Secretary-General, *id.* ¶¶ 58-68.

15. *Id.* ¶ 106(a).

16. General Assembly, *supra* note 3, ¶ 19.3

17. U.N. Secretary-General, *supra* note 8, ¶¶ 45-46.

18. *Id.* ¶ 79.

19. U.N. Secretary-General, *supra* note 1, ¶ 80.

refers to patents once in a sentence asserting that “[e]asily accessible databases on research and development investment, patents and the pricing of medicines can help ensure that investments in innovation lead to equitable access.”<sup>20</sup> Notwithstanding the failure to consider patent-related barriers to TB medicines, both Secretary-General reports acknowledge that “achieving equitable access to new TB medicines and technologies remains a major challenge.”<sup>21</sup>

In September 2023, the UN General Assembly held the second TB UNHLM.<sup>22</sup> The meeting’s theme was “Advancing science, finance and innovation, and their benefits, to urgently end the global tuberculosis epidemic, in particular, by ensuring equitable access to prevention, testing, treatment and care.”<sup>23</sup> Member States reviewed the progress they made in meeting the targets set in 2018 Political Declaration, and they adopted a new declaration, aiming to end the TB epidemic by 2030.<sup>24</sup> A thorough analysis of the 2023 Political Declaration is beyond the scope of this paper. Notably, the declaration recommits Member States to protecting and promoting the right to health, increasing access to affordable medicines, and eliminating all forms of TB-related stigma and discrimination.<sup>25</sup>

This paper empirically evaluates the fulfillment of Member States’ legal and human rights commitments in the 2018 TB UNHLM Political Declaration by examining law and policy in ten countries with high DR-TB burdens. The paper develops the TB UNHLM Legal Rights Index, a novel assessment framework modeled on the Human Development Index, comprising the TB UNHLM Legal Rights Indicator (LRI) and quantitative indicators for the three legal and human rights pledges. Using this empirical framework, this paper evaluates more than 150 legal instruments from the ten countries and finds that each nation has failed to meet all three commitments. The assessment nonetheless demonstrates significant variation among the countries and highlights challenges and opportunities for Member States as they work to fulfill their pledges in the 2023 Political Declaration.

This paper proceeds as follows. Section II sets the global context, focusing on DR-TB. Section III details the assessment’s scope, methodology, and limitations, introducing the TB UNHLM Legal Rights Index. Section IV presents the assessment results and discussion. Finally, section V concludes and shares reflections on fulfilling the TB UNHLM legal and human rights commitments.

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20. U.N. Secretary-General, *supra* note 11, ¶ 80.

21. *Id.* ¶ 57; U.N. Secretary-General, *supra* note 8, ¶ 82.

22. *United Nations High-Level Meeting on the Fight to End Tuberculosis*, GEN. ASSEMB. OF THE UNITED NATIONS, (Sept. 22, 2023), <https://www.who.int/activities/preparing-for-the-un-high-level-meeting-on-the-fight-against-tuberculosis--2023> [<https://perma.cc/EN45-HQNA>].

23. *Id.*

24. G.A. Res. 78/5 (Oct. 16, 2023).

25. *Id.* ¶¶ 39, 70, 77.

## II. GLOBAL CONTEXT

TB is preventable and curable, yet it remains one of the leading causes of death worldwide.<sup>26</sup> In 2022, 10.6 million people fell ill with TB, and 1.3 million died—more than 3,500 people a day.<sup>27</sup> About 3% of the people who got sick with TB—more than three million overall—were “missed” by national TB programs.<sup>28</sup> Some of the “missing millions” may have obtained testing and treatment in the private sector, but many likely went undiagnosed and untreated, further contributing to the spread of the disease.

The COVID-19 pandemic had a terrible impact on the TB response. Key global indicators moved in the wrong direction in 2020 for the first time in more than a decade and continued doing so in 2021, placing hard-earned gains at stake.<sup>29</sup> In its 2021 Global Tuberculosis Report, WHO reported that while TB incidence remained essentially the same as the year before, the number of people newly diagnosed with TB and registered by their national health systems fell from 7.1 million to 5.8 million.<sup>30</sup> WHO also reported an increase in TB deaths in 2020 and 2021 for the first time in fifteen years, erasing more than a decade of progress.<sup>31</sup> In 2023, WHO reported “a major global recovery in the number of people diagnosed with TB and treated” during 2022 following these two years of disruptions caused by the COVID-19 pandemic.<sup>32</sup> Notwithstanding this notable recovery, WHO also reports that “COVID-related disruptions” are estimated to have caused about half a million more TB deaths from 2020 to 2022 as compared with the number that would have likely occurred if pre-pandemic trends in TB mortality had continued.<sup>33</sup>

### A. Drug-Resistant Tuberculosis

Drug-resistant TB (DR-TB) is TB that is resistant to at least one of the main drugs used to treat the disease. DR-TB is one of the most common forms of antimicrobial resistance,<sup>34</sup> which WHO has declared to be one of the top “global

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26. Taghreed Adam et al., *Global Tuberculosis Report 2023*, WORLD HEALTH ORG., at 1 (2023).

27. *Id.* at 2.

28. *Id.* The first figure is calculated by dividing the total number of people reported as newly diagnosed with TB (7.5 million) by the global number of people estimated to have developed TB (10.6 million) in 2022. The second figure is calculated by subtracting the number of newly diagnosed from the number of people who fell ill.

29. Tereza Kasaeva, *Global Tuberculosis Report 2021*, WORLD HEALTH ORG., at v (2021).

30. *Id.* at 1, 4.

31. Annabel Baddeley et al., *Global Tuberculosis Report 2022*, WORLD HEALTH ORG., at 2 (2022).

32. *Global Tuberculosis Report 2023*, *supra* note 25, at 2.

33. *Id.*

34. *Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis*, ANTIMICROBIAL RESISTANCE COLLABORATORS 399 *Lancet* 629 (2022).

public health threats facing humanity.”<sup>35</sup> There are several types of DR-TB. Multidrug-resistant TB (MDR-TB) is resistant to two of the most effective TB drugs—rifampicin and isoniazid.<sup>36</sup> Rifampicin-resistant TB (RR-TB) is resistant to rifampicin.<sup>37</sup> Extensively drug-resistant TB (XDR-TB) is resistant to rifampicin (and possibly isoniazid), at least one fluoroquinolone (levofloxacin or moxifloxacin), and bedaquiline, linezolid, or both.<sup>38</sup> Pre-extensively drug-resistant TB (pre-XDR-TB) is resistant to rifampicin (and possibly isoniazid) and at least one fluoroquinolone (levofloxacin or moxifloxacin).<sup>39</sup>

More than 400,000 people fell ill with MDR- or RR-TB in 2022.<sup>40</sup> However, only 175,650 of those were diagnosed and started on treatment, about two in five people and still below the number diagnosed and treated for DR-TB in 2019 before the pandemic (181,533).<sup>41</sup> Diagnosing DR-TB requires bacteriological confirmation of TB plus testing for drug resistance using advanced diagnostics, such as rapid molecular tests, culture methods, or sequencing technologies.<sup>42</sup> In 2022, only 47% of people newly diagnosed with TB were tested with WHO-recommended advanced diagnostics that detect drug resistance.<sup>43</sup> To explain the gaps in DR-TB incidence and the number of people tested and treated for the disease, experts emphasize the “[p]rohibitive pricing and lack of transparency” around the cost of production of a leading rapid, molecular diagnostic for TB—the GeneXpert MTB/RIF Assay, a cartridge-based nucleic acid amplification test.<sup>44</sup> The company that manufactures the diagnostic received more than USD 250 million in public funding, primarily from the US government, to develop the technology.<sup>45</sup> Yet, the diagnostic is prohibitively costly, limiting access to the tests in low-and middle-income countries. A 2019 study modeled the necessary investments required for twenty-four high-burden countries to use the GeneXpert to meet the TB UNHLM target of diagnosing and treating forty-

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35. World Health Org., *Global Antimicrobial Resistance and Use Surveillance System (GLASS) Report 2021*, at 2 (2021).

36. World Health Org., *WHO Consolidated Guidelines on Tuberculosis, Module 4: Treatment, Drug-Resistant Tuberculosis Treatment, 2022 Update*, at xi (2022).

37. *Id.* at xii.

38. *Id.* at xi.

39. *Id.* at xii.

40. *Global Tuberculosis Report 2023*, *supra* note 25, at 2.

41. *Id.*

42. *Id.* at 28.

43. *Summary of Tuberculosis Data: Tuberculosis in the World*, WORLD HEALTH ORG., [https://worldhealthorg.shinyapps.io/TBrief/?\\_inputs\\_&group\\_code=%22global%22&entity\\_type=%22group%22&sidebarCollapsed=true&sidebarItemExpanded=null](https://worldhealthorg.shinyapps.io/TBrief/?_inputs_&group_code=%22global%22&entity_type=%22group%22&sidebarCollapsed=true&sidebarItemExpanded=null) (last visited Jan. 12, 2024).

44. David Branigan, *Realizing Returns on U.S. Government Investments in GeneXpert Diagnostic Technologies*, TREATMENT ACTION GROUP AND MÉDECINS SANS FRONTIÈRES (Sept. 2021), [https://www.treatmentactiongroup.org/wp-content/uploads/2021/09/realizing\\_returns\\_govt\\_investments\\_geneXpert.pdf](https://www.treatmentactiongroup.org/wp-content/uploads/2021/09/realizing_returns_govt_investments_geneXpert.pdf). [<https://perma.cc/6N8H-8873>]

45. Dzintars Gotham et al., *Public Investments in the Development of GeneXpert Molecular Diagnostic Technology*, 16 PLOS ONE (2021).

million people by 2023. The analysis revealed that it would require an additional USD one billion in investments—five times the amount invested at the time—to meet the UNHLM target.<sup>46</sup> In September 2023, under global pressure from advocates, GeneXpert’s manufacturer reduced the cost of a key component of the diagnostic by 20%.<sup>47</sup> Médecins Sans Frontières (Doctors Without Borders) called the reduction a “significant step in the right direction” but noted that the test for the most severe form of TB (XDR-TB) remains prohibitively priced.<sup>48</sup>

The success rate for MDR-TB treatment is only 63% globally, compared with 88% for drug-sensitive TB treatment.<sup>49</sup> Until recently, the standard DR-TB treatment comprised a regimen of multiple second-line drugs for at least nine and as long as twenty months.<sup>50</sup> This regimen has potentially severe side effects, including cardiac toxicity, depression, liver dysfunction, neuropathy, and hearing loss.<sup>51</sup> But after more than forty-years during which no new TB drugs were approved, three newer drugs are now available for DR-TB: bedaquiline, delamanid, and pretomanid. The new drugs have led to shorter, more tolerable DR-TB treatments. These include a six-month treatment for MDR/RR-TB and pre-XDR-TB called BPaL(M) and a nine-month, all-oral MDR/RR-TB treatment that eliminates the need for painful injections used in older treatments that can lead to hearing loss.<sup>52</sup>

However, globally, only 30% of people with DR-TB receive these new, shorter treatments.<sup>53</sup> WHO acknowledges there are “major economic and financial barriers to accessing and completing TB treatment.”<sup>54</sup> Experts point to intellectual property protections and pricing as major barriers to accessing the new DR-TB drugs.<sup>55</sup> The primary patent on the basic compound in the drug delamanid expired in October 2023, but the manufacturer, Otsuka, still holds

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46. Amy S. Piatek et al., *Realizing the “40 by 2022” Commitment from the United Nations High-Level Meeting on the Fight to End Tuberculosis: What Will It Take to Meet Rapid Diagnostic Testing Needs?*, 7 GLOBAL HEALTH: SCIENCE AND PRACTICE 551 (2019).

47. Médecins Sans Frontières, *Technical Brief: Access to TB Testing and Treatments: GeneXpert and Delamanid*, at 3 (Nov. 2023), [https://msfaccess.org/sites/default/files/2023-11/MSF-AC\\_TB\\_GeneXpert%2BDIm\\_Final.pdf](https://msfaccess.org/sites/default/files/2023-11/MSF-AC_TB_GeneXpert%2BDIm_Final.pdf).

48. *Id.*

49. *Global Tuberculosis Report 2023*, *supra* note 25, at 2.

50. *Global Tuberculosis Report 2021*, *supra* note 28, at 19.

51. Christoph Lange et al., *Management of Drug-Resistant Tuberculosis*, 394 THE LANCET 953 (2019); Francesca Conradie et al., *Bedaquiline–Pretomanid–Linezolid Regimens for Drug-Resistant Tuberculosis*, 387 NEW ENG. J. MED. 810 (2022).

52. *WHO Consolidated Guidelines on Tuberculosis*, *supra* note 35, at xvi.

53. *Summary of Tuberculosis Data*, *supra* note 42.

54. *Global Tuberculosis Report 2023*, *supra* note 25, at 2.

55. See Eskild Petersen et al., *End of the Bedaquiline patent – a crucial development for moving forward affordable drugs, diagnostics, and vaccines for infectious diseases in low- and middle-income countries*, 131 Int’l J. Infectious Disease 180 (2023); Lindsay McKenna, *An Activist’s Guide to Shorter Treatment for Drug-Resistant Tuberculosis*, TREATMENT ACTION GROUP (Nov. 2023), [https://www.treatmentactiongroup.org/wp-content/uploads/2023/11/activists\\_guide\\_shorter\\_tx\\_dr\\_tb\\_2023.pdf](https://www.treatmentactiongroup.org/wp-content/uploads/2023/11/activists_guide_shorter_tx_dr_tb_2023.pdf); Médecins Sans Frontières, *DR-TB Drugs Under the Microscope 2022: Pricing and patent landscape of medicines for adults and children*, 8<sup>th</sup> ed. (Nov. 2022), <https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition>.



secondary patents and further patent applications pending.<sup>56</sup> In September 2023, Otsuka reduced the price of delamanid for countries buying through the Stop TB Partnership's bulk purchasing mechanism, the Global Drug Facility.<sup>57</sup> But at \$1,700 per six-month treatment course, delamanid remains prohibitively expensive for countries that need it.<sup>58</sup> In 2017, researchers estimated that manufacturers could produce and sell delamanid for a profit at \$30 to \$96 per six-month treatment.<sup>59</sup> The drug bedaquiline, manufactured by Johnson & Johnson, was on patent and priced prohibitively high until its primary patent expired in July 2023,<sup>60</sup> and the company, under mounting pressure from a decades-long global advocacy campaign, announced its intention in September 2023 not to enforce its remaining patents on the drug.<sup>61</sup> In March 2023, the Indian Controller of Patents also rejected Johnson & Johnson's application to extend its patent on bedaquiline in the country, opening the door to Indian generic manufacturers to produce the drug for domestic use and global export.<sup>62</sup> The TB Alliance, a non-profit partnership funded entirely by governments and philanthropies, sponsored the development of the drug pretomanid.<sup>63</sup> The TB Alliance has signed non-exclusive licensing agreements with several generic manufacturers to produce pretomanid.<sup>64</sup> However, experts note that the price of the drug is still high, constituting over 50% of the cost of the BPaL(M) regimen, though prices may fall as the other producers enter the market and volumes increase.<sup>65</sup>

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56. Medicines Patent Pool, *MedsPaL Medicines Patents and Licenses Database: Delamanid 50mg*, <https://www.medsपाल.org/?product%5B%5D=Delamanid+50+mg&page=1>.

57. Médecins Sans Frontières, *supra* note 46.

58. *Id.* at 4.

59. Dzintars Gotham et al., *Estimated generic prices for novel treatments for drug-resistant tuberculosis*, 72 J. Antimicrobial Chemotherapy 1243 (2017).

60. Medicines Patent Pool, *MedsPaL Medicines Patents and Licenses Database: Bedaquiline 100mg*, <https://www.medsपाल.org/?product%5B%5D=Bedaquiline+100+mg&page=1>.

61. Médecins Sans Frontières, *supra* note 47; Johnson & Johnson, *Johnson & Johnson Confirms Intent Not to Enforce Patents for SIRTURO® (bedaquiline) for the Treatment of Multidrug-Resistant Tuberculosis in 134 Low- and Middle-Income Countries* (Sept. 29, 2023), <https://www.jnj.com/johnson-johnson-confirms-intent-not-to-enforce-patents-for-sirturo-bedaquiline-for-the-treatment-of-multidrug-resistant-tuberculosis-in-134-low-and-middle-income-countries>.

62. In the matter of Patent Application No. 1220/MUMNP/2009 by Janssen Pharmaceutica and In the matter representation by way of opposition by Network of Maharashtra people living with HIV, Nandita Venkatesan, and Phumeza Tisile (Mar. 23, 2023), available at [https://www.patentoppositions.org/en/drugs/bedaquiline/patent\\_office\\_decisions/641c1136d2708f00050ab275](https://www.patentoppositions.org/en/drugs/bedaquiline/patent_office_decisions/641c1136d2708f00050ab275); see also Sankalp Yadav, Gautam Rawal, and Madhan Jeyaraman, *India's Decision to Deny an Extension of Patent for Bedaquiline: A Public Health Imperative*, 15 *Cureus* e49542.

63. TB Alliance, *The Pathway to Potential New TB Treatments*, <https://www.tballiance.org/pathway-potential-new-tb-treatments> (last visited Jan. 12, 2023).

64. TB Alliance, *Realizing our "Triple-A Mandate"* (Aug. 14, 2023), <https://www.tballiance.org/news/realizing-our-triple-mandate>.

65. McKenna, *supra* note 54, at 13.

### III. ASSESSMENT SCOPE, METHODOLOGY, AND LIMITATIONS

This section lays out the scope, methodology, and limitations of this paper's empirical assessment framework.

#### *A. Scope*

The scope of this assessment involves three parameters: (1) TB UNHLM commitments, (2) legal jurisdictions (i.e., countries), and (3) sources of law.

##### *1. TB UNHLM Commitments*

UN Member States made three distinct legal and human rights commitments in the 2018 Political Declaration from the TB UNHLM. They are commitments concerning the right to health, non-discrimination, and access to medicines. The right to health pledge comes primarily from paragraph thirty-seven of the Political Declaration, in which countries:

Commit to protect and promote the right to the enjoyment of the highest attainable standard of physical and mental health, in order to advance towards universal access to quality, affordable and equitable prevention, diagnosis, treatment, care and education related to tuberculosis and multidrug-resistant tuberculosis . . . .<sup>66</sup>

The right to health is also mentioned in paragraph thirteen, in which States:

Note with concern that the protection and promotion of the right to the enjoyment of the highest attainable standard of physical and mental health, . . . remains challenging, especially in developing countries . . . .<sup>67</sup>

The non-discrimination commitment also comes primarily from paragraph thirty-seven of the Political Declaration, in which countries:

Commit to . . . promote and support an end to stigma and all forms of discrimination, including by removing discriminatory laws, policies and programmes against people with tuberculosis . . . .<sup>68</sup>

The preamble to the Political Declaration also mentions discrimination.

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66. G.A. Res. A/RES/73/3 (Oct. 18, 2018). (The “right to the enjoyment of the highest attainable standard of physical and mental health” is the full term for the “right to health” as enshrined in article 12 of the International Covenant on Economic, Social and Cultural Rights. G.A. Res. 2200A (XXI), ¶ 37 (Dec. 16, 1966)).

67. G.A. Res. 2200A (XXI), ¶ 13 (Dec. 16, 1966).

68. *Id.* ¶ 37.

States affirm that “poverty, gender inequality, vulnerability, discrimination and marginalization exacerbate the risks of contracting tuberculosis and its devastating impacts, including stigma and discrimination . . . .”<sup>69</sup> Countries raise “serious concerns” about the “enormous costs” people affected by TB incur from stigma and discrimination in paragraph seven.<sup>70</sup> And countries make further commitments to reducing discrimination and ensuring the non-discriminatory “involvement of communities and civil society” in the disease response in paragraphs fourteen and seventeen, respectively.<sup>71</sup> The access to medicines pledge comes primarily from paragraph nineteen, in which States:

Commit to promoting access to affordable medicines, including generics, for scaling up access to affordable tuberculosis treatment, including the treatment of multidrug-resistant and extensively drug-resistant tuberculosis, reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as amended, and also reaffirming the 2001 World Trade Organization Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and notes the need for appropriate incentives in the development of new health products.<sup>72</sup>

Countries raise further concerns about the lack of access to affordable TB medicines and diagnostics in paragraphs six and thirteen. They underscore the importance of affordable drugs and diagnostics, including new technologies, to the global disease response in paragraphs nine and forty-five.<sup>73</sup>

## 2. *Legal Jurisdictions*

The ten legal jurisdictions in this assessment are from WHO’s 2021–2025 list of countries with the highest DR-TB incidence rates, one of three “global lists of [TB] high-burden countries.”<sup>74</sup> They are:

⇒ China, Democratic Republic of the Congo (DRC), India, Indonesia, Myanmar, Nigeria, Pakistan, Philippines, Russian Federation, and Vietnam.

Combined, these ten nations also accounted for almost 80% of the global DR-

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69. *Id.* at 1.

70. *Id.* ¶ 7.

71. *Id.* ¶¶ 14, 17.

72. *Id.* ¶¶ 19.

73. *Id.* ¶¶ 6, 9, 13, 45.

74. *Global Tuberculosis Report 2022*, *supra* note 30. The full list contains 30 countries: 20 with the highest MDR/RR-TB incidence rates in absolute numbers plus the 10 (not already in the top 20) with the highest number of new cases per 100,000 people worldwide.

TB treatment gap in 2019, the first year of the TB UNHLM Political Declaration.<sup>75</sup> In other words, at that time, approximately 80% of people with DR-TB worldwide who could not access treatment resided in these ten countries.

### 3. Sources of Law

This assessment examines three sources of law at the national level in each country—constitutions, legislation, and executive branch materials. The review does not consider sources of law from subnational jurisdictions, such as states, provenances, districts, or cities. Constitutions comprise each State’s national constitution. Legislation encompasses laws and statutes enacted by legislatures, including health, intellectual property, disability, labor, and other laws. The specific subject matter of the legislation examined is described below in the three commitment indicators. Executive branch sources comprise directives promulgated by ministries of health and labor, including regulations, policies, strategic plans, and other decrees. This assessment reviews each source of law using the three indicators developed for the TB UNHLM legal and human rights pledges, as detailed in the next section.

#### B. Methodology: TB UNHLM Legal Rights Index

This assessment’s methodology is modeled on the UN Human Development Index (HDI).<sup>76</sup> The HDI measures the “average achievement in key dimensions of human development,” calculated from the geometric mean of normalized indices for three dimensions—health, education, and standard of living.<sup>77</sup> Similarly, the TB UNHLM Legal Rights Index measures UN Member States’ fulfillment of the three legal and human rights commitments in the TB UNHLM Political Declaration. The TB UNHLM Legal Rights Indicator (LRI) is a country’s overall score between zero and one calculated from the arithmetic mean of its three UNHLM commitment indicator scores (right to health (RtH), non-discrimination (ND), and access to medicines (A2M)):

$$\text{LRI} = (I_{\text{RtH}} + I_{\text{ND}} + I_{\text{A2M}}) / 3$$

A country’s LRI represents its progress in fulfilling the three TB UNHLM legal and human rights pledges. The TB UNHLM Legal Rights Index lists the ten assessment countries ranked by their LRI scores. This assessment also produces indices for the three commitment indicators—the Right to Health Index, Non-

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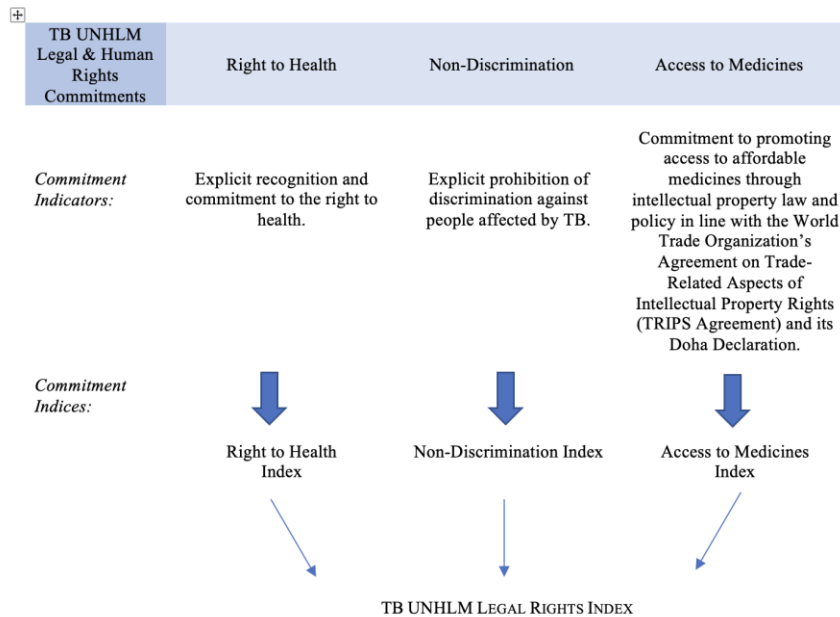
<sup>75</sup>Annabel Baddeley et al., *Global Tuberculosis Report 2020*, WORLD HEALTH ORG., at xvii (2020).

<sup>76</sup> *Human Development Index (HDI)*, UNITED NATIONS DEVELOPMENT PROGRAM, [https://perma.cc/H52X-can7] (last visited January 31, 2023).

<sup>77</sup> *Id.*

Discrimination Index, and Access to Medicines Index. Like the TB UNHLM Legal Rights Index, they comprise lists of the assessment countries ranked by their indicator scores.

Figure 1: TB UNHLM Legal Rights Index



This assessment uses the arithmetic mean to calculate the LRI rather than the geometric mean, as in the HDI, for three reasons. First, the TB UNHLM Index inputs—the three commitment indices—comprise scaled data sets with scores between zero and one. Second, the commitment indices zero to one scale means no large, outlier numbers skew the arithmetic mean. Third, the commitment indices' data sets contain zeros. Using the geometric mean would require an imperfect workaround because geometric means always produce a zero when there is a zero in the data set.<sup>78</sup>

### 1. Right to Health Indicator

As explained above, the right to health commitment indicator stems from paragraph 37 of the TB UNHLM Political Declaration and is formulated as:

⇒ Explicit recognition and commitment to the right to health.

A country's right to health indicator score is calculated as follows:

78. See Roberto de la Cruz & Jan-Ulrich Kreft, *Geometric Mean Extension for Data Sets with Zeros*, CORNELL, <https://arxiv.org/pdf/1806.06403.pdf> [<https://perma.cc/3KYX-MGUH>] (last visited January 31, 2023).

Figure 2: Right to Health Indicator

Source of law		Score	
Constitutional recognition	Full recognition	1.0	
	Partial recognition	Judicial	0.75
		State commitment	0.50
Legislative recognition	Health or human rights law	0.50	
	HIV law	0.15	
Executive branch recognition		0.25	

Constitutional recognition means the establishment of a right to health in the national constitution. Full recognition requires explicit, unambiguous language establishing an individual right to health (1.0). In the absence of an explicit right to health in the text of the constitution, partial recognition includes either judicial recognition of a constitutional right to health in case law (0.75) or a State commitment in the constitution to protect or promote individual or public health that falls short of establishing an individual right (0.50). Legislative recognition means the explicit, unambiguous establishment of a right to health in health or human rights legislation (0.50)<sup>79</sup> or HIV legislation (0.15).<sup>80</sup> Executive branch recognition means the explicit recognition of the right to health in an executive branch decree from the ministry of health (0.25).

The right to health indicator score has a minimum value of zero and a maximum value of 1.0 and represents a nation's progress in fulfilling the TB UNHLM right to health commitment. The score is partly additive. Partial constitutional recognition is added with legislative recognition or executive branch recognition. Legislative recognition and executive branch recognition are also added together. The two elements of partial constitutional recognition—judicial recognition and State commitment to protect or promote health—are mutually exclusive; a country may only receive points for one or the other. Any sum above 1.0 is reduced to the maximum value of 1.0.

## 2. *Non-discrimination Indicator*

As explained above, the non-discrimination commitment indicator stems from paragraph thirty-seven of the TB UNHLM Political Declaration and is formulated as:

79. This assessment only considers human rights legislation that establishes enforceable, statutory human rights. It does not include laws that solely establish National Human Rights Commissions or equivalent bodies.

80. This assessment includes HIV legislation because TB is the leading killer of people living with HIV, closely connecting the diseases, and many people are co-infected with both.

⇒ Explicit prohibition of discrimination against people affected by TB.<sup>81</sup>  
A country's non-discrimination indicator score is calculated as follows:

Figure 3: Non-Discrimination Indicator

Source of law		Score	
Constitutional recognition	Health status	0.50	
	Other status, catch-all	0.25	
Legislative recognition	Health or human rights law	TB, infectious disease	1.0
		Health status	0.50
	Disability law	TB, infectious disease	0.75
	Labor law	TB, infectious disease	0.50
		Health status	0.25
	HIV law	HIV status	0.10
Executive branch recognition		0.25	

Constitutional recognition means the explicit prohibition of discrimination or establishment of the right to be free from discrimination in the national constitution on the basis of health status (0.50), or “other” status or another inclusive, catch-all category (0.25). Legislative recognition means the explicit prohibition of discrimination or establishment of a statutory right to be free from discrimination in health or human rights legislation<sup>82</sup> on the basis of TB or infectious, contagious, or communicable disease (1.0) or health status (0.50); or in disability legislation on the basis of disability wherein “disability” is explicitly defined to include TB or infectious, contagious, or communicable

81. *United Nations High-Level Meeting on the Fight to End Tuberculosis*, *supra* note 1. (Countries further commit in paragraph 37 to “removing discriminatory laws, policies and programmes.” However, this assessment only considers whether countries have affirmatively prohibited discrimination against people affected by TB for two main reasons. First, as with other kinds of discrimination, such racial, ethnic, or gender discrimination, ending discrimination against people affected by TB requires targeted legal prohibitions, not only the elimination of discriminatory policies. Second, from a methodological perspective, it is prohibitively difficult to identify laws, policies, or programs that have been removed and are no longer in effect.).

82. As noted above for the right to health indicator, this assessment only considers human rights legislation that establish enforceable, statutory human rights. It does not include laws that solely establish National Human Rights Commissions or equivalent bodies.

disease (0.75); or in employment or labor legislation on the basis of TB or infectious, contagious, or communicable disease (0.50) or health status (0.25); or in HIV legislation on the basis of HIV status (0.10).<sup>83</sup> Executive branch recognition means an explicit prohibition of discrimination, the establishment of the right to be free from discrimination, or a specific commitment to non-discrimination on the basis of TB in health care, employment, education, social protection, housing, or other areas in an executive branch decree from the ministries of health or labor (0.25).

The non-discrimination indicator score has a minimum value of 0 and a maximum value of 1.0 and represents a nation's progress in fulfilling the TB UNHLM non-discrimination commitment. The score is partly additive. Constitutional recognition for health status or "other" status or catch-all category are mutually exclusive—a country may only receive points for health status recognition or "other" status or a catch-all category recognition. Constitutional recognition is added with legislative recognition. Legislative recognition in health or human rights legislation, disability legislation, labor legislation, or HIV legislation are all added together. Constitutional recognition and legislative recognition are both added with executive branch recognition. Any sum above 1.0 is reduced to the maximum value of 1.0.

### *3. Access to Medicines Indicator*

As explained above, the access to medicines commitment indicator stems from paragraph nineteen of the TB UNHLM Political Declaration and is formulated as:

- ⇒ Commitment to promoting access to affordable medicines through intellectual property law and policy in line with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and its Doha Declaration.

A country's access to medicines indicator score is calculated as follows:

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83. As noted above for the right to health indicator, this assessment includes HIV legislation because TB is a leading killer of people living with HIV, so the diseases are closely connected, and many people are co-infected with both. However, legislative recognition of the non-discrimination commitment in HIV legislation (0.10) receives less points than legislative recognition of the right to health in HIV legislation (0.15) because discrimination prohibitions protecting people living with HIV are unlikely to apply to all people affected by TB. By contrast, recognition of the right to health in any kind of health-related legislation may have a broader impact across diseases.



Figure 4: Access to Medicines Indicator

Source of law		Score	
Constitutional recognition	Access to medicines or health goods, products, or technologies	0.25	
Legislative or executive branch recognition	IP/Patent law or regulation	6 TRIPS flexibilities	1.0
		5 TRIPS flexibilities	0.75
		3-4 TRIPS flexibilities	0.50
		1-2 TRIPS flexibility	0.25
		Textual commitment	0.10
	Health law or regulation	Institutional commitment	0.20
		Textual commitment	0.10

Constitutional recognition means an explicit State commitment to promoting access to medicines or health goods, products, or technologies in the national constitution (0.25). Legislative or executive branch recognition means recognition of TRIPS flexibilities (6 = 1.0; 5 = 0.75; 3-4 = 0.50; 1-2 = 0.25) or an explicit, textual commitment to promote access to medicines (0.10) in legislation or executive branch decree on intellectual property or patents; or an explicit, textual commitment (0.10) or concrete institutional commitment<sup>84</sup>—i.e., the establishment of institutional structures, procedures, mandates or authority—(0.20) to promote access to medicines in legislation or executive branch decree on health.<sup>85</sup>

According to the World Trade Organization (WTO), World Intellectual Property Organization (WIPO), and WHO, TRIPS flexibilities comprise a “wide range of policy options and flexibilities” built into the global intellectual property regime that “can be used to pursue public health objectives.”<sup>86</sup> Relatedly, in the Doha Declaration on the TRIPS Agreement, WTO members

84. For institutional and textual commitments in health legislation or executive branch decree, this assessment considers any kind of explicit commitment to ensuring access to medicines, not only those related to intellectual property or patents. However, it does not include guarantees for access to health care or health services, more broadly.

85. This assessment does not consider TB national strategic plans for executive branch recognition of the access to medicines commitment. Tuberculosis national strategic plans do not possess the same level of legal authority as legislation or other executive branch decrees, such as directives, orders, or regulations, that legally mandate certain actions as opposed to setting forth an overarching, often aspirational strategy.

86. WORLD TRADE ORG. ET AL., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 21 (2d ed. 2020).

emphasized the importance of implementing the agreement “in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines.”<sup>87</sup> This assessment considers six flexibilities:<sup>88</sup>

1. *Compulsory licensing or government use*—allows governments to grant non-voluntary licenses to third parties to manufacture and sell medicines without the consent of the patent holder or to produce and use the invention themselves for public, non-commercial uses, both subject to payment of adequate remuneration (i.e., a royalty) to the patent holder.
2. *Parallel importation and the international exhaustion principle*—allows drugs legally placed on the market in one country to be imported by another country for sale based on the principle that the patent holder’s exclusive marketing rights were exhausted when it placed the drug on the foreign country’s market.
3. *Limited exceptions to patent rights for research and experimental use and “early working” or Bolar exceptions for regulatory review*—allow third parties to use patented medicines for research and experimental purposes and to prepare for regulatory review for generic drugs.
4. *Heightened patentability criteria*—allows governments to set their own legal standards for what constitutes an invention eligible for a patent, including defining “novelty,” “inventive step,” and “industrial application,” and precluding certain things from being patented, such as plants and animals.
5. *Patent opposition or revocation procedures*—allow interested parties other than a patent-holder to challenge drug patents before (opposition) and after (revocation) they are granted.
6. *Transition period for least developed countries (LDCs)*—allows LDCs to refrain from granting or enforcing patent protections for medicines until January 1, 2033, or a later date as agreed upon by WTO members.<sup>89</sup>

The access to medicines indicator score has a minimum value of 0 and a

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87. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 17 (2001).

88. For TRIPS flexibilities, *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, (Sept. 2016). For patent opposition and revocation procedures, see generally *Opposition Systems*, WORLD INTELL. PROP. ORG., [http://www.wipo.int/scp/en/revocation\\_mechanisms/opposition/index.html](http://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html) [<https://perma.cc/LC58-AARF>] (last visited Jan. 31, 2023).

89. There are currently forty-six LDCs on the United Nations list; thirty-five of them are members of the World Trade Organization, including the DRC. *Understanding the WTO: The Organization: Least-developed Countries*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm) [<https://perma.cc/4HKD-LRFA>] (last visited Jan. 31, 2023).

maximum value of 1.0 and represents a nation's progress in fulfilling the TB UNHLM access to medicines commitment. The score is partly additive. Constitutional recognition is added with legislative or executive branch recognition. Recognition in intellectual property or patent legislation or executive branch decree of 1-6 TRIPS flexibilities are added with textual commitments to promote access to medicines in intellectual property or patent legislation or executive branch decree and textual or institutional commitments in health legislation or executive branch decree. If both textual and institutional commitments occur in the same legislation or executive branch decree, points are only awarded for institutional commitment; if they appear in separate instruments, they are added together. Any sum above 1.0 is reduced to the maximum value of 1.0.

### *C. Limitations*

This assessment has two main limitations. First, it does not assess the implementation or enforcement of the sources of law it examines. Legal and policy commitments on paper are necessary to fulfill the TB UNHLM legal and human rights pledges. But laws and policies must be implemented and enforced to achieve their intended results. Notwithstanding this concern, evaluating the implementation and enforcement of more than 150 laws and policies in ten countries would be highly challenging from logistical, financial, and epistemological standpoints.

Second, due to challenges in identifying, obtaining, and analyzing documents containing the sources of law, the TB UNHLM Legal Rights Index may reflect gaps in the underlying research. The challenges included identifying and obtaining documents not available online, searching primarily in English to identify sources of law in other languages, and using unofficial machine translations for documents in non-English languages. To mitigate their impact, the author sent letters to government authorities requesting their assistance in obtaining documents and confirming aspects of the research. The author also engaged lawyers and civil society in the assessment countries to the same ends. The author received further assistance obtaining policy documents from the Stop TB Partnership Country and Community Support for Impact (CCS4i) team that works directly with National TB Programs and civil society in the assessment countries. To reduce language barriers in the assessment, the author conducted keyword searches in the original languages for non-English language sources of law. For example, the author searched for the word "discrimination" in Bahasa, Burmese, Chinese, French, Russian, and Vietnamese while reviewing sources of law for the non-discrimination commitment.

#### IV. ASSESSMENT RESULTS: FULFILLING TB UNHLM LEGAL AND HUMAN RIGHTS COMMITMENTS

This section presents the assessment results of ten high DR-TB-burden countries' progress in fulfilling their legal and human rights commitments in the TB UNHLM Political Declaration. The subsections contain the four indices, basic quantitative analyses of the results, tabulations of the underlying research and scoring, and brief discussions.

##### A. TB UNHLM Legal Rights Index

The TB UNHLM Legal Rights Index below displays the overall assessment results, with the ten countries ranked in order of their TB UNHLM Legal Rights Indicator (LRI) scores.

Table 1: TB UNHLM Legal Rights Index

		TB UNHLM Commitment Indicators			LRI
		Right to Health	Non-Discrimination	Access to Medicines	
1	Russia	1.0	1.0	0.90	0.97
2	Vietnam	1.0	1.0	0.70	0.90
3	China	1.0	0.75	0.80	0.85
4	Indonesia	1.0	0.50	0.90	0.80
5	Philippines	1.0	0.35	1.0	0.78
6	DRC	1.0	0.25	0.60	0.62
7	India	0.75	0.10	0.95	0.60
8	Myanmar	1.0	0.25	0.50	0.58

		TB UNHLM Commitment Indicators			
		Right to Health	Non-Discrimination	Access to Medicines	LRI
9	Nigeria	0.75	0.35	0.55	0.55
10	Pakistan	0	0	0.50	0.17

The TB UNHLM Legal Rights Index has a range of 0.80 from 0.17 to 0.97. The mean LRI score is 0.682, with a standard deviation of approximately 0.232. The median score is 0.70, and there is no mode.

### *B. Right to Health*

The Right to Health Index below displays the ten assessment countries ranked by their right to health indicator scores.

Table 2: Right to Health Index

		Right to Health
1	China	1.0
2	DRC	1.0
3	Indonesia	1.0
4	Myanmar	1.0
5	Philippines	1.0
6	Russia	1.0
7	Vietnam	1.0
8	India	0.75

		Right to Health
9	Nigeria	0.75
10	Pakistan	0

The Right to Health Index has a range of 1.0 from 0 to 1.0. The mean right to health indicator score is 0.85, with a standard deviation of 0.30. The median and mode scores are both 1.0.

The research and scoring underlying the Right to Health Index are tabulated here. The table contains the sources of law assessed for each country. As explained above, the assessment evaluated the national constitution of each nation to determine constitutional recognition. Countries that received the maximum value (1.0) for full constitutional recognition were not assessed for legislative or executive branch recognition, represented by “n/a” in the table. Sources of law for legislative and executive branch recognition listed with specific provisions above an ellipsis contribute to a country’s right to health indicator score. Sources of law without specific provisions do not meet the definitions for legislative or executive branch recognition of the right to health commitment. Where necessary, scoring designations and information about the author’s ability to obtain sources of law are in brackets and footnotes, respectively.

Table 3: Right to Health Index Scoring and Sources of Law

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
	0.50	0.50	0	
China	Arts. 21, 45 [state commitment]	<i>Law on Basic Healthcare and Health Promotion</i> (2020) arts. 4-5 ... <i>Law on the Prevention and Treatment of Infectious Diseases</i> (1989, rev. 2013)	<i>Implementing Measures for the Law on the Prevention and Treatment of Infectious Diseases</i> (1991) <i>Healthy China 2030 Blueprint</i> (2016) <i>Opinions of the State Council on Implementing the Healthy</i>	1.0

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
			<i>China Action Plan (2019)</i> <i>Healthy China Action (2019–2030) (2019)</i>	
DRC	1.0			1.0
	Art. 47	n/a	n/a	
Indonesia	1.0			1.0
	Art. 28H	n/a	n/a	
Myanmar	1.0			1.0
	Art. 367	n/a	n/a	
Philippines	1.0			1.0
	Art. II, § 15	n/a	n/a	
Russia	1.0			1.0
	Art. 41	n/a	n/a	
Vietnam	1.0			1.0
	Art. 38	n/a	n/a	
India	0.75	0	0	0.75
	Arts. 21, 39, 47 [judicial recognition] <i>Consumer Education &amp; Research Centre v. Union of</i>	<i>Epidemic Diseases Act (1897)</i> <i>The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act (2017)</i>	<i>National Health Policy 2017 (2017)</i> <i>National Strategic Plan for Tuberculosis: 2017–25, Elimination by</i>	

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
	<i>India</i> (1995) 3 SCC 42 (India)  <i>State of Punjab v. Mohinder Singh Chawla</i> (1997) 2 SCC 83 (India)	<i>Epidemic Diseases (Amendment) Act</i> (2020)	2025 (2017)	
	0	0.50	0.25	
Nigeria		<i>African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act</i> (1983) art. 16  <i>National Health Act</i> (2014) § 1(1)(d, e)  ... <i>HIV and AIDS (Anti-Discrimination) Act</i> (2014)	<i>National Health Policy 2016</i> (2016) §§ 3.4.1, 5.3  ... <i>National Strategic Plan for Tuberculosis Control 2021–2025</i> (2021) <i>Human Rights and Gender Action Plan for Tuberculosis Care and Prevention in Nigeria 2021–2025</i> (2021) <sup>90</sup>	0.75
	0	0	0	
Pakistan		<i>Public Health (Emergency Provision) Ordinance</i> (1944) <i>West Pakistan Epidemic Diseases Act</i> (1958) <i>Epidemic Diseases (Amendment) Act</i> (2011)	<i>National Health Vision, 2016–2025</i> (2016) <i>National Strategic Plan for Tuberculosis Control, 2020–2023</i> (2020)	0

90. Surprisingly, the Human Rights and Gender Action Plan for Tuberculosis Care and Prevention in Nigeria 2021–2025 does not recognize the right to health. However, the plan does assert that “the right to health is not guaranteed for most Nigerians due to poverty [and] inaccessibility of . . . health care services,” among other things (see page 7).



Six of the ten assessment countries score full constitutional recognition (1.0) by enshrining the right to health in their national constitutions. For example, the Constitution of the Democratic Republic of the Congo states that the “right to health and to [a] secure food supply is guaranteed.”<sup>91</sup> The Constitution of Indonesia provides that every “person has a right to a life of well-being in body and mind . . . and to receive medical care.”<sup>92</sup>

By contrast, the Constitution of the People’s Republic of China contains a state commitment to “protect the people’s health” through the State’s development of health services and promotion of sanitation.<sup>93</sup> China nonetheless scores the maximum value 1.0 because its 2019 *Law of the People’s Republic of China on Basic Healthcare and Health Promotion* establishes that the State shall “respect and protect citizens’ right to health,” including the “right to receive basic medical and healthcare services.”<sup>94</sup>

The Supreme Court of India has judicially recognized a constitutional right to health through the right to life and health-related “directive principles of state policy” enshrined in the Constitution of India.<sup>95</sup> In doing so, the court established a justiciable, individual right to health even though the Constitution of India does not explicitly recognize the right. India scores 0.75 as a result, despite not recognizing the right to health through legislation or executive branch decree.

Similarly, Chapter II of the Constitution of the Federal Republic of Nigeria sets forth a series of State objectives for socioeconomic policy. The objectives include pledges to ensure the “health, safety and welfare of all persons in employment” and “adequate medical and health facilities for all persons.”<sup>96</sup> However, an earlier provision in the constitution makes these sections nonjusticiable, meaning they are not enforceable in court.<sup>97</sup> And unlike India, Nigerian courts have not interpreted a justiciable constitutional right to health through the right to life. Some courts have nonetheless enforced a statutory right to health in legislation domesticating the regional *African Charter on Human and People’s Rights*.<sup>98</sup> The *National Health Act* also commits to “protect, promote and fulfil the rights of the people of Nigeria to . . . access . . . health

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91. CONST. (2005), art. 47. (Dem. Rep. Congo).

92. UNDANG-UNDANG DASAR NEGARA REPUBLIK INDONESIA [CONSTITUTION] art. 28H(1) (1945) (Indon.).

93. XIANFA art. 21, § 1 [CONSTITUTION] (1982) (China).

94. Law of the People’s Republic of China on Basic Healthcare and Health Promotion, arts. 4-5 (2020) (China).

95. INDIA CONST. art. 21, 39, 47; *see also* Consumer Educ. & Rsch. Ctr. v. Union of India, Judgment, 1995 3 SCC 42 (India) (Jan. 27); State of Punjab v. Mohinder Singh Chawla, Judgment, 1997 2 SCC 83 (India) (Dec. 17).

96. CONSTITUTION OF NIGERIA (1999), § 17(3).

97. *Id.* § 6(6)(c).

98. African Charter on Human and Peoples’ Rights (Ratification and Enforcement) Act (1983) L.F.N. 1990, Cap. 10 (Nigeria); Odafe. v. Attorney General, Judgment, 2004 FHC/PH/CS/680/2003 (Nigeria) (Feb. 23) and Georgina Ahamefule v. Imperial Med. Ctr., Judgment, 2012 ID/1627/2000 (Nigeria) (Sept. 27).

care.”<sup>99</sup> The *National Health Policy* further asserts that the right to health is a fundamental right and a “guiding principle” for the policy.<sup>100</sup> The policy also calls for a “review of the Constitution . . . to make health an enforceable right in Nigeria.”<sup>101</sup> Nigeria thus obtains a score of 0.75 and is the only nation that recognizes the right to health through executive branch decree.

The Constitution of Pakistan does not contain a right to health. But like in India, courts have sometimes given wide meaning to the constitutional right to life. For example, in 1994, the Supreme Court of Pakistan held that environmental hazards threatening human health implicate the constitutional rights to life and dignity.<sup>102</sup> More recently, in a 2020 case about the government response to COVID-19, the court affirmed the “fundamental right . . . to life, under which [the] Government of Pakistan is required to provide . . . safe and healthy living conditions.”<sup>103</sup> However, in both cases, the court stopped short of declaring a constitutional right to health and has not done so in other rulings. Pakistan also does not recognize the right to health through legislation or executive branch decree and therefore scores 0 for the right to health indicator.

### *C. Non-Discrimination*

The Non-Discrimination Index below displays the ten assessment countries ranked by their non-discrimination indicator scores.

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99. National Health Act (2014), Cap. (A139), §1(1)(e) (Nigeria).

100. National Health Policy (2016), § 3.4.1 (Nigeria).

101. *Id.* § 5.3.

102. Ms. Shehla Zia v. WAPDA, (1994) 1994 PLD (SC) 693 (Pak.).

103. Suo Moto Action Regarding Combating the Pandemic of Corona Virus (COVID-19), 2020 SCMR (SC) 1006 (Pak.), [https://www.supremecourt.gov.pk/downloads\\_judgements/s.m.c.\\_1\\_2020\\_19052020.pdf](https://www.supremecourt.gov.pk/downloads_judgements/s.m.c._1_2020_19052020.pdf) [https://perma.cc/TMB4-247A].

Table 4: Non-Discrimination Index

		Non-Discrimination
1	Russia	1.0
2	Vietnam	1.0
3	China	0.75
4	Indonesia	0.50
5	Nigeria	0.35
6	Philippines	0.35
7	DRC	0.25
8	Myanmar	0.25
9	India	0.10
10	Pakistan	0

The Non-Discrimination Index has a range of 1.0 from 0 to 1.0. The mean non-discrimination indicator score is 0.455, with a standard deviation of 0.335. The median score is 0.35, and the modes are 1.0, 0.35, and 0.25.

The research and scoring underlying the Non-Discrimination Index are tabulated here. The table contains the sources of law assessed for each kind of recognition for each country. The constitutional recognition column contains the equality and non-discrimination provisions evaluated in each national constitution. Sources of law for legislative and executive branch recognition listed with specific provisions above an ellipsis contribute to a country's non-discrimination indicator score. Sources of law without specific provisions do not meet the definitions for legislative or executive branch recognition of the non-discrimination commitment. Information about the author's assessment or ability to obtain or review sources of law is in footnotes where necessary.

Table 5: Non-Discrimination Index Scoring and Sources of Law

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
Russia	0.25	1.0	0	1.0
	Art. 19(2)	<p><i>Law on the Basics of Health Protection of Citizens in the Russian Federation</i> (2011) art. 5(3)</p> <p>...</p> <p><i>Law on Social Protection of the Disabled</i> (1995)</p> <p><i>Law on the Sanitary and Epidemiological Welfare of the Population</i> (1999)</p> <p><i>Labor Code</i> (2001)</p> <p><i>Law on Preventing the Spread of Tuberculosis</i> (2001)</p> <p><i>Law on the Circulation of Medicines</i> (2010)</p>	<p><i>State Strategy for the Elimination of Tuberculosis in the Russian Federation until 2025 and Beyond</i> (2018)</p> <p><i>Strategy for the Development of Healthcare in the Russian Federation for the Period until 2025</i> (2019)</p>	
Vietnam	0.25	1.10	0.25	1.0
	Art. 16(2)	<p><i>Law on Prevention and Control of Infectious Disease</i> (2007) art. 8(5)</p> <p><i>Law on</i></p>	<p><i>Vietnam National Tuberculosis Program Draft National Strategic Plan 2021–2025</i> (2020) §§ 3.1.1.4, 3.3.5.4</p> <p>...</p>	

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
		<p><i>HIV/AIDS Prevention and Control</i> (2006, rev. 2020), arts. 3(4), 8, 10(7)</p> <p>...</p> <p><i>Law on Persons with Disabilities</i> (2010)</p> <p><i>Labor Code</i> (2012)</p>	<p><i>Plan for People's Health Protection, Care and Promotion 2016–2020</i> (2016)</p>	
	0	0.75	0	
China	Art. 4	<p><i>Law on the Prevention and Treatment of Infectious Diseases</i> (1989, rev. 2013) art. 16</p> <p><i>Employment Promotion Law</i> (2007, rev. 2015) arts. 25, 26, 30</p> <p>...</p> <p><i>Law on the Protection of Persons with Disabilities</i> (2008, rev. 2018)</p> <p><i>Law on Basic Healthcare and Health Promotion</i> (2020)</p>	<p><i>Implementing Measures for the Law on the Prevention and Treatment of Infectious Diseases</i> (1991)</p> <p><i>Administrative Measures for the Prevention and Treatment of Tuberculosis</i> (2013)</p> <p><i>Healthy China 2030 Blueprint</i> (2016)</p> <p><i>Healthy China Action (2019–2030)</i> (2019)</p> <p><i>Opinions of the State Council on Implementing the Healthy China Action Plan</i> (2019)</p>	0.75
Indonesia	0.25	0	0.25	0.50

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
	Art. 28I	<i>Health Principles Law</i> (1960) <i>Outbreaks of Infectious Diseases Law</i> (1984) <i>Human Rights Law</i> (1999) <i>Labor Law</i> (2003) <sup>104</sup> <i>Medical Practice Law</i> (2004) <i>Health Law</i> (2009) <i>Hospital Law</i> (2009) <i>Law on Persons with Disabilities</i> (2016) <i>Omnibus Law on Job Creation Law</i> (2020)	<i>Presidential Regulation 67/2021 on Tuberculosis Management</i> (2021) arts. 12(8), 24(3), 29(2) <i>National Strategy of Tuberculosis Care and Prevention in Indonesia 2020–2024</i> (2020) §§ 4.5.2, 4.5.3, 5.1.5 <i>Ministry of Health Regulation 67/2016 on Tuberculosis Treatment</i> arts. 7(4), 25(1, 3) ... <i>Ministry of Health Decree 1278/Menkes/SK/XII/2009 on Guidelines for Implementing Collaborative TB and HIV Control</i> <i>Ministry of Health Circular Letter HK.03.03/D1 III.I/951/2016 on Increasing TB Case Findings</i> <sup>105</sup>	

104. The preamble of Indonesia's Labor Law (Undang-undang tentang Ketenagakerjaan [Labor Law], No. 13 of 2003) establishes the objective "to secure the implementation of equal opportunity and equal treatment without discrimination on whatever basis." Chapter III, entitled "Equal Opportunities," provides in article 5 that "[e]very person available for a job shall have the same opportunity to get a job without discrimination," and in article 6 that "[e]very worker/labourer has the right to receive equal treatment without discrimination from their employer." But the law does not explicitly prohibit discrimination based on TB, infectious disease, or health status.

105. The author was unable to obtain a copy of and thus could not assess the *Ministry of Health Circular Letter HK.03.03/D1 III.I/951/2016 on Increasing TB Case Findings*.

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
			<i>Ministry of Health Regulation 39/2016 on Guidelines for Implementing the Healthy Indonesia Program with a Family Approach</i> <i>Ministry of Health Regulation 43/2016 on Minimum Health Service Standards</i> <i>Ministry of Health Strategic Plan 2020–2024 (2020)</i>	
	0	0.10	0.25	
Nigeria	Art. 15	<i>HIV and AIDS (Anti-Discrimination) Act (2014) Part II</i> ... <i>Labour Act (1971)</i> <i>African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act (1983)</i> <i>National Health Act (2014)</i> <i>Discrimination Against Persons with Disabilities (Prohibition) Act (2018)</i>	<i>National Strategic Plan for Tuberculosis Control, 2021–2025 (2021) §§ 2.2, 2.2.1.2, 4.2.6.2</i>  <i>Human Rights and Gender Action Plan for Tuberculosis Care and Prevention in Nigeria 2021–2025 (2021) §§ 5, 8, 11</i> ... <i>National Health Policy 2016 (2016)</i>	0.35
	0	0.10	0.25	
Philippines	Art. III, § 1	<i>Philippine HIV and AIDS Policy Act (2018) art. VII</i>	<i>Guidelines for the Implementation of Policy and Program on Tuberculosis (TB)</i>	0.35

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
		<p><i>Labor Code of the Philippines</i> (1974)</p> <p><i>Magna Carta for Disabled Persons</i> (1992)</p> <p><i>Universally Accessible Cheaper and Quality Medicines Act of 2008</i> (2008)</p> <p><i>Comprehensive Tuberculosis Elimination Plan Act</i> (2016)</p> <p><i>Universal Health Care Act</i> (2019)</p>	<p><i>Prevention and Control in the Workplace</i> (2005) § 4.1</p> <p><i>National Tuberculosis Control Program Manual of Procedures 6th ed.</i> (2020) Ch. 1, 3-4</p> <p>...</p> <p><i>The Philippine Health Agenda 2016–2022</i> (2016)</p> <p><i>Implementing Rules and Regulations of the Comprehensive Tuberculosis Elimination Plan Act</i> (2017)</p> <p><i>Strategic Framework and Implementing Guidelines for FOURmula One Plus for Health (F1+)</i> (2018)</p> <p><i>Implementing Rules and Regulations of Universal Health Care Act</i> (2019)</p> <p><i>National TB Control Program Adaptive Plan for the COVID-19 Pandemic</i> (2020)</p> <p><i>Updated Philippine Strategic TB Elimination Plan, Phase 1: 2020-2023</i> (2020)</p>	
DRC	0	0	0.25	0.25



	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
	Art. 13	<i>Labor Code (2002)</i> <i>Law for the Protection of the Rights of People Living with HIV/AIDS and Affected Persons (2008)</i> <i>Public Health Law (2018)</i> <sup>106</sup> <i>Law on the Protection and Promotion of the Rights of Persons with Disabilities (2022)</i>	<i>National Strategic Plan for the Fight Against Tuberculosis 2021-2022 (2023)</i> §§ 2.2.7, 6.5.4.7 ... <i>National Health Development Plan 2019-2022: Towards Universal Health Coverage (2018)</i>	
	0	0	0.25	
Myanmar	Art. 348	<i>Public Health Law (1972)</i> <sup>107</sup> <i>Prevention and Control of Infectious Diseases Law (1995)</i> <i>Amendment of Prevention and Control of Infectious Diseases Law (2011)</i> <i>Employment and Skill Development</i>	<i>National Strategic Plan 2021-2025: National TB Programme (2020)</i> §§ 3.2.3, 3.3 ... <i>Myanmar National Health Plan 2017–2021 (2016)</i>	0.25

106. Article 16 of the DRC's Public Health Law (Loi n° 18/035 du 13 décembre 2018 fixant les principes fondamentaux relatifs à l'organisation de la Santé publique [Public Health Law], Dec. 13, 2018) protects against discrimination in accessing health care, but the law does not prohibit discrimination on grounds of TB, infectious disease, or health status.

107. The author was unable to obtain an English language version of the ပြည်သူ့ကျန်းမာရေးဥပဒေ [Public Health Law], 1972. The Burmese language version he obtained was not searchable in Burmese and google translate did not produce a coherent English language machine translation of the Burmese language document. As a result, the author did not assess this law.

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
		<i>Law (2013)</i> <i>The Minimum Wage Law (2013)</i> <i>Rights of Persons with Disabilities Law (2015)</i> <i>Payment of Wages Law (2016)</i> <i>Shops and Workplaces Law (2016)</i> <i>Myanmar Companies Law (2017)</i>		
	0	0.10	0	
India	Arts. 14, 15, 16	<i>The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act (2017) § 3</i> ... <i>Epidemic Diseases Act (1897)</i> <i>Rights of Persons with Disabilities Act (2016)</i> <i>Code on Wages (2019)</i>	<i>National Health Policy 2017 (2017)</i> <i>National Strategic Plan for Tuberculosis: 2017–25, Elimination by 2025 (2017)</i> <sup>108</sup>	0.10

108. Ministry of Health with Fam. Welfare, *Nat'l Strategic Plan for Tuberculosis: 2017–25, Elimination by 2025* at 86, 87, and 120 (Mar. 2017) mentions discrimination but does not explicitly prohibit discrimination, establish the right to be free from discrimination, or commit to non-discrimination of people affected by tuberculosis.

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
		<i>Epidemic Diseases (Amendment) Act (2020)</i> <i>Industrial Relations Code (2020)</i> <i>Occupational Safety, Health and Working Conditions Code (2020)</i>		
	0	0	0	
Pakistan	Arts. 25, 26, 27	<i>Factories Act (1934)</i> <i>Public Health (Emergency Provision) Ordinance (1944)</i> <i>West Pakistan Epidemic Diseases Act (1958)</i> <i>West Pakistan Industrial and Commercial Employment (Standing Orders) Ordinance (1968)</i> <i>West Pakistan Shops and Establishments Ordinance (1969)</i> <i>Disabled Persons (Employment and Rehabilitation) Ordinance (1981)</i>	<i>National Health Vision: Pakistan 2016–2025 (2016)</i> <i>National Strategic Plan for Tuberculosis Control, 2020–2023 (2020)</i>	0

	Constitutional recognition	Legislative recognition	Executive branch recognition	Score
		<i>Epidemic Diseases (Amendment) Act (2011)</i>		

Russia and Vietnam both receive maximum scores of 1.0 by prohibiting discrimination based on disease in legislation. Russia “guarantees citizens protection against any form of discrimination due to the presence of any disease.”<sup>109</sup> Vietnam prohibits “[d]iscriminating against and publishing negative images of and information on persons suffering from an infectious disease.”<sup>110</sup> Russia and Vietnam, along with Indonesia, are also the only countries that include inclusive, catch-all categories in their constitutional prohibitions against discrimination. Indonesia’s constitution enshrines the right to be free from discrimination “based upon any grounds whatsoever.”<sup>111</sup> Vietnam’s constitution prohibits discrimination in “political, civic, economic, cultural, and social life,” and Russia’s constitution “guarantees the equality of human and civil rights and freedoms regardless” of ten listed categories and any “other circumstances.”<sup>112</sup>

China’s score of 0.75 results from points awarded for non-discrimination provisions in infectious disease and employment legislation. Article 16 of the *Law on the Prevention and Treatment of Infectious Diseases* prohibits discrimination against people with infectious diseases.<sup>113</sup> Article 30 of the *Employment Promotion Law* prohibits employers from refusing to hire people because they have an infectious disease.<sup>114</sup> However, both provisions also bar people affected by TB from jobs prohibited by “laws, administrative regulations, or the health administration department under the State Council.”<sup>115</sup> The Chinese *Regulations on Hygiene Management in Public Places* prohibit

109. Об основах охраны здоровья граждан в Российской Федерации [Law on the Basics of Health Protection of Citizens in the Russian Federation], 2011, no. 323-FZ, art. 5(3), ¶ 2 (Russ.).

110. Luật Phòng, chống bệnh truyền nhiễm [Law on Prevention and Control of Infectious Disease], No. QH12, art. 8(5).

111. UNDANG-UNDANG DASAR NEGARA REPUBLIK INDONESIA TAHUN [UUD 1945] [CONSTITUTION] art. 28I (Indon.).

112. HIẾN PHÁP NƯỚC CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM [HIẾN PHÁP] [CONSTITUTION] 1992 art. 50 (Viet.); KONSTITUSIA ROSSIJSKOI FEDERATSII [KONST. RF] [CONSTITUTION] art. 19 (Russ.).

113. Law of the People's Republic of China on the Prevention and Treatment of Infectious Diseases (promulgated by Order No. 17 of the President of the People's Republic of China., Aug. 28, 2004), art. 16 (China).

114. Employment Promotion Law of the People's Republic of China (promulgated by Standing Committee of the National People's Congress of China., June 29, 2007, effective Jan. 1, 2008), art. 30 (China).

115. *Id.*; Law of the People's Republic of China on the Prevention and Treatment of Infectious Diseases, *supra* note 112.

people with pulmonary TB from “direct customer service work until they are cured,” and the *General Standard for Medical Examination for Civil Servants (Trial)* disqualifies people affected by TB from civil service until one to two years after they are cured.<sup>116</sup>

People with TB are usually no longer contagious after two weeks of the standard 6-month treatment.<sup>117</sup> People who successfully complete TB treatment are considered disease-free and are no longer contagious. Therefore, China receives 0.50 rather than 1.0 points for its infectious disease law and 0.25 rather than 0.50 points for its employment law because both laws are subject to overly broad administrative regulations at odds with the non-discrimination commitment in unnecessarily restricting people affected by TB’s employment opportunities.

India, Nigeria, the Philippines, and Vietnam prohibit discrimination based on HIV status in HIV legislation, reflecting the proliferation of HIV laws during past decades.<sup>118</sup> By contrast, only two countries have enacted TB laws—Russia and the Philippines—neither of which prohibits discrimination against people affected by TB. The DRC has an HIV law, but it does not prohibit discrimination against people living with HIV. In 2006, China’s State Council promulgated the “Regulations on AIDS Prevention and Treatment.”<sup>119</sup> The decree prohibits discrimination against people living with HIV. But the State Council is an executive branch body, so the regulations do not constitute legislation and do not contribute to China’s non-discrimination indicator score.<sup>120</sup>

Nine countries have strategic plans or implementation guidelines for their national TB programs but only six address discrimination. For example, the DRC’s plan includes a section on reducing “stigma and discrimination in TB prevention and care” with ten subsections outlining a detailed approach.<sup>121</sup> Myanmar’s plan commits to combatting stigma and discrimination through “community engagement” as an “essential intervention” and highlights the need

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116. Regulations on Hygiene Management in Public Places (promulgated by Decree of the State Council of the People’s Republic of China., 1987) No. 24 art. 7 (China) [<https://perma.cc/URF5-Q74X>]; General Standards for Medical Examination for Civil Servants (Trial) (promulgated by Circular of the Ministry of Personnel and the Ministry of Health., 2005), No. 1, art. 4 (China) [<https://perma.cc/W4Z2-7LFM>].

117. Division of Tuberculosis Elimination, CORE CURRICULUM ON TUBERCULOSIS: WHAT THE CLINICIAN SHOULD KNOW, 139 (Centers for Disease Control and Prevention, 7<sup>th</sup> ed. 2021).

118. See The Lancet HIV, *Time to End Discriminatory Laws Against People with HIV*, 8 THE LANCET HIV e729 (2021); Matthew M. Kavanagh et al., *Law, Criminalisation and HIV in the World: Have Countries That Criminalise Achieved More or Less Successful Pandemic Response?* 6 BMJ GLOBAL HEALTH (Aug. 2, 2021).

119. Regulations on AIDS Prevention and Treatment 2006 (Decree No. 457) (promulgated by the State Council of the People’s Republic of China, Jan. 18, 2006) §§ 3, 10 (China).

120. *State Structure of the People’s Republic of China: The State Council*, THE NAT’L PEOPLE’S CONG. OF THE PEOPLE’S REPUBLIC OF CHINA, [www.npc.gov.cn/zgrdw/englishnpc/stateStructure/2007-12/06/content\\_1382098.htm](http://www.npc.gov.cn/zgrdw/englishnpc/stateStructure/2007-12/06/content_1382098.htm) (last visited Jan. 31, 2023) [<https://perma.cc/G4DJ-FR55>].

121. *National Strategic Plan for the Fight Against Tuberculosis 2021-2022* (2023) § 2.2.7 WORLD HEALTH ORG. DEM. REP. CONGO (2019) [<https://perma.cc/9MZW-J5FX>].

to reduce TB-based discrimination in the workplace.<sup>122</sup> By contrast, Pakistan's 100-page plan does not mention discrimination and only refers once to TB stigma in the summary of a sub-national jurisdiction's plan.<sup>123</sup>

#### *D. Access to Medicines*

The Access to Medicines Index below displays the ten assessment countries ranked by their access to medicines indicator scores.

Table 6: Access to Medicines Index

		Access to Medicines
1	Philippines	1.0
2	India	0.95
3	Indonesia	0.90
4	Russia	0.90
5	China	0.80
6	Vietnam	0.70
7	DRC	0.60
8	Nigeria	0.55
9	Myanmar	0.50
10	Pakistan	0.50

The Access to Medicines Index has a range of 0.50 from 0.50 to 1.0. The mean access to medicines indicator score is 0.74, with a standard deviation of approximately 0.184. The median score is also 0.74, and the modes are 0.90 and

122. Ministry of Health and Sports, *National Strategic Plan, 2021-2025: National TB Programme* § 3.2.3, 3.3 WORLD HEALTH ORG. MYAN. (Mar. 2020).

123. Ministry of National Health Services, *National Strategic Plan for Tuberculosis Control, 2020-2023* § 4 WORLD HEALTH ORG. PAK. (2019).

0.50.

The research and scoring underlying the Access to Medicines Index are tabulated here. The table contains the sources of law assessed for each kind of recognition for each country. The constitutional recognition column contains the relevant provisions evaluated in each national constitution when such provisions exist. Sources of law for legislative and executive branch recognition listed with specific provisions above an ellipsis contribute points to a country's access to medicines indicator score. Sources of law without specific provisions do not meet the definitions for legislative or executive branch recognition of the access to medicines commitment. Information in brackets designates the TRIPS flexibilities and textual and institutional commitments in the sources of law contributing to the indicator scores.

Table 7: Access to Medicines Index Scoring and Sources of Law

	Constitutional recognition	Legislative and executive branch recognition	Score
	0.25	1.40	
Philippines	Art. XIII, § 11	<p><i>Intellectual Property Code</i> (1998, 2015 ed.) § 22.1 [heightened patentability criteria], 72.1 [parallel importation, int'l exhaustion], 72.3 [limited exceptions—research, experimental use], 72.4 [limited exceptions—Bolar], 74 [government use], 93 [compulsory licensing]</p> <p><i>Universally Accessible Cheaper and Quality Medicines Act of 2008</i> (2008) [institutional, textual commitments]</p> <p><i>Implementing Rules and Regulations of the Comprehensive Tuberculosis Elimination Plan Act</i> (2017) § 5.2 [institutional commitment]</p> <p><i>Implementing Rules and Regulations of Universal Health Care Act</i> (2019) § 28 [institutional commitment]</p> <p><i>Universal Health Care Act</i> (2019) § 3(b), 28 [institutional, textual commitments]</p> <p>...</p>	1.0

	Constitutional recognition	Legislative and executive branch recognition	Score
		<i>Comprehensive Tuberculosis Elimination Plan Act</i> (2016)	
	0	0.95	
India		<p><i>The Patents (Amendment) Act</i> (2005) § 3(d) [heightened patentability criteria], 25 [opposition procedures], 64 [revocation procedures], 84, 92, 92A [compulsory licensing, government use], 107A(a) [limited exceptions—Bolar], 107A(b) [parallel importation, int'l exhaustion]</p> <p><i>National Health Policy 2017</i> (2017) §§ 3.3.3, 14.4, 14.7, 17 [institutional commitment]</p> <p>...</p> <p><i>Drugs and Cosmetics Act</i> (1940)</p>	0.95
	0	0.90	
Indonesia		<p><i>Law on Patents</i> (2016) arts. 19(3) [limited exceptions— research, experimental use], 93, 109, 111 [compulsory licensing, government use], 132 [revocation procedures], 167 [parallel importation, int'l exhaustion]</p> <p><i>Ministry of Law and Human Rights Regulation 30/2019 on Procedures for Granting Compulsory Patent Licenses</i> [compulsory licensing, government use] art. 33(1, 2) [textual commitment]</p> <p><i>Presidential Regulation 77/ 2020 on Procedures of Patent Implementation by the Government</i> [compulsory licensing, government use] art. 13 [textual commitment]</p> <p><i>Health Law</i> (2009) arts. 36-41 [institutional, textual commitments]</p> <p><i>Omnibus Law on Job Creation Law</i> (2020)</p>	0.90



	Constitutional recognition	Legislative and executive branch recognition	Score
		art. 107 [compulsory licensing]. <sup>124</sup>  ...  <i>Presidential Regulation 67/2021 on Tuberculosis Management</i> <i>Ministry of Health Decree 67/2016 on Tuberculosis Treatment</i>	
	0	0.90	
Russia		<i>Civil Code, Part IV, § VII, Rights in the Results of Intellectual Activities and Means of Individualization</i> (2006) arts. 1359(2) [limited exceptions— research, experimental use], 1360, 1362 [compulsory licensing, government use], 1398 [revocation procedures]  <i>Law on Preventing the Spread of Tuberculosis</i> (2001) art. 14(4) [textual commitment]  <i>Law on the Circulation of Medicines</i> (2010) art. 9.3, Ch. 12 (arts 60-63) [institutional commitment]  <i>Law on the Basics of Health Protection of Citizens in the Russian Federation</i> (2011) art. 18(2) [textual commitment]  <i>Law on Amendments to Article 60 of the Federal Law ‘On the Circulation of Medicines’ and Article 38 of the Federal Law ‘On the Basics of Protecting the Health of Citizens in the Russian Federation’</i> (2020) [institutional	0.90

124. Part 4 of the *Omnibus Law on Job Creation* (2020) amends the compulsory licensing articles of the *Law on Patents* (2016) allowing compulsory licenses for patents that have been “exercised by the patent holder . . . [in] a way that detracts from the interests of the community.” Indonesia passed a new version of the Omnibus Job Creation law in 2023, repealing the 2020 law. However, this paper’s assessment covers the inclusive four year period 2019-2022 during which the 2018 TB UNHLM Political Declaration was in effect. The new 2023 law is outside this timeframe.

	Constitutional recognition	Legislative and executive branch recognition	Score
		commitment]. <sup>125</sup>	
	0	0.80	
China		<p><i>Patent Law</i> (1984, rev. 2020) arts. 54-55 [compulsory licensing], 75(1) [parallel importation, int'l exhaustion], 75(5) [limited exceptions—Bolar]</p> <p><i>Implementing Rules of the Patent Law</i> (2010) Ch. 5 [compulsory licensing]</p> <p><i>Measures for the Compulsory Licensing of Patent Implementation</i> (2012) [compulsory licensing]</p> <p><i>Drug Administration Law</i> (2019) art. 3 [textual commitment]</p> <p><i>Law on Basic Healthcare and Health Promotion</i> (2020) arts. 58-59 [institutional commitment]</p> <p>...</p> <p><i>Implementing Measures for the Law on the Prevention and Treatment of Infectious Diseases</i> (1991)</p> <p><i>Measures for the Administration of Drug Registration</i> (2020)</p> <p><i>Regulations for the Implementation of the Drug Administration Law</i> (2020)</p>	0.80
	0	0.70	
Vietnam		<i>Law on Intellectual Property</i> (2022) <sup>126</sup> arts. 125(2)(a) [limited exceptions—research, Bolar], 125(2)(b) [parallel importation,	0.70

125. The institutional commitment in the *Law on Amendments to Article 60 of the Federal Law 'On the Circulation of Medicines' and Article 38 of the Federal Law 'On the Basics of Protecting the Health of Citizens in the Russian Federation'* (2020) is not aggregated with the institutional commitment in the *Law on Circulation of Medicines* (2010) because, as amending legislation, it is technically part of the *Law on Circulation of Medicines*.

126. The relevant articles in Luật của Quốc hội: Luật Sở Hữu Trí Tuệ [Law on Intellectual Property], No. 11/VBHN-VPQH, July 8, 2022 are amended but not meaningfully modified by Luật của Quốc hội: Luật sửa đổi, bổ sung một số điều của Luật sở hữu trí tuệ [Law Amending and Supplementing a Number of Articles of the Intellectual Property Law], No. 07/2022/QH15, June 16, 2022.

	Constitutional recognition	Legislative and executive branch recognition	Score
		<p>int'l exhaustion], 133-133a [government use], § 3 (arts 145-147) [compulsory licensing]</p> <p><i>Plan for People's Health Protection, Care and Promotion 2016–2020</i> (2016) §§ 2.2 [textual commitment], 4.7 [institutional commitment]</p> <p>...</p> <p><i>Law on Prevention and Control of Infectious Disease</i> (2007)</p> <p><i>Guidance the Confidential Protection of Trial Data in Drug Registration</i> (2010)</p>	
	0	0.60	
DRC		<p><i>Industrial Property Law</i> (1982) arts. 49 [limited exceptions—research], 79-82 [compulsory licensing, government use], 149 [revocation procedures]</p> <p><i>National Health Development Plan 2019-2022: Towards Universal Health Coverage</i> (2018) art. 5.2.5 [textual commitment]</p>	0.60
	0	0.55	
Nigeria		<p><i>Patents and Designs Act</i> (1971) first sch [compulsory licensing, government use]</p> <p><i>National Health Act</i> (2014) §§ 2(1) [textual commitment], 11(3)(b) [institutional commitment]</p> <p><i>National Health Policy 2016</i> (2016) § 4.2.5 [textual commitment]</p>	0.55
	0	0.50	
Myanmar		<p><i>Patent Law</i> (2019) §§ 14(b) [LDCs transition period], 33-35 [opposition procedures], 54(b) [limited exceptions—research, experimental use], 65-73 [compulsory licensing], 77 [revocation procedures]</p> <p>...</p>	0.50

	Constitutional recognition	Legislative and executive branch recognition	Score
		<i>Public Health Law (1972)</i> <sup>127</sup> <i>Prevention and Control of Infectious Diseases Law (1995)</i> <i>Amendment of Prevention and Control of Infectious Diseases Law (2011)</i> <i>Myanmar National Health Plan 2017–2021 (2016)</i>	
	0	0.50	
Pakistan		<i>Patents Ordinance (2000)</i> § 23 [opposition procedures], § 30(5)(a) [parallel importation, int'l exhaustion], <sup>128</sup> § 30(5)(c, e, f) [limited exceptions—research, Bolar], § 46–49 [revocation procedures], § 58 [compulsory licensing, government use]  <i>The Patent Rules (2003)</i> § 18 [opposition procedures], § 26 [revocation procedures], § 44 [compulsory licensing]  ...  <i>Public Health (Emergency Provision) Ordinance (1944)</i> <i>West Pakistan Epidemic Diseases Act (1958)</i> <i>Epidemic Diseases (Amendment) Act (2011)</i> <i>National Health Vision: Pakistan 2016–2025 (2016)</i>	0.50

The Philippines is the only nation to score the maximum value of 1.0 and obtain points for constitutional, legislative, and executive branch recognition. The Philippines has established four TRIPS flexibilities in intellectual property legislation and made both textual and institutional commitments in law and

127. See *supra* note 113. The author was unable to obtain an English language version of the *Public Health Law (1972)*. The Burmese language version he obtained was not searchable in Burmese. And Google Translate did not produce a coherent English language machine translation of the Burmese language document. As a result, the author did not assess this law.

128. PAK., PATENTS ORDINANCE, Ch. 8, § 30(5)(a) (2000), does not mention importation in the statute. Additionally, importation is generally prohibited in 30(a, b) for patented products and processes. However, § 30(5)(a) clearly establishes the international principle of exhaustion of patent rights as an exception to the rights of patent holders, establishing that “rights under patent shall not extend” to articles in Pakistan that “have been put on the market anywhere in the world.”

executive branch decrees. The Constitution of the Philippines commits the country to adopting an “approach to health development which shall endeavor to make essential goods, health and other social services available . . . at affordable cost.”<sup>129</sup> The intellectual property law is also remarkable for explicitly addressing access to medicines in the TRIPS flexibilities provisions. For example, section 72.1 establishes limitations on patent rights, including allowing parallel importation of medicines based on the international exhaustion principle. The provision states that “with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention.”<sup>130</sup> Section 93 sets forth the legal grounds for compulsory licensing, including when “the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms.”<sup>131</sup>

India enacted *The Patents (Amendment) Act* in 2005 to comply with the TRIPS Agreement.<sup>132</sup> The law contains five of this assessment’s TRIPS flexibilities, including a provision heightening patentability criteria for medicines. The provision excludes from the statutory definition of “inventions” the “mere discovery of a new form of a known substance which does not result in the enhancement of [its] known efficacy.”<sup>133</sup> In 2015, the Supreme Court of India upheld the provision declaring that it requires new patents for existing chemical substances used in medicine to enhance a drug’s “therapeutic efficacy.”<sup>134</sup> The court acknowledged that drug patents might “put[] life-saving medicines beyond the reach” of people who need them.<sup>135</sup> And it discussed India’s history of protecting process rather than product patents for medicines that fostered the development of the country’s generic pharmaceutical industry.<sup>136</sup> The Philippines’ *Intellectual Property Code* contains an article modeled on the Indian provision with the same language requiring the “enhancement of the known efficacy” of new forms of known substances used in medicines.<sup>137</sup>

India’s patent legislation is also noteworthy because it is the only intellectual property law in this assessment that mentions TB. Section 92 sets forth special procedures for granting compulsory licenses during national

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129. CONST. (1987), art. XIII, § 11 (Phil.).

130. INTELL. PROP. CODE, § 72.1, Rep. Act 8293, as amended (Phil.).

131. *Id.* at § 93.6.

132. See Shamnad Basheer, *India’s Tryst with TRIPS: The Patents (Amendment) Act*, 1 Indian J. of L. & Tech. 15, 42 (2005).

133. The Patents (Amendment) Act, 2005, § 3(d) (India).

134. Novartis AG v. Union of India, (2013) 13 S.C.R. 148, 180 (India).

135. *Id.*; see Understanding the WTO: The Organization: Least-developed Countries *supra* note 88.

136. *Id.* ¶ 47-59.

137. INTELL. PROP. CODE, §§ 22.1, 26.2., Rep. Act 8293, as amended (Phil.).

emergencies or “circumstances of extreme urgency.”<sup>138</sup> The procedures supersede the normal statutory requirements and allow the government to expedite the process for granting a compulsory license. The circumstances warranting this expedited process include “public health crises[] relating to . . . tuberculosis.”<sup>139</sup>

Indonesia’s patent legislation and regulations notably include community concerns and drug prices as considerations for challenges and limitations on intellectual property rights. The *Law on Patents* empowers individual parties who “represent the national interest” to file suit to revoke a patent “for the benefit of the community.”<sup>140</sup> A 2019 regulation on compulsory licensing designates “difficulty . . . accessing drugs in the community” as an “emergency” for which the Minister of Law and Human Rights may grant a compulsory license.<sup>141</sup> A 2020 presidential regulation on public, non-commercial use authorizes the government to make use of a patent to address “expensive prices” of medicines and other biotechnologies needed to combat a deadly disease.<sup>142</sup>

Russia is the only country that has committed in legislation to providing free medicines to people with TB.<sup>143</sup> Russia also makes an institutional commitment to access to medicines in its *Law on the Circulation of Medicines* which authorizes State price controls of drugs on its essential medicines list.<sup>144</sup> A 2020 amendment of the law expands the program to allow price controls of drugs not included in the essential medicines list to confront “extraordinary situations” or emerging infectious diseases.<sup>145</sup>

## V. CONCLUSION

In 2018, the UN General Assembly’s High-Level Meeting on TB prompted countries worldwide to make ambitious commitments to end TB and DR-TB by 2030. These included groundbreaking legal and human rights commitments on

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138. The Patents (Amendment) Act, 2005, § 92(1) (India).

139. *Id.* § 92(3).

140. Law on Patents, No. 13 of 2016, art. 132(4) (Indon.); Explanation of the Law on Patents, No. 13 of 2016, § II (132(4)) (Indon.).

141. Regulation of the Minister of Law and Human Rights, No. 30 of 2019 on Procedures for Granting a Patent’s Mandatory License, art. 33(2) (Indon.).

142. Regulation of the President of the Republic of Indonesia, No. 77 of 2020 on Government Procedures for Implementing Patents, art. 13(a) (Indon.).

143. Федеральный закон "О предупреждении распространения туберкулеза в Российской Федерации" [Federal Law on Preventing the Spread of Tuberculosis], No. 77-FZ, June 18, 2001, art. 14(4) (Russ.).

144. Федеральный закон "Об обращении лекарственных средств" [Federal Law on the Circulation of Medicines], No. 61-FZ, Apr. 12, 2010, as amended, arts. 9.3, 60-63 (Russ.).

145. Федеральный закон "О внесении изменений в статью 60 Федерального закона "Об обращении лекарственных средств" и статью 38 Федерального закона "Об основах охраны здоровья граждан в Российской Федерации" [Federal Law on Amendments to Article 60 of the Federal Law “On the Circulation of Medicines” and Article 38 of the Federal Law “On the Basics of Protecting the Health of Citizens in the Russian Federation”], No. 67-FZ, Mar. 26, 2020, art. 1 (Russ.).

the right to health, non-discrimination, and access to medicines. This paper represents the first effort to empirically measure countries' progress in fulfilling these pledges.

This paper developed and applied a novel empirical framework modeled on the UN Human Development Index to assess ten countries with high DR-TB burdens. The results show that none of the countries has fulfilled all three legal and human rights pledges. Nonetheless, several nations have fulfilled one commitment, and two have fulfilled two commitments, as illustrated in the TB UNHLM Legal Rights Index above. The laws and policies in these countries provide concrete examples of legal instruments that satisfy the legal and human rights pledges as nations work to fulfill their commitments in the new Political Declaration from the second TB UNHLM held in September 2023. However, as noted in the limitations discussed above, this paper's assessment does not evaluate the implementation or enforcement of these laws and policies. Countries must fully implement their laws and policies to achieve their intended impact. As a result, even the countries receiving maximum scores (1.0) in this assessment must implement and enforce their laws and policies to fully realize the TB UNHLM legal and human rights commitments.

To this end, countries whose national constitutions do not fully recognize the right to health should consider amending their constitutions to establish an individual right to health. All nations should consider amending relevant legislation to explicitly prohibit TB-based discrimination. And all countries should consider enshrining the full set of TRIPS flexibilities in intellectual property legislation and regulations while making clear textual and institutional commitments to ensuring access to medicines in patent and health law and policy.

## APPENDIX

This appendix contains citations for the legal instruments evaluated in this paper's assessment listed by country and source of law.

### China

#### Constitutional

XIANFA [CONSTITUTION] (1982).

#### Legislative

Zhuānlǐ fǎ (专利法) [Patent Law] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, effective Apr. 1, 1985).

Chuánrǎn bìng fángzhì fǎ (传染病防治法) [Law on the Prevention and Treatment of Infectious Diseases] (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 21, 1989, effective Sept. 1, 1989).

Jiùyè cùjìn fǎ (就业促进法) [Employment Promotion Law] (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 30, 2007, effective Jan. 1, 2008).

Cánjǐ rén bǎozhàng fǎ (残疾人保障法) [Law on the Protection of Persons with Disabilities] (promulgated by the Standing Comm. Nat'l People's Cong., Apr. 24, 2008, effective July 1, 2008).

Yàopǐn guǎnlǐ fǎ (药品管理法) [Drug Administration Law] (promulgated by the Standing Comm. Nat'l People's Cong., Sept. 20, 1984, effective July 1, 1985).

Jīběn yīliáo hé jiànkāng cùjìn fǎ (基本医疗和健康促进法) [Law on Basic Healthcare and Health Promotion] (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 28, 2019, effective June 1, 2020).

#### Executive branch

Chuánrǎn bìng fángzhì fǎ shíshī bànfǎ (传染病防治法实施办法) [Implementing Measures for the Law on the Prevention and Treatment of Infectious Diseases] (implemented by the State Council Letter [1991] 66 on Oct. 4, 1991).



Zhuānli shíshī qiángzhì xǔkě bànfǎ (专利实施强制许可办法) [Measures for the Compulsory Licensing of Patent Implementation] (promulgated by the State Intellectual Property Office, Mar. 15, 2012, effective May 1, 2012).

Jiéhébing fángzhì guǎnlǐ bànfǎ (结核病防治管理办法) [Administrative Measures for the Prevention and Treatment of Tuberculosis] (promulgated by the Ministry of Health, Jan. 9, 2013, effective Mar. 24, 2013).

Zhuānli fǎ shíshī xìzé (专利法实施细则) [Implementing Rules of the Patent Law] (promulgated by the State Council of the People's Republic of China, June 15, 2001, effective July 1, 2001, rev. Jan. 9, 2010).

“Jiànkāng zhōngguó 2030” guīhuà gāngyào (“健康中国2030”规划纲要) [Healthy China 2030 Blueprint] (promulgated by the Central Comm. of the Communist Party of China and the State Council of the People's Republic of China, Oct. 25, 2016).

Jiànkāng zhōngguó xíngdòng (2019—2030 nián) (健康中国行动 (2019—2030年)) [Healthy China Action (2019–2030)] (promulgated by the Healthy China Action Promotion Comm., July 9, 2019).

Guówùyuan guānyú shíshī jiànkāng zhōngguó xíngdòng de yìjiàn (国务院关于实施健康中国行动的意见) [Opinions of the State Council on Implementing the Healthy China Action Plan] (promulgated by the State Council of the People's Republic of China, July 15, 2019).

Yàopǐn zhùcè guǎnlǐ bànfǎ (药品注册管理办法) [Measures for the Administration of Drug Registration] (promulgated by the State Admin. Market Regul., Jan. 15, 2020, effective July 1, 2020).

Yàopǐn guǎnlǐ fǎ shíshī tiáoli (药品管理法实施条例) [Regulations for the Implementation of the Drug Administration Law] (promulgated by the State Council of the People's Republic of China, Aug. 4, 2002, effective Sept. 15, 2002).

### **Democratic Republic of the Congo**

#### Constitutional

CONSTITUTION DE LA RÉPUBLIQUE DÉMOCRATIQUE DU CONGO [CONSTITUTION] (2005).

#### Legislative

Loi n° 82/001 du 7 janvier 1982 sur la Propriété industrielle [Industrial Property Law] (Jan. 7, 1982).

Loi n° 015/2002 du 16 octobre 2002 portant Code du Travail [Labor Code] (Oct. 16, 2022).

Loi n° 08/011 du 14 juillet 2008 portant protection des droits des personnes vivant avec le VIH/SIDA et des personnes affectées [Law for the Protection of the Rights of People Living with HIV/AIDS and Affected Persons] (July 14, 2008).

Loi n° 18/035 du 13 décembre 2018 fixant les principes fondamentaux relatifs à l'organisation de la santé publique [Public Health Law] (Dec. 13, 2018).

Loi organique n° 22/003 du 3 mai 2022 portant protection et promotion des droits des personnes vivant avec handicap [Law on the Protection and Promotion of the Rights of Persons with Disabilities] (May 3, 2022).

#### Executive branch

Ministry of Public Health, *Plan Stratégique National de Lutte Contre la Tuberculose 2021-2022 (2023)* [National Strategic Plan for the Fight Against Tuberculosis 2021-2022 (2023)] (Dec. 2019).

Ministry of Public Health, *Plan National de Développement Sanitaire recadré pour la période 2019-2022: Vers la couverture sanitaire universelle* [National Health Development Plan 2019-2022: Towards Universal Health Coverage] (Sept. 2018).

### **India**

#### Constitutional

CONST. OF INDIA (1950).

Consumer Educ. & Rsch. Ctr. v. Union of India, (1995) 3 SCC 42.

State of Punjab v. Mohinder Singh Chawla, (1997) 2 SCC 83.

### Legislative

The Epidemic Diseases Act, 1897.

The Drugs and Cosmetics Act, 1940.

The Patents (Amendment) Act, 2005.

The Rights of Persons with Disabilities Act, 2016.

The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017.

The Code on Wages, 2019.

The Epidemic Diseases (Amendment) Ordinance, 2020.

The Industrial Relations Code, 2020.

The Occupational Safety, Health and Working Conditions Code, 2020.

### Executive branch

Ministry of Health with Family Welfare, *National Health Policy 2017* (2017).

Ministry of Health with Family Welfare, *National Strategic Plan for Tuberculosis: 2017–2025 Elimination by 2025* (Mar. 2017).

## **Indonesia**

### Constitutional

UNDANG-UNDANG DASAR NEGARA REPUBLIK INDONESIA [CONSTITUTION] (1945).

### Legislative

Undang-Undang Tentang Pokok-Pokok Kesehatan [Health Principles Law], No. 9 of 1960.

Undang-Undang Tentang Wabah Penyakit Menular [Outbreaks of Infectious Diseases Law], No. 4 of 1984.

Undang-Undang Tentang Hak Asasi Manusia [Human Rights Law], No. 39 of 1999.

Undang-Undang Tentang Ketenagakerjaan [Labor Law], No. 13 of 2003.

Undang-Undang Tentang Praktik Kedokteran [Medical Practice Law], No. 29 of 2004.

Undang-Undang Tentang Kesehatan [Health Law], No. 36 of 2009.

Undang-Undang Tentang Rumah Sakit [Hospital Law], No. 44 of 2009.

Undang-Undang Tentang Paten [Patents Law], No. 13 of 2016).

Undang-Undang Tentang Penyandang Disabilitas [Law on Persons with Disabilities], No. 8 of 2016.

Undang-Undang Tentang Cipta Kerja [Omnibus Law on Job Creation Law], No. 11 of 2020.

#### Executive branch

Keputusan Menteri Kesehatan Tentang Pedoman Pelaksanaan Kolaborasi Pengendalian Penyakit TB dan HIV [Ministry of Health Decree on Guidelines for Implementing Collaborative TB and HIV Control], No. 1278/Menkes/SK/XII/2009.

Surat Edaran Menteri Kesehatan Tentang Peningkatan Penemuan Kasus Tuberkulosis [Ministry of Health Circular Letter on Increasing TB Case Findings], No. HK.03.03/D1 III.I/951/2016.

Peraturan Menteri Kesehatan Tentang Pedoman Penyelenggaraan Program Indonesia Sehat Dengan Pendekatan Keluarga [Ministry of Health Regulation on Guidelines for Implementing the Healthy Indonesia Program], No. 39 of 2016.

Peraturan Menteri Kesehatan Tentang Standar Pelayanan Minimal Bidang Kesehatan [Ministry of Health Regulation on Minimum Health Service Standards], No. 43 of 2016.

Peraturan Menteri Kesehatan Tentang Penanggulangan Tuberkulosis [Ministry of Health Regulation on Tuberculosis Treatment], No. 67 of 2016.

Peraturan Menteri Hukum Dan Hak Asasi Manusia Tentang Tata Cara Pemberian Lisensi-Wajib Paten [Ministry of Law and Human Rights Regulation on Procedures for Granting Compulsory Patent Licenses], No. 30 of 2019.

Rencana Strategis Kementerian Kesehatan Tahun 2020-2024 [Ministry of Health Strategic Plan 2020–2024] (2020).

Ministry of Health, *National Strategy of Tuberculosis Care and Prevention in Indonesia 2020–2024* (2020).

Peraturan Presiden Tentang Tata Cara Pelaksanaan Paten Oleh Pemerintah [Presidential Regulation on Procedures of Patent Implementation by the Government], No. 77 of 2020.

Peraturan Presiden Tentang Penanggulangan Tuberkulosis [Presidential Regulation on Tuberculosis Management], No. 67 of 2021.

## Myanmar

### Constitutional

ပြည်ထောင်စုသမ္မတမြန်မာနိုင်ငံတော်ဖွဲ့စည်းပုံအခြေခံဥပဒေ [CONSTITUTION] (2008).

### Legislative

ပြည်သူ့ကျန်းမာရေးဥပဒေ [Public Health Law], 1972.

ကူးစက်ရောဂါများ ကာကွယ်နှိမ်နင်းရေး ဥပဒေ [Prevention and Control of Infectious Diseases Law], No. 1 of 1995.

ကူးစက်ရောဂါများ ကာကွယ်ထိန်းချုပ်ရေးဥပဒေကို ပြင်ဆင်သည့်ဥပဒေ [Amendment of Prevention and Control of Communicable Diseases Law], No. 16 of 2011.

အလုပ်အကိုင်နှင့် ကျွမ်းကျင်မှု ဖွံ့ဖြိုးတိုးတက်ရေးဥပဒေ [Employment and Skill Development Law], No. 29 of 2013.

၂၀၁၃ ခုနှစ်၊ အနည်းဆုံးအခကြေးငွေဥပဒေ [The Minimum Wage Law], No. 7 of 2013.

မသန်စွမ်းသူများ၏ အခွင့်အရေးဥပဒေ [Rights of Persons with Disabilities Law], No. 30 of 2015.

၂၀၁၆ ခုနှစ်၊ အခကြေးငွေပေးချေရေးဥပဒေ [Payment of Wages Law], No. 17 of 2016.

၂၀၁၆ ခုနှစ်၊ ဆိုင်များနှင့် အလုပ်ဌာနများဥပဒေ [Shops and Workplaces Law], No. 18 of 2016.

မြန်မာနိုင်ငံကုမ္ပဏီများဥပဒေ [Myanmar Companies Law], No. 29 of 2017.

တီထွင်မှုပိုင်ခွင့်ဥပဒေ [Patent Law], No. 7 of 2019.

#### Executive branch

Ministry of Health and Sports, *Myanmar National Health Plan 2017–2021* (Dec. 2016).

Ministry of Health and Sports, *National Strategic Plan 2021-2025: National TB Programme* (Mar. 2020).

### **Nigeria**

#### Constitutional

CONST. OF NIGERIA (1999).

#### Legislative

Labour Act (1971) L.F.N. 1990, Cap. (198).

Patents and Designs Act (1971) L.F.N. 1990, Cap. (344).

African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act (1983) L.F.N. 1990, Cap. (10).

HIV and AIDS (Anti-Discrimination) Act (2014) O.G., A123.

National Health Act (2014) O.G., A139.

Discrimination Against Persons with Disabilities (Prohibition) Act (2018) O.G., A97 (2019).

Executive branch

Federal Ministry of Health, *National Health Policy 2016* (Sept. 2016).

Department of Public Health, *Human Rights and Gender Action Plan for Tuberculosis Care and Prevention in Nigeria 2021–2025* (2021).

Federal Ministry of Health, *National Strategic Plan for Tuberculosis Control, 2021–2025* (2021).

**Pakistan**

Constitutional

CONST. OF PAKISTAN (1973).

Legislative

Factories Act, No. XXV of 1934.

Public Health (Emergency Provision) Ordinance, No. XXI of 1944.

West Pakistan Epidemic Diseases Act, No. XXXVI of 1958.

West Pakistan Industrial and Commercial Employment (Standing Orders) Ordinance, No. VI of 1968).

West Pakistan Shops and Establishments Ordinance, No. VIII 1969.

Disabled Persons (Employment and Rehabilitation) Ordinance, No. XL of 1981.

Patents Ordinance, No. LXI of 2000, *amended by Patents (Amendment) Ordinance, No. XCV of 2002.*

Epidemic Diseases (Amendment) Act, No. XX of 2011.

Executive branch

The Patent Rules, S.R.O.1142 (i)/2003, THE GAZETTE OF PAKISTAN EXTRAORDINARY, Dec. 31, 2003.

Ministry of National Health Services Regulations and Coordination, *National Health Vision: Pakistan 2016–2025* (2016).

Ministry of National Health Services, Regulations and Coordination, *National Strategic Plan for Tuberculosis Control, 2020–2023* (2020).

**Philippines**Constitutional

CONST. OF THE PHILIPPINES (1987).

Legislative

LABOR CODE, Pres. Dec. No. 442, as amended.

Magna Carta for Disabled Persons, Rep. Act No. 7277 (Mar. 24, 1992).

INTELLECTUAL PROPERTY CODE, Rep. Act No. 8293, as amended.

Universally Accessible Cheaper and Quality Medicines Act of 2008, Rep. Act No. 9502 (June 6, 2008).

Comprehensive Tuberculosis Elimination Plan Act, Rep. Act No. 10767 (Apr. 26, 2016).

Philippine HIV and AIDS Policy Act, Rep. Act No. 11166 (Dec. 20, 2018).

Universal Health Care Act, Rep. Act No. 11223 (Feb. 20, 2019).

Executive branch

Dept. of Labor and Employment, Guidelines for the Implementation of Policy and Program on Tuberculosis (TB) Prevention and Control in the Workplace, Dept. Ord. No. 73-05 (2005).

Office of the Secretary, The Philippine Health Agenda 2016–2022, Admin. Ord. No. 2016-0038 (Oct. 26, 2016).



Office of the Secretary of Health, Implementing Rules and Regulations of the Comprehensive Tuberculosis Elimination Plan Act, Mem. Circ. No. 2017-0014 (May 2, 2017).

Office of the Secretary of Health, Strategic Framework and Implementing Guidelines for *FOURmula One Plus for Health* (F1+), Admin. Ord. No. 2018-0014 (May 30, 2018).

Office of the Secretary of Health, Implementing Rules and Regulations of Universal Health Care Act (July 23, 2018).

Office of the Secretary of Health, National TB Control Program Adaptive Plan for the COVID-19 Pandemic, Admin. Ord. No. 2020-0056 (Nov. 9, 2020).

Department of Health, *National Tuberculosis Control Program Manual of Procedures 6th edition* (2020).

Department of Health, *Updated Philippine Strategic TB Elimination Plan, Phase 1: 2020-2023* (2020).

### **Russian Federation**

#### Constitutional

KONSTITUTSIJA ROSSIJSKOJ FEDERATSII [CONSTITUTION] (1993)

#### Legislative

Федеральный закон "О социальной защите инвалидов в Российской Федерации" [Federal Law on Social Protection of Disabled People], No. 181-FZ, Nov. 24, 1995, as amended.

Федеральный закон "О санитарно-эпидемиологическом благополучии населения" [Federal Law on the Sanitary and Epidemiological Welfare of the Population], No. 52-FZ, Mar. 30, 1999.

ТРУДОВОЙ КОДЕКС РОССИЙСКОЙ ФЕДЕРАЦИИ [LABOR CODE], No. 197-FZ, Dec. 30, 2001.

Федеральный закон "О предупреждении распространения туберкулеза в Российской Федерации" [Federal Law on Preventing the Spread of Tuberculosis], No. 77-FZ, June 18, 2001, as amended.

ГРАЖДАНСКИЙ КОДЕКС РОССИЙСКОЙ ФЕДЕРАЦИИ [CIVIL CODE], Part IV, § VII, No. 230-FZ, Dec. 18, 2006, as amended.

Федеральный закон "Об обращении лекарственных средств" [Federal Law on the Circulation of Medicines], No. 61-FZ, Apr. 12, 2010, as amended.

Федеральный закон "Об основах охраны здоровья граждан в Российской Федерации" [Federal Law on the Basics of Health Protection of Citizens in the Russian Federation], No. 323-FZ, Nov. 21, 2011.

Федеральный закон "О внесении изменений в статью 60 Федерального закона "Об обращении лекарственных средств" и статью 38 Федерального закона "Об основах охраны здоровья граждан в Российской Федерации" [Federal Law on Amendments to Article 60 of the Federal Law "On the Circulation of Medicines" and Article 38 of the Federal Law "On the Basics of Protecting the Health of Citizens in the Russian Federation"], No. 67-FZ, Mar. 26, 2020.

#### Executive branch

Государственная стратегия ликвидации туберкулеза в Российской Федерации до 2025 года и дальнейшую перспективу [State Strategy for the Elimination of Tuberculosis in the Russian Federation until 2025 and Beyond], 2018.

Указ Президента РФ "О Стратегии развития здравоохранения в Российской Федерации на период до 2025 года" [Decree of the President of the Russian Federation "On the Strategy for the Development of Healthcare in the Russian Federation for the Period until 2025"], No. 254, June 6, 2019.

### **Vietnam**

#### Constitutional

HIẾN PHÁP CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM [CONSTITUTION] (1992).

#### Legislative

Luật của Quốc hội: Luật Phòng, chống nhiễm vi rút gây ra hội chứng suy giảm miễn dịch mắc phải ở người (HIV/AIDS) [Law on HIV/AIDS Prevention and Control], No. 64/2006/QH11, June 29, 2006, as amended.

Luật của Quốc hội: Luật Phòng, Chống Bệnh Truyền Nhiễm [Law on Prevention and Control of Infectious Disease], No. 03/2007/QH12, Nov. 21, 2007

Luật của Quốc hội: Luật Người Khuyết Tật [Law on Persons with Disabilities], No. 51/2010/QH12, June 17, 2010.

LUẬT CỦA QUỐC HỘI: BỘ LUẬT LAO ĐỘNG [LABOR CODE], No. 10/2012/QH13, June 18, 2012.

Luật của Quốc hội: Luật Sở Hữu Trí Tuệ [Law on Intellectual Property], No. 11/VBHN-VPQH, July 8, 2022.

#### Executive branch

Ministry of Health, Hướng dẫn bảo mật dữ liệu thử nghiệm trong đăng ký thuốc [Guidelines for the Security of Testing Data in Drug Registration], No: 05/2010/TT-BYT, Mar. 1, 2010.

Ministry of Health, *Plan for People's Health Protection, Care and Promotion 2016–2020* (Mar. 2016).

Ministry of Health, *Vietnam National Tuberculosis Program Draft National Strategic Plan 2021–2025* (May 2020).