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Submission for People's Republic of China

Submitted by:

Treatment Action Group (TAG)

90 Broad St, Suite 2503

New York, NY 10004

Tel: 212.253.7922

Fax: 212.253.7923

[tag@treatmentactiongroup.org](mailto:tag@treatmentactiongroup.org)

[www.treatmentactiongroup.org](http://www.treatmentactiongroup.org)

Organization description:

Treatment Action Group (TAG), established in January 1992, is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus.

TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

## Introduction

1. This submission focuses on China's obligations to address its drug-resistant tuberculosis (DR-TB) crisis analyzed from the perspective of the human right to enjoy the benefits of scientific progress and its applications (i.e., the Right to Science or RtS).
2. DR-TB is a more deadly and difficult-to-treat form of tuberculosis (TB), the world's leading cause of death from a single infectious agent. To a significant extent, the lethality of DR-TB in China and globally is a consequence of State failures to promote biomedical innovation and secure equitable access to health services and technologies.
3. TAG stipulates that by responding to DR-TB in ways that respect, protect, and fulfill the RtS, China can more fully achieve its own health targets, while complying with its obligations under the Universal Declaration of Human Rights (UDHR) and International Covenant on Economic, Social, and Cultural Rights (ICESCR).

## Background on the Right to Science

4. The right of all people to share in the benefits of scientific progress is enshrined in Article 27 of the UDHR.
5. ICESCR Article 15 asserts the right of everyone "to enjoy the benefits of scientific progress and its applications."
6. ICESCR Article 15 lays out State parties' responsibilities to include "the conservation, the development and the diffusion of science [...]" (Art. 15.2); and to "recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields" (Art. 15.4).
7. The dimensions of RtS, its intersection with other human rights, and its application to health include the importance of participation in science and science-based policy-making, and the importance of science for human rights-based policy-making.<sup>1</sup>
8. In a May 2012 report, the Special Rapporteur (SR) in the field of cultural rights noted the strong interdependence of RtS and other human rights, including the obvious linkage with the Right to Health.<sup>2</sup> The SR points in particular to non-discriminatory access to scientific knowledge and its advances. The concept of access includes access not only to the results, but also to the means and processes of scientific inquiry, as part of the right's benefits.<sup>3</sup>
9. ICESCR Article 15 speaks of "development and diffusion of science [...]" as State obligations. Together with the SR's reading of access, development must be understood as a State's obligation to support scientific innovation; and diffusion as the ability to enjoy scientific benefits in a non-discriminatory manner.<sup>4</sup>
10. Thus, States must take measures to guarantee not only availability, but also affordability of health technologies, including medicines and diagnostics.
11. The above analysis clarifies that RtS is inseparable from several other human rights, including the Right to Health, Right to Participation, and Right to Non-Discrimination, among others. This submission will describe shortcomings in China's response to DR-TB with respect to China's obligations under RtS and interrelated rights.

### Prior UPR Recommendations

12. Recommendations under previous UPR cycles either submitted or accepted by China indicate that China already recognizes the importance of human rights principles in the context of innovation and access to health technologies.
13. China accepted recommendation 186.90/Netherlands to “include a prohibition of discrimination of any kind, including discrimination based on sexual orientation and gender identity, ethnicity, religion and infection with HIV, in labour and employment law in line with international standards.” Yet China has no standalone non-discrimination legislation, and the Employment Promotion Law in fact “may permit discrimination against people with TB in hiring.”<sup>5</sup>
14. China accepted three recommendations (i.e. 186.148/Nigeria; 186.149/Ireland; 186.50/Netherlands) to grant civil society a greater role in safeguarding human rights including through expanded registration of organizations. World Health Organization (WHO) guidelines on TB equally point to the indispensable role of community-based organizations (CBO) and civil society in responding to TB. China’s Charity Law for domestic organizations and the Overseas Nongovernment Organization Law curb rather than facilitate organizations’ ability of to operate, undermining the participation principle central to RtS.
15. China accepted recommendation 186.188/Mauritius to “intensify its efforts to eradicate poverty and improve health care facilities for its people.” China has made poverty alleviation an explicit policy priority, and succeeded. However, great disparities in health still exist, undermining further progress against diseases of poverty, especially TB.
16. China recognizes the challenges posed by health inequities between rural and urban populations, as exemplified by its recommendations to e.g. the 2<sup>nd</sup> Cycle UPR of Armenia and Azerbaijan.
17. China publicly attaches great value to preventive health and universal access as shown by its 2<sup>nd</sup> Cycle UPR recommendation to Venezuela. Yet the organization of China’s National TB Program does not reflect a preventive health approach, and China has fallen short of extending universal access to the best available prevention, diagnosis, and treatment services for all people with and at risk of TB, as the analyses below demonstrate.

### China’s TB Burden

18. China has made significant strides in eliminating TB as a public health threat.<sup>6</sup>
19. Simultaneously, China has experienced rising rates of DR-TB, and populations most vulnerable to TB, including people with TB/HIV co-infection and children, remain neglected in China’s TB response.<sup>7</sup> These factors threaten to rollback China’s past successes in fighting TB.
20. Annually, China has an estimated 900,000 new cases of TB.<sup>8</sup> Only India and Indonesia have a higher TB incidence.<sup>9</sup>
21. In 2016, 11,000 people living with HIV (PLHIV) in China developed TB. An estimated 50,000 HIV-negative people and 1,800 HIV-positive people in China died from TB in 2016. China does not systematically track and report to WHO the percentage of PLHIV on TB preventive therapy; less than half of people diagnosed with TB know their HIV status.<sup>10</sup>

22. China has the second highest incidence of DR-TB globally.<sup>11</sup> Within China, the highest burden is among the rural poor, because they are more likely to experience the deprivations that give rise to DR-TB (e.g., inappropriate or interrupted TB treatment).<sup>12</sup>
23. Of the 73,000–100,000 new cases of DR-TB in China in 2017, fewer than 12,000 had a laboratory-confirmed diagnosis and fewer than 6,000 were started on treatment. Among those started on treatment, less than half had a successful outcome.<sup>13</sup>

#### Violations of the Right to Science in the context of TB

24. TAG's research found that China falls short of its RtS obligations for participation; financial investment in TB services and research; and non-discrimination in access to TB prevention, diagnosis, and treatment in line with international standards.
25. Moreover, policies shaping China's TB response and laws protecting the rights of people with TB are not fully developed, and are incongruent with progress made on HIV law and policy.<sup>14</sup>

#### *Participation:*

26. Public health responses that disregard the participation of communities can contribute to stigma, and therefore discrimination and other human rights violations.
27. China's TB response shows particularly weak civil society engagement. From a RtS perspective, community health workers and CBOs assist in the diffusion of medical advancement by bringing health services into the community. This is a critical enabler of patient-centered care, which is a central pillar of the WHO End TB Strategy.<sup>15</sup>
28. Community health workers and community organizations play an especially critical role in the management of DR-TB. The WHO recognizes the benefits of community-based treatment of DR-TB over hospitalization. China, however, has centralized TB services in large hospitals, instead of locating TB services in the community.
29. Moreover, China's 2017 Overseas NGO Law and domestic Charity Law are burdensome and restrict rather than enable Chinese organizations to engage with their international counterparts and government partners.
30. China's hospital-focused TB response, in combination with the country's well-documented restrictions on domestic civil society, make promoting participation in accordance with RtS obligations close to impossible.

#### *Investment in TB Services and Research:*

31. China has not fully financed and incorporated DR-TB and TB/HIV interventions into the National TB Program.<sup>16</sup> China's total reported budget in its National Strategic Plan for TB in 2017 was \$384 million; only \$28 million was allocated for DR-TB and \$0 for TB/HIV.<sup>17</sup>
32. Yet China reported only a \$4 million funding gap for its TB program, indicating a nearly fully funded program.<sup>18</sup> TAG contends that a TB program that successfully diagnoses, treats, and cures less than 10% of people with DR-TB cannot by definition be considered a fully funded program.

33. TAG notes with alarm China's failure to adequately finance and assume responsibility for DR-TB services in the wake of graduating from eligibility to receive support from the Global Fund to Fight AIDS, TB and Malaria (Global Fund) in 2014. With support from the Global Fund, China's TB program expanded DR-TB diagnostic and treatment services from two prefectures in 2006 to 92 prefectures by 2014.<sup>19</sup>
34. Before its support to China ended, the Global Fund was providing 26% of the national budget for DR-TB with domestic resources contributing 19%, leaving a 55% funding gap. China has not filled this gap in the years since.<sup>20</sup>
35. As a result, the quality of existing services has suffered and national expansion of DR-TB services has stalled. Enrolment of DR-TB patients at treatment sites declined by 70% in the first two quarters following Global Fund withdrawal.<sup>21</sup>
36. China has shown receptiveness to international cooperation in responding to DR-TB.<sup>22</sup> However, China has yet to expand successful DR-TB pilot initiatives supported by the Global Fund and other partners nationwide.<sup>23</sup> Access to care remains severely limited and contingent on geography.
37. With its substantial economic resources and stated commitment to health i.e. the Healthy China initiative,<sup>24</sup> China could become a global example of a successful DR-TB response if it prioritized a RtS approach to TB prevention, diagnosis, and treatment.<sup>25</sup>
38. TB remains a global epidemic precisely because decades of underfunding research has left patients and health systems reliant on outdated technologies.<sup>26</sup> China could become a key player in TB innovation and a global leader in advancing RtS by increasing its investment in TB research and development (R&D) to develop new tools to fight DR-TB.<sup>27</sup>
39. China should direct its investments in TB R&D toward a "purposive development" of technologies to benefit underserved populations most in need of better TB prevention, diagnosis, and treatment options, including PLHIV, children, and pregnant women.<sup>28</sup>

*Nondiscrimination and Equitable Access:*

40. China's progress in reducing the burden of TB remains uneven, keeping China from upholding its RtS obligation to provide equitable access to the benefits of scientific advancement.
41. Inequities in access manifest most acutely in the context of DR-TB. In 2016, only 50% of notified DR-TB cases started treatment. An even greater number of people with DR-TB were not notified, indicating they went undiagnosed or their diagnosis was never reported to China's National TB Program. Of the total estimated number of people in China who develop DR-TB, only 8% start treatment each year.<sup>29</sup>
42. At the root of the problem, China's TB policies are woefully out of step with international standards:
  - a. Diagnostics: TB diagnostic practices do not reflect WHO guidelines. For example, Xpert MTB/ RIF Ultra is not the initial TB test for all adults and children, and drug-susceptibility testing is not yet widely implemented—a major barrier to tackling DR-TB.<sup>30</sup>

- b. Treatment: China has not done enough to make available new drugs to treat DR-TB, i.e. bedaquiline and delamanid. China's national policy remains out of step with WHO guidance on bedaquiline for adults, and registration of this important drug took years. Although bedaquiline is now registered and has been piloted in 15 hospitals (where at least 1,000 people will receive the drug for free), there is no evidence that China has expanded use beyond these limited pilot sites.<sup>31</sup> Delamanid, another WHO-recommended DR-TB drug, was only recently registered in China and remains largely unavailable for either adults or children.<sup>32</sup> China has no policy to support the use of a new, shorter 9-month treatment regimen for DR-TB. Counter to WHO guidelines, China still requires routine hospitalization for DR-TB treatment, and even quarantine in many cases<sup>33</sup>
  - c. Regulatory considerations: China does not have a legal framework to support pre-approval access to drugs under development but not yet approved (e.g., compassionate use). Many existing DR-TB drugs have severe toxicities and limited efficacy; consequently, many people cannot receive a safe, effective combination of drugs using already-approved drugs. For these patients, trying an unapproved drug still in clinical development may be their only chance for a cure.
  - d. Pediatric TB: WHO-recommended pediatric fixed dose combinations are not standard of care in China. In fact, a lot of pediatric TB, particularly among girls, goes undiagnosed.<sup>34</sup>
  - e. TB/HIV: Integration of TB/HIV services is essential: PLHIV are 26 times more likely to develop TB, and TB is the leading cause of death for PLHIV. Still, China does not use the recommended TB-LAM test to diagnose TB in PLHIV with CD4  $\leq$  100  $\mu$ L or who are seriously ill.<sup>35</sup>
43. In addition to the above policy gaps, the organization of China's healthcare system poses major barriers to universal access to TB services, in particular for the rural poor.<sup>36</sup> China must direct resources toward TB detection and treatment in poor rural areas.<sup>37</sup>
- a. China's household registration (*hukou*) system ties the provision of social services, including healthcare, to the location of one's birth. This further marginalizes China's high number of internal, rural-to-urban economic migrants, a population already more vulnerable to TB.
  - b. China's health system instructs rural patients to seek local healthcare first.<sup>38</sup> However, studies of rural TB services found significant deficits, poor performance in the correct TB diagnosis and management, and low rates of necessary referrals. Healthcare providers finance services in part through medication sales, incentivizing patient retention over referral to more specialized health centers.<sup>39</sup>
  - c. DR-TB treatment cannot be initiated at the district level: DR-TB patients must be referred through prefecture/city-level healthcare providers to the county level (the lowest administrative level at which DR-TB treatment can be initiated).<sup>40</sup>
  - d. While DS-TB treatment is supposed to be free of charge, studies reveal TB patients still shoulder substantial costs. China's reliance on inpatient treatment and favorable insurance coverage rates for inpatient services form a structural impediment to community-based care, as recommended by the WHO. Rural insurance schemes have lower average coverage rates, further marginalizing already poorer populations. Peripheral costs for seeking medical treatment in rural areas, e.g. transportation to designated infectious-disease hospitals, pose another economic burden.<sup>41</sup>

- e. China's reliance on hospital-based treatment is concerning because hospitals are often hotspots for DR-TB transmission. Infection control is a particular challenge, as China accounts for 39% of healthcare workers infected with TB globally.<sup>42</sup>

## Recommendations

44. As science progresses, the understanding of what constitutes the “highest attainable standard of [...] health” must equally evolve.<sup>43</sup> RtS ensures that with the advancement of science, new health technologies become available, meaning the benchmark for State obligations are always progressing alongside new discoveries.

45. Based on this understanding of the RtS in relation to health and the current situation of DR-TB in China, TAG makes the following recommendations to the People's Republic of China:

**A. Enact specific legislation to protect the rights of people with TB, in particular against discrimination.**

- a) Revise the prohibition keeping people with TB from working during the full course of treatment to allow people to return to work once found to be no longer infectious.<sup>44</sup>
- b) Abolish the prohibition keeping TB survivors and people with TB from holding civil service positions.
- c) Amend the Implementation Measures for the Law on the Prevention and Treatment of Infectious Diseases to include TB as a disease that affords privacy protections.

**B. Align national TB program policies with international standards to ensure that all people with and at risk of TB have access to the highest available standard of prevention, diagnosis, and treatment in accordance with WHO guidelines.** In particular:

- a) End mandatory hospitalization/quarantine for DR-TB treatment and develop models for treating DR-TB in the community.
- b) Align the National Essential Medicines List with WHO recommendations; fully scale up use of bedaquiline and delamanid for DR-TB treatment; and enact legislation to allow for pre-approval access to drugs still under development.
- c) Provide universal access to GeneXpert MTB/RIF Ultra as the first diagnostic test for adults and use TB-LAM as a preliminary test in seriously ill PLHIV or those with low CD4 counts.
- d) Ensure full coverage of DR-TB services under both rural and urban insurance schemes.

**C. Promote the participation of civil society and communities affected by TB in the TB response.** In particular:

- a) Include TB survivors and people living with and vulnerable to TB in all regulatory and public health decision-making processes that affect access to interventions.
- b) Facilitate the registration of CBOs and civil society working on health under the Charity Law and Overseas Nongovernment Organization Law.

**D. Increase domestic investments in TB programs and research.** In particular:

- a) Significantly increase the budget for DR-TB and TB/HIV interventions in National Strategic Plan.
- b) Significantly increase financing for TB R&D, including the full spectrum of TB research from basic science to product development to operational research.
- c) Fund TB research that supports the “purposive development” of technologies to meet the needs of those most vulnerable to TB.

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END NOTES:

<sup>1</sup> Mancisidor M. Is There Such a Thing as a Human Right to Science in International Law? In: ESIL Reflections Volume 4, Issue 1. April 7, 2015.

<sup>2</sup> Shaheed F. Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: the right to enjoy the benefits of scientific progress and its applications (UN Doc No. A/HRC/20/26). Human Rights Council 20<sup>th</sup> Session. 14 May 2002. P. 8. [http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26\\_en.pdf](http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf)

<sup>3</sup> Ibid.

<sup>4</sup> Frick M, et al. Falling Short of the Rights to Health and Scientific Progress: Inadequate TB Research and Access. In: Health and Human Rights Journal. June 21, 2016. (<https://www.hhrjournal.org/2016/06/falling-short-of-the-rights-to-health-and-scientific-progress-inadequate-tb-drug-research-and-access/>).

<sup>5</sup> Citro B, et al. China TB Law Reform and Global Legislation Survey Memo p.2 [*On file with submitting organization*]

<sup>6</sup> Overall TB prevalence halved between 1990 and 2010, falling from 215/100,000 people to 108/100,000. TB mortality declined at an average rate of 8.6% during the same timeframe.

<sup>7</sup> Zhu S, et al. The Burden and Challenges of Tuberculosis in China: Findings from the Global Burden of Disease Study 2015. In: *Scientific Reports*. Vol 7. Article number: 14601(2017). (<https://www.nature.com/articles/s41598-017-15024-1>)

<sup>8</sup> That is over 8% of the global burden of disease.

<sup>9</sup> World Health Organization. 2017 Global TB Report. Geneva: World Health Organization; 2017. [http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/)

<sup>10</sup> Ibid.

<sup>11</sup> Globally, there were an estimated 600,000 new cases of DR-TB in 2016. India, China, and the Russian Federation contributed half of those cases.

<sup>12</sup> Qian L, et al. Drug-resistant Tuberculosis Control in China: Progress and Challenges. In: *Infectious Diseases of Poverty* (2016) 5:9.

<sup>13</sup> World Health Organization. 2017 Global TB Report. Geneva: World Health Organization; 2017. [http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/)

<sup>14</sup> See, for example, Citro B, et al. China TB Law Reform and Global Legislation Survey Memo p.2 [*On file with submitting organization*]

<sup>15</sup> By 2030, 80% reduction in new cases; 90% reduction in mortality; 100% protection of catastrophic costs.

<sup>16</sup> Tang et al. Access to affordability of healthcare for TB patients in China: issues and challenges. In: *Infectious Diseases of Poverty* (2016) 5:10.

<sup>17</sup> In comparison, India, with a comparable burden of DR-TB, allocated \$97 million to its DR-TB response.

<sup>18</sup> WHO Global TB Report (2017) p. 118. ([http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/))

<sup>19</sup> Roughly one-third of China’s 3000 counties.

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- <sup>20</sup> Wang L, et al. (2017). The Global Fund in China: Multidrug-resistant tuberculosis nationwide programmatic scale-up and challenges to transition to full country ownership. In: PLoS ONE 12(6): e0177536. (<https://doi.org/10.1371/journal.pone.0177536>)
- <sup>21</sup> Ibid.
- <sup>22</sup> For example an initiative with the Gates Foundation to develop a comprehensive program to provide universal access to care for DR-TB in four Chinese cities. This cooperation and earlier support from the Global Fund enabled China to pilot new DR-TB program models and insurance schemes to cover patient costs.
- <sup>23</sup> See, for example, Li R, et al. Effect of a comprehensive programme to provide universal access to care for sputum-smear-positive multidrug-resistant tuberculosis in China: a before-and-after study. *Lancet Glob Health*;2015;3:e217–28.
- <sup>24</sup> Xi Jinping: Secure a Decisive Victory in Building a Moderately Prosperous Society in All Respects and Strive for the Great Success of Socialism with Chinese Characteristics for a New Era. Delivered at the 19th National Congress of the Communist Party of China October 18, 2017.
- <sup>25</sup> Including moving from a hospital-centered treatment system to a community-centered treatment model while changing its insurance reimbursement scheme.
- <sup>26</sup> Frick, Mike et al. Falling Short of the Rights to Health and Scientific Progress: Inadequate TB Research and Access. In: *Health and Human Rights Journal*. June 21, 2016. (<https://www.hhrjournal.org/2016/06/falling-short-of-the-rights-to-health-and-scientific-progress-inadequate-tb-drug-research-and-access/>)
- <sup>27</sup> Médecins Sans Frontières. Out Of Step: TB Policies in 29 Countries (2017). (<https://www.msfaccess.org/outofstep2017>)
- <sup>28</sup> For information on what “purposive development” under the right to science entails see, for example, Chapman A. Towards an understanding of the right to enjoy the benefits of scientific progress and its applications. *Journal of Human Rights*. 2009;8(1):1–36.
- <sup>29</sup> Ibid; WHO Global TB Report (2017). ([http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/))
- <sup>30</sup> Medicines Sans Frontieres. Out Of Step: TB Policies in 29 Countries (2017). (<https://www.msfaccess.org/outofstep2017>)
- <sup>31</sup> New drug to be provided free to Chinese TB patients. *China Daily*. 16 March 2018. <http://www.ecns.cn/2018/03-26/297108.shtml>
- <sup>32</sup> Otsuka Pharmaceutical Co. Otsuka’s DELTYBA [Delamanid] approved in China for the treatment of multidrug-resistant tuberculosis [Press Release]. 23 March 2018. . [https://www.otsuka.co.jp/en/company/newsreleases/2018/20180323\\_2.html](https://www.otsuka.co.jp/en/company/newsreleases/2018/20180323_2.html)
- <sup>33</sup> Médecins Sans Frontières. Out Of Step: TB Policies in 29 Countries (2017). (<https://www.msfaccess.org/outofstep2017>); and Citro B, et al. China TB Law Reform and Global Legislation Survey Memo p.2 [*On file with submitting organization*]
- <sup>34</sup> While overall prevalence declined, the percentage among girls under 5 increased by approximately 189% to 23.71/100,000 between 1990 to 2015. Zhu Sui et al. The Burden and Challenges of Tuberculosis in China: Findings from the Global Burden of Disease Study 2015. In: *Scientific Reports*. Vol 7. Article number: 14601(2017). (<https://www.nature.com/articles/s41598-017-15024-1>)
- <sup>35</sup> Ibid.
- <sup>36</sup> TB continues to affect rural poor populations at a higher percentage than urban populations: in 2010, rural TB prevalence was almost double of urban areas; and TB prevalence in economically less-developed Western China almost triple that in more prosperous Eastern China. See: Tang et al. Access to affordability of healthcare for TB patients in China: issues and challenges. In: *Infectious Diseases of Poverty* (2016) 5:10.
- <sup>37</sup> Sylvia S, Xue H, Zhou C, Shi Y, Yi H, Zhou H, et al. (2017) Tuberculosis detection and the challenges of integrated care in rural China: A cross-sectional standardized patient study. *PLoS Med* 14(10): e1002405. (<https://doi.org/10.1371/journal.pmed.1002405>)
- <sup>38</sup> I.e. village-based.

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<sup>39</sup> Ibid.

<sup>40</sup> Ibid.

<sup>41</sup> Tang et al. Access to affordability of healthcare for TB patients in China: issues and challenges. In: *Infectious Diseases of Poverty* (2016) 5:10.

<sup>42</sup> The TB notification rate among healthcare workers measured against the notification rate among the general population is used to measure infection control in closed settings. China is performing poorly in this regard.

WHO Global TB Report (2017). ([http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/))

<sup>43</sup> For a discussion on the minimum core, human rights and scientific advancement see, for example, <https://www.hhrjournal.org/2015/06/evolving-human-rights-and-the-science-of-antiretroviral-medicine/>.

<sup>44</sup> Usually under two weeks after starting effective treatment.