To:
Dr Phalin Kamolwat, Deputy Director, Bureau of Tuberculosis
Dr Booncherd Kladphuang, Public Health Technical Officer, Senior Professional Level
Division of Tuberculosis. Department of Disease Control. Ministry of Public Health
Mrs Bussaba Tantisak, Policy and Plan Analyst - Senior Professional (Program Specialist on AIDS and TB/HIV). Office of Global Fund Project Administration Department of Disease Control. Ministry of Public Health

Cc:

Payam Nahid
Susan Dorman
Dick Chaisson
Sue Swindells

From: The Community Research Advisors Group (CRAG).

Subject: Request to make the four-month tuberculosis treatment regimen available to the communities that participated in TBTC Study 31/ ACTG A5349

It is our honor to write you on behalf of the Community Research Advisors Group (CRAG), the community advisory board to the United States Centers for Disease Control and Prevention (CDC) Tuberculosis Trials Consortium (TBTC). With this letter, we strongly encourage you to take actions necessary to accelerate access to new, shorter tuberculosis (TB) treatment regimens for the communities you serve. The development of your National Strategic Plan (NSP) and proposals to the Global Fund, including under NFM4, if applicable, are excellent opportunities for your government to guarantee the right to science and health for people affected by TB in Thailand.

The World Health Organization (WHO) consolidated guidelines on TB module 4 and module 5 include, among others, two new recommended regimens based on the research conducted in your country collaboratively by the TBTC, AIDS Clinical Trials Group (ACTG): TBTC Study 31/ ACTG A5349. This landmark phase III clinical trial that enrolled over 2,500 people across 13 countries found that drug-sensitive TB could be treated in four rather than six months using rifapentine in place of rifampicin and moxifloxacin in place of ethambutol. The results of the study were published in the New England Journal of Medicine in May 2021, and with the WHO's endorsement in June 2021, adults and adolescents from 12 years of age with drug-susceptible pulmonary TB can now benefit from a shorter, four-month treatment regimen, a major improvement over the six month standard of care regimen that hasn't been improved upon in last 50 years.

This scientific advance in the care of people with TB is due, principally, to the volunteers who participated unselfishly in TBTC Study 31 / ACTG A5349. This includes people with TB in Thailand and their communities**. The communities that were part of**

this innovation process deserve to share in its benefits, in this case, access to the four-month treatment regimen.

However, introduction of the new regimen worldwide has been slow, particularly in countries where the trial was conducted, where you would expect introduction to be the fastest. This slow introduction is a missing opportunity to improve the quality of life of thousands of people with tuberculosis.

International ethics regulations state the obligation to guarantee communities that participate in research access to tested health tools. For instance, the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects declares:

> In advance of a clinical trial, sponsors, researchers and **host country governments** should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Although drug costs for the S31/A5349 regimen are higher, this is expected to be temporary. The market for rifapentine is growing, as is the number of suppliers. Increased competition and volumes will bring down the price of rifapentine and the cost of the S31/A5349 regimen. Additionally, the shorter duration of treatment will also mean savings in human resources in the short and long term. Thus, securing extra funding from multilateral agencies can be a key step towards ensuring access to patients' fundamental rights.

As such, the CRAG formally requests that you include the above-mentioned four-month regimen within your NSP, and rapidly update national guidelines and take other actions necessary to introduce the 4-month regimen before the end of 2024. Acting expeditiously to take up innovations like the four-month regimen better enables patient-centered models of TB treatment and care.

We hope that you will attend to our request as an urgent priority, and that we will soon see the four-month regimen available in Thailand. Access to shorter regimens will improve the lives of thousands of people and prevent unnecessary suffering.

Yours sincerely,

The Community Research Advisors Group

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About the Community Research Advisors Group (CRAG)

The Community Research Advisors Group (CRAG) is an international, community-driven advisory body that works to ensure the meaningful representation and engagement of affected communities in research conducted by the U.S. Centers for Disease Control and Prevention's Tuberculosis Trials Consortium (TBTC). This group of research-literate activists supports a robust, comprehensive, and innovative TBTC research agenda that is responsive to community needs as well as scientific priorities. Our mission is to enhance the value and impact of TBTC research for the benefit of TB-affected communities.