TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

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Open letter to support India's refusal of any Trade-Related Aspects of Intellectual Property Rights (TRIPS)-Plus Provisions in Free-Trade Agreement (FTA) negotiations with the European Union (EU)

Honorable Health Minister,

The Global TB Community Advisory Board (TB CAB) extends its heartfelt congratulations to the Indian government in the recent decision of the Indian Supreme Court upholding the strict interpretation of one of the most important public health safeguards in the Indian patent law – Section 3(d). The Indian government's strong defense of this provision in the legal challenge launched by a multinational company has been heartening for those of us struggling to make the global pharmaceutical system more responsive to diseases that most affect developing and least developed countries.

Our concerns relate to the access of tuberculosis (TB) treatment and enhanced investment in TB research and development. It has taken almost half a century for a new anti-TB drug to be developed and subsequently approved by the U.S. Food and Drug Administration. It is in this regard that we particularly welcome the finding of the Supreme Court that the patent law in India is designed to ensure recognition for genuine inventions and not ever-greening products.

We urgently need commitment and financial investment in research and development to be invested in genuine novel medicines. In this regard we also welcome the commitment of the Indian government to TB research including its investment through the Open Source Drug Discovery (OSDD) project.

It is crucial and ethical that universal access to existing medicines is ensured. In this regard we are also writing to express our firm support to the Indian government in refusing any and all TRIPS-plus provisions in the ongoing negotiations of the EU-India FTA. Since 2007, these negotiations have caused global concern over the EU's demands for intellectual property protection far in excess of India's obligations under the World Trade Organization.

Over the years, leaked versions of the negotiating text have been made public. The leaked text analysed by multiple experts show that these provisions are designed to hamper generic production. While India's great importance in supplying HIV medicines throughout the developing world is well appreciated, the fact that it plays a similar role in the case of TB medicines may be less appreciated.

We acknowledge the various statements of the United Nations, UNITAID, the Global Fund and the UN Special Rapporteur on the Right to Health recommending that developing countries should not adopt TRIPS-plus provisions based on hard evidence from around the world that these provisions hamper generic production.

We therefore urge the Indian government to reject in their entirety the proposals of the European Commission that hinder generic competition including:

- **Data exclusivity**: Any provisions that may result in exclusive rights on medicines based on clinical trial data are likely to result in monopolies even on existing medicines. As a TB community looking for simplified regimens, fixed dose combinations and pediatric versions of TB drugs, it is of great concern to us that these versions would not have generic versions easily accessible in the developing world.

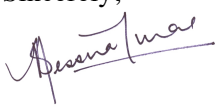
- **IP Enforcement Provisions**: We may note that we are particularly alarmed to read of the enforcement provisions proposed by the European Commission. For instance, if Indian courts freeze bank accounts of generic companies in the course of patent disputes, this would result in the halting of their production of all their medicines. Or if treatment providers can also be dragged into patent disputes many of the health and public interest groups we work with that provide treatment would then be at risk of having their work interrupted by these disputes!

- **Investment Provisions**: Provisions that would allow private companies to sue the Indian government in private, secret arbitration over pro-health policies are also a matter of concern particularly after we have witnessed the Indian government valiantly withstand the protracted litigation over the challenge to Section 3(d) over the past 7 years.

Respected Health Minister, we look forward to the continuing leadership of the Indian government on ensuring that research and development on TB and access to safe, efficacious and affordable generic medicines continues.

As negotiations on the EU-India FTA enter their final lap, we reiterate our support for the Indian government's uncompromising stand on the EU's demands. We understand that the Honorable Prime Minister and Honorable Commerce Minister will be meeting with the European Commission over the next few months to finalise the EU-India FTA. We urge you to convey our concerns and support for the Indian government's uncompromising stand on the EU's demands.
We strongly believe that access to medicines and patient lives cannot be placed on the table of trade negotiations.
Please do not hesitate to contact us for any information and support in getting to zero TB deaths, new infections and suffering. We look forward to hearing from you.

Sincerely,



Blessina Kumar, (on behalf of The Global TB Community Advisory Board)

(The Global TB Community Advisory Board (TB CAB) is dedicated to increasing community involvement in tuberculosis (TB) research and to mobilizing political will regarding key TB product development issues. The TB CAB is comprised of research activists from Brazil, India, Kenya, Russia, South Africa, the UK, and the US who are extensively involved in HIV and TB research networks.)

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