

Indian Civil Society Statement

CALLING ON THE GOVERNMENT OF INDIA TO SUPPORT INNOVATION AND ACCESS FOR COVID-19 DIAGNOSTICS, THERAPEUTICS AND VACCINES

New Delhi, 24 June 2020

COVID-19 was declared a pandemic by the WHO on 11th March 2020. There is an urgent need for policies that will effectively encourage and regulate research, production and access to diagnostics, therapeutics and vaccines for COVID-19 to ensure that they are accessible to all without any discrimination.

We appreciate the fact that the Government of India has initiated policies and mobilized funding for COVID-19 Research and Development (R&D) for diagnostics, therapeutics and vaccines. Prominent among these policies and efforts is the funding for various vaccine candidates from Department of Biotechnology (DBT)- Biotechnology Industry Research Assistance Council (BIRAC)¹, ‘Research Strategy for immediate response and long-term preparedness to combat COVID-19 infection’; setting up of the COVID-19 Research Consortium²; Council of Scientific and Industrial Research’s (CSIR) work on the synthesis of drugs under clinical trials for generic manufacturers.³

While various government research institutions, pharmaceutical companies and universities across the world - including in India - race to develop vaccines, therapeutics and diagnostics against COVID-19, there is a growing concern on accessibility, affordability and availability of these medical products for people and the most vulnerable communities in developing countries.

The current public health emergency specifically demands a shift from ‘business as usual’ practices of the pharmaceutical Industry. Entrenched in proprietary control of data, know-how and Intellectual Property (IP) run counter to the need of the hour: increased openness in the sharing of research knowledge, data and IP - based on the ethos of ‘science benefiting all of humanity’.

¹ Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs. See COVID-19 Research Consortium Follow-Up Call of DBT & BIRAC at https://birac.nic.in/webcontent/1586013981_covid_19_consortium.pdf

² <http://dbtindia.gov.in/sites/default/files/uploadfiles/COVID-19%20Research%20Update.pdf>

³ <https://urdip.res.in/covid19/vertical3.jsp>

In this context, we highlight the call from UN Secretary-General and various world leaders to treat COVID-19 diagnostics, therapeutics and vaccines as **global public goods**. However, India needs to proactively support this call and pave the strategic roadmap to ensure that the same translates into action nationally and internationally.

Concerns on access primarily emanate from the lack of clarity on how to achieve open sharing of research knowledge, data and IP - both at the national and the global level – desperately needed to accelerate scientific progress and scaling up of manufacturing for COVID-19 diagnostics, therapies and vaccines.

In this regard, we call upon the government of India:

1. To take measures at the international and national level to ensure support for open innovation for COVID-19 related drugs, diagnostics, and vaccines development. An international project COVID-19 Technology Access Pool (C-TAP)⁴ to share IP, scientific data, and know-how to fight the coronavirus pandemic was launched by the World Health Organization. India while supporting this initiative should call for binding norms to be adopted by the WHO and its member states to ensure that sharing of data, know-how and IP is applicable to all stakeholders – public and private – involved in developing COVID-19 medical tools.
2. To ensure that the DBT-BIRAC COVID-19 Research Consortium and other initiatives by DST, CSIR, Indian Council of Medical Research (ICMR) and the office of the Principal Scientific Advisor follow the approach of the erstwhile Open Source Drug Discovery in India for sharing data and know-how and further ensure that the government retains the rights to issue non-exclusive licenses to manufacturers, for the products developed from such funding.
3. To invoke provisions⁵ under Indian Patents Act to ensure that patents granted by Indian patent office on COVID-19 related diagnostics, treatment and vaccines are identified and are revoked immediately in public interest or compulsory licenses are issued without prior negotiation or government use provisions are invoked, or inventions and/or patents are acquired by the government for public purposes which

⁴ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>

⁵ The Patents Act, 1970: Section 66 (Revocation of patent in public interest); Section 92 (Special provision for compulsory licences on notifications by Central Government) and Section 100 (Power of Central Government to use inventions for purposes of Government); Section 102 (Acquisition of inventions and patents by the Central Government)

will facilitate efficiency in access and increase manufacturing capacity for any COVID-19 related diagnostics, treatment and vaccines. In this regard government should also urgently remedy the erroneous grant of patents to the drug remdesivir under Section 66 of the Patents Act.⁶

4. To require the submission of all license agreements⁷ related to COVID-19 related diagnostics, treatment and vaccines including Gilead's license agreement⁸ on remdesivir and scrutinize the same to assess their impact on access to the medical products for patients globally. While Indian companies commercially benefit from the agreement with Gilead, it is not acceptable that India, which claims to be the 'pharmacy of the world' should support an agreement that leaves out 70 countries, nearly half the world population, from benefiting from generic competition on a COVID-19 drug from India. The agreement undermines India's role as a leader in global public health.
5. To ensure that any of the COVID-19 related diagnostics, therapeutics and vaccines, whether patented or not be made available free of cost to patients in the public and private sector. In this context, we would like to draw your attention to drugs that are being used and recently included in India's clinical management protocol⁹ to treat COVID-19 disease. We request the government to ensure that there is no profiteering by private hospitals and companies from the pandemic who are selling such drugs to patients. An example of such profiteering is the price charged by Roche for the drug tocilizumab prescribed in the private sector to severe COVID-19 patients with Cytokine-Release Syndrome (CRS)¹⁰ at INR 60,000 (approx. USD 600) for a vial¹¹. Multiple sources of tocilizumab are needed to increase manufacturing capacity and decrease the price of the drug. We also urge the government to invoke the provisions of the Drug Price Control Order, to ensure prices for COVID-19 diagnostics, treatment and vaccines are controlled based on the cost of manufacture.

⁶ <https://www.thepharmaletter.com/article/call-for-indian-government-to-revoke-gilead-s-remdesivir-patent>

⁷ The Patents Act, 1970: Section 68 (Assignments, etc., not to be valid unless in writing and duly executed), Section 69 (Registration of assignments, transmissions, etc.)

⁸ <https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/>

⁹ <https://www.mohfw.gov.in/pdf/ClinicalManagementProtocolforCOVID19.pdf>

¹⁰ Administered intravenously or subcutaneously, tocilizumab can be used in a single dose (vial of 400mg/20mL), and repeated one or two times if necessary to treat a person with COVID-19. Tocilizumab may reverse the cytokine storm and ARDS not by direct action against the virus but by blocking interleukin-6 (IL-6), a substance produced by the body that boosts this exaggerated inflammatory response.

¹¹ <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/dilemma-for-docs-as-roches-covid-drug-is-life-saver-but-too-costly/articleshow/75855100.cms>

The cost of manufacture of tocilizumab is estimated to be as low as USD 40 (approx. INR 3050), given that the manufacturing costs of monoclonal antibodies are often below USD 100 (approx. INR 7625) per gram when produced on a large-scale¹².

6. To ensure that guidelines and rules for ‘monitored emergency use’¹³ are in place so that if the Central Drugs Standard Control Organization (CDSCO) approves and Indian Health Ministry introduces new drugs like remdesivir it will be done so in compliance with such guidelines and rules. The WHO recommends¹⁴ that new investigational drugs such as remdesivir be introduced after a scientific risk-benefit analysis and ethical review, efforts to ensure informed consent of the patient and requirements that the results of such emergency use are documented and shared promptly with the wider medical and scientific community and the public.
7. To ensure that all rapid approvals and various permissions by the CDSCO on therapeutics and vaccines for COVID-19 be published on time making full disclosure of the data while ensuring that all people participating in clinical trials are protected, including respecting their dignity and human rights.
8. To ensure rapid sharing of genome sequencing of SARS-CoV-2 viruses conducted by ICMR-National Institute of Virology and CSIR. This is significant for the development and evaluation of new diagnostics, drugs and vaccines considering how the virus is spreading in India. However, such sharing should be subject to terms and conditions that ensure fair and equitable sharing of benefits as well as those conditions which ensure that intellectual property on the sequences and its use is claimed. We also call upon the CSIR, ICMR and DBT to ensure that the sequencing should be accompanied with de-identified meta-data from patients and shared upon request with laboratories, clinicians, epidemiologists in India to improve research on the impact of different strains of the disease.¹⁵

With effective leadership, India can contribute to R&D underway to develop effective diagnostics, treatments and vaccines for COVID-19 by scaling up their manufacture to

¹² <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005361>

¹³ Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI) is an ethical protocol developed by the World Health Organization to evaluate the potential use of experimental drugs in the event of public health emergencies. The protocol was created first created by the WHO Ebola Ethics Working Group in 2014 in the context of the 2014 West Africa Ebola outbreak. The WHO recommends that the term be preferred to the term "compassionate use" or "expanded access" for the controlled use of unregistered treatments in public health emergency measures.

¹⁴ <https://www.who.int/publications/i/item/clinical-management-of-covid-19>

¹⁵ <https://www.natureasia.com/en/nindia/article/10.1038/nindia.2020.75>

meet global needs and ensuring policies and norms so that they can be accessed and distributed to people who need them most in developing countries.

As civil society, we call on the Indian government to take immediate action by prioritizing public health needs and ensure availability, accessibility, and affordability of medical diagnostics, treatments and vaccines needed to respond to the COVID-19 pandemic. Lives of millions of people in India, and across the world depend on it.

Individuals

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7. Achin Vanaik, retired professor
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245. Tariq Islam, Professor
246. Teesta Setalvad, Secretary Citizens for Justice and Peace
247. Thomas Matthew, Defence scientist & engineer

248. Tripti Tandon, Advocate
249. Uma Chakravarti, Feminist historian & film maker
250. Vaibhav Babar, Businessman- Lawyer
251. Vaidehi Dubey, MBA Candidate
252. Vanita Mukherjee, Independent Researcher on Gender and Rights
253. Varda Mehrotra, Activist
254. Varghese Iype, Advocate
255. Varun Mehta, Student
256. Veena Johari, Advocate
257. Venkatchala Sarma, Chartered Account
258. Venkatesh Nayak, Transparency and accountability activist
259. Vinay Kumar, Student-Lawyer
260. Vineet Nigam, Consultant
261. Virginia Saldanha, Co-ordinate, Indian Christian Women's Movement, Mumbai
262. Yadavendra Singh
263. Yogesh Jain, Public Health Physician
264. Yogita Bharat Pawar, Ahmednagar, Maharashtra, Global Alliance for Human Rights (GAHR)
265. Yuvan Sharma, Lawyer

Organizations

1. All India Drug Action Network
2. Campaign for access to medicines, medical devices, diagnostics-India(CAMD-India)
3. Centre for Justice and Peace
4. Citizens for Justice and Peace
5. Delhi Network of Positive People (DNP+)
6. Drug Action Forum, Karnataka
7. Freedom Foundation
8. Gujarat State Network of People Living with HIV
9. India Alliance for Child Rights
10. Initiative for Health & Equity in Society
11. ITPC-South Asia
12. Jan Swasthya Abhiyan
13. Kripa Foundation, Nagaland
14. Lawyers Collective
15. Lok Manch National Facilitation Centre, New Delhi
16. National Coalition of People Living with HIV
17. National Trade Union Initiative
18. Naz Foundation
19. Payal Foundation
20. Samraksha
21. Sangram Sanstha
22. Sankalp Foundation
23. South India AIDS Action Programme
24. TWN Trust

25. Women Initiatives, WINS