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## India's Bio-War against a Pandemic Threat COVID-19

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### ABSTRACT

Coronavirus is a common type of virus that usually infects humans and results in a high breathing infection. This virus transmits through the air by coughing and sneezing, near physical contacts, and touching virus-contaminated substances or surfaces. Symptoms include runny nose, sore throat, feeling unwell, cough, and fever. The coronavirus outbreak (officially known as COVID-19), which started in China, has so far taken lives of over 190,656 people and affected 2,718,797 people across the world. The infection has spread to 185 countries. According to the official report released by the Ministry of Health and Family Welfare of the Union (MoHFW), 23,077 confirmed cases and 718 deaths have been registered so far in India. The transmission of COVID-19 was successfully controlled by India until now. The Department of Indian Health Science is well organized to control the corona epidemic. The Indian Health Sciences Department and the Regulatory Team (CDSCO) are advancing bio-war against the pandemic by providing effective and constructive updates to the pharmaceutical industry and making it easier for the citizens to prevent transmission in India. The most critical factor in preventing the local spread of the virus is to motivate the public to obtain the right information and take precautions in compliance with the health ministry's warnings.



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### INTRODUCTION

Coronavirus (COVID-19) is a recently discovered coronavirus-infectious disease. It is a kind of common human virus, which usually leads to upper respiratory infection. (Stöppler, 2020). The risk of

contracting severe illness is higher in older people, including those with underlying medical conditions such as cardiovascular disease, diabetes, chronic respiratory diseases, and cancer (Coronavirus, 2020). It is structured with critical structural proteins, as shown in Figure 1.

Currently, there are no clear COVID-19 vaccines or treatments. However, several clinical trials to determine alternative therapies are in development.

### Prevention

The following parameters should be followed to avoid infection and slow transmission

1. Regularly wash your hands with soap and water or with an alcohol-based sanitizer.
2. Keep a distance of at least one meter from the people who are coughing and sneezing and also cover your mouth and nose.

3. Do not touch your face.
4. It's better to stay at home when you feel sick ([Coronavirus, 2020](#)).

### Symptoms

The Virus COVID-19 affects different people in various ways. COVID-19 is a respiratory infection and the majority of people infected experience mild to moderate symptoms. People with chronic medical problems and over 60 years of age are at greater risk for serious illness and death ([Coronavirus, 2020](#); [India Readies, 2020](#); [COVID-19, 2020a](#)).

Common Symptoms: Dry cough, Tiredness, Fever or Elevated temperature.

Other symptoms: Difficulty in breathing, aches and pains, sore throat & very few will report diarrhea, nausea or a runny nose.

### COVID -19 – A threat of bio war

Covid-19 was declared a pandemic earlier this month by WHO. The greatest chance of global disaster is bio-war in the form of viruses. The Indian government has taken steps to prevent and control the widespread spread of Covid-19 with help of the citizens in India ([COVID-19, 2020b](#)). Almost every visa has been suspended for entry into India. Indians could be quarantined when they return. State borders are sealed. It's just as real as a war. The greatest fight since independence against a pandemic in India. ([Bioterrorism, 2020](#); [Threat of Bio War, 2020](#)).

The transmission of COVID-19 by now was regulated successfully by India. Indian Ministry of Health, well organized with the outbreak of Corona. India's pharmaceutical and sanitary skills; mass public knowledge using digital systems; and a central political control; indeed it has helped to contain this spread up to now, among other things. The Department of Health and CDSCO have provided several announcements or alerts to challenge the pandemic threat as a bio-war ([E Times, 2020](#)). Health professionals are the warriors in the battleground ([Nalgundwar and Forbes India, 2020](#)).

### Steps taken- Department of Health Science and Indian Regulatory Authority - (CDSCO)

#### CDSCO responds with new authorization, import and protection steps to COVID-19

Indian Regulatory Authority, the Central Drug Quality Control Organization (CDSCO) has been issuing many reports on the current pandemic since mid-March. These include new steps designed to improve COVID-19 prevention/handling tools to ensure the delivery of additional essential In-Vitro

Diagnostics (IVDs) and restrict the exposure of CDSCO workers to SARS-CoV-2 ([Emergo, 2020](#)).

#### COVID-19 IVD Test Kits priority

The CDSCO announced its priority to grant accelerated approval to the COVID-19 IVD test kits. Manufacturers already with IVD clearance in other markets are motivated to approach DCGI (Drug Controller General, India) to seek fast track clearance. Therefore, producers wishing to develop new IVDs should directly contact the DCGI to ask for clarification on the appropriate regulatory route.

In seven days, priority applications shall be processed. Data specifications can also be streamlined, postponed, or suspended on a case-by-case basis in the context of the accelerated approval process, for example, clinical trial assessments ([Emergo, 2020](#)).

#### A fast COVID-19 response control framework

To monitor regulatory approvals for vaccines, treatments, prophylactics and therapeutics for the prevention or treatment of COVID-19 was published in the CDSCO's second notice in detail. To resolve technology issues, CDSCO has developed a dedicated coronavirus team.

#### Major IVDs import release

The CDSCO published short-term updated release techniques, which disrupted traditional sampling and test procedures for other important IVDs (for example, the HIV and HBsAG test kits) during the COVID-19 pandemic. Port offices that hold consignments publish such IVDs based on the document analysis, protocol, certification of the release of the batch by the supplier, and compliance history. Importers are, however, expected to maintain "appropriate quantities" for future testing and commit to recalling items that do not meet potential laboratory testing requirements ([Emergo, 2020](#)).

#### CDSCO workers' current stance on disease prevention

The final notification includes measures to restrict government officials' exposure to the SARS-CoV-2 virus. CDSCO industries are advised, instead of accessing their premises, to make contact by telephone and e-mail whenever necessary. CDSCO workers and visitors will follow the required procedures for washing hands and sanitation and, if appropriate, wear masks. In CDSCO's premises, detailing "dos and don'ts" for COVID-19 prevention signage will be provided. The CDSCO distributes, via e-mail until further notice, official papers, such as approvals or letters of clarification ([Emergo, 2020](#)).

#### CDSCO approves institutes to conduct clinical trials in COVID-19 patients

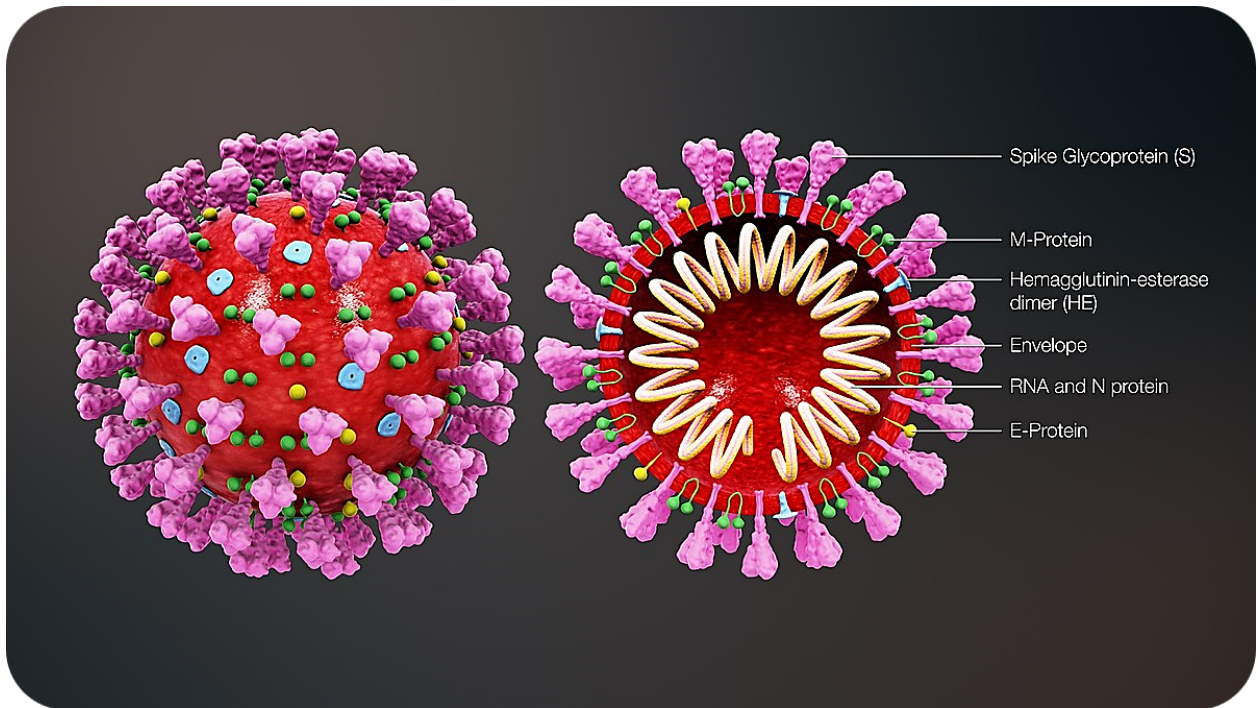


Figure 1: Structure of Corona Virus (COVID-19)

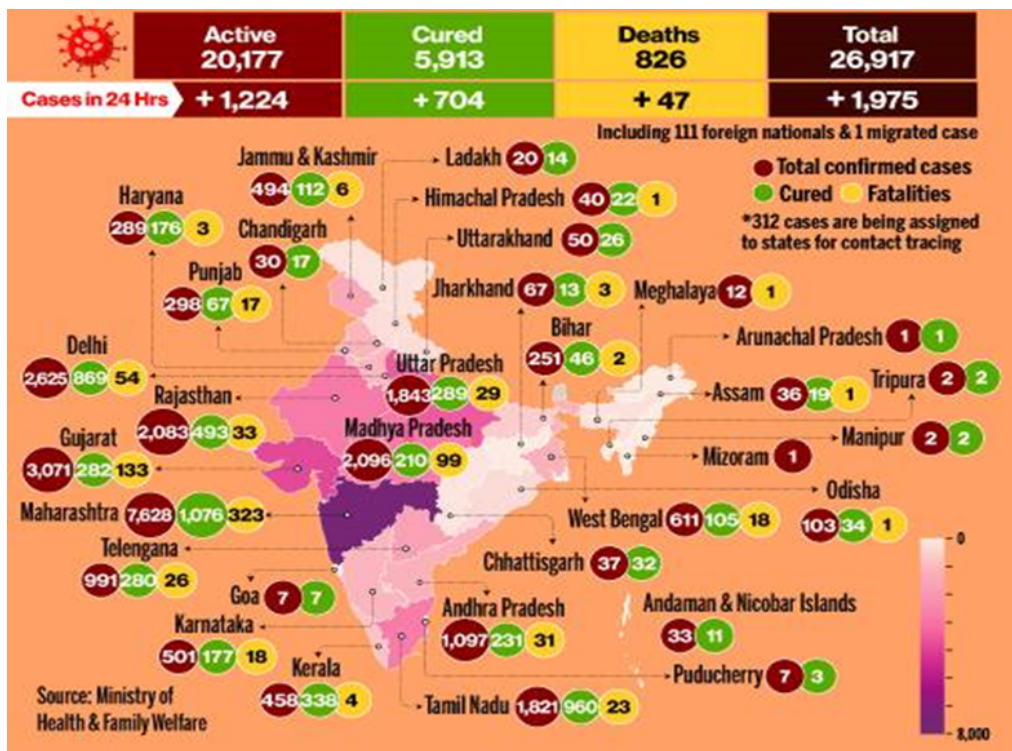


Figure 2: Statistics of People infected, recovered and Dead in India

The CDSCO has sent a green signal to the interested organizations, under the protocol developed by the Indian Council of Medical Research (ICMR), to carry out the clinical trial of COVID-19 patients with convalescent plasma ([COVID-19, 2020a](#)).

In a study for the clinical trial in COVID-19 patients for convalescent plasma, the CDSCO reported: "It is to inform that in light of public interest the proposal of ICMR for conducting the said trial has been reviewed through the Subject Expert Committee (SEC) in its meeting held on April 13 under accelerated approval process in light of the current situation of COVID-19 and based on the recommendation of the committee" ([BloombergQuint, 2020](#)).

The ICMR provided a list of institutes to CDSCO which showed interest in conducting the said trial. During that meeting, the SEC opined that the ICMR had established a clinical trial guided protocol of moderate COVID-19 patients with convalescent plasma which had been approved by the commission and which could also be recognized as acceptable by the applicants.

Any individual or organization interested in carrying out plasma convalescent test under the protocol developed by ICMR and CDSCO may do so in consultation with ICMR and, accordingly, as indicated in a notification signed by VG Somani (DCGI), the applicant may consult the ICMR for the conducting the clinical study ([COVID-19, 2020a](#)).

#### **DCGI to fast-track approval for COVID-19 drug, vaccine**

The Drug Controller General of India (DCGI) said that all companies with a medicine or vaccine for coronavirus therapy could quickly be licensed, an effort to speed up research and development, which could provide treatment for the disease that has not been in use worldwide until now. Seven steps have been put forward by the DCGI for speeding up the process, from the approval of a quick-track medication to an abandonment of animal studies and flexible paths which would be needed months earlier ([Rajagopal and The Economic Times, 2020](#)).

Where a drug or vaccine in some other country has been approved for COVID-19, the company will approach DCGI directly to obtain a fast-track marketing approval for the Indian market. Therefore, animal toxicity research and clinical trial data criteria may be excluded. The DCGI has also confirmed that testing and review applications to import drugs to verify the effectiveness of the original molecules will be processed within seven days ([Asia Regulatory Roundup, 2020](#)).

#### **Benefit to other countries by Indian Regulatory**

#### **Authorities**

India is naming 13 countries that are eligible for hydroxychloroquine: The United States, Spain, Germany, Nepal, Bhutan, Afghanistan, the Maldives, Bangladesh, Seychelles, Mauritius, Brazil, Dominicans, and Bahrain among the 13 approved countries ([India today, 2020](#)).

The Department of External Affairs has compiled an inventory of those countries which have requested assistance from India. Hydroxychloroquine is first sent to the countries that are severely affected by coronavirus. "Depending on demand, the government accepts applications for medicines from other countries and these will be commercially distributed." Several countries have entered India for assistance in drugs, medical supplies, and medical equipment ([India Readies, 2020](#)).

#### **Indian Statistics on COVID-19**

(As on April 26, 2020). COVID-19 cases progressed in each State or Union Territories (U.T) are shown in Figure 2, ([Coronavirus In India, 2020](#)).

#### **CDSCO approves COVID-19 PCR Kits by Mylab**

As India combats the COVID-19 outbreak, the authorities are more concerned about the limited testing and costly testing kits. To meet this challenge, Mylab Discovery Solutions Pvt Ltd, a Pune-based molecular diagnostic company that specializes in molecular diagnostic kits, has produced its first COVID-19 test kit for India in a record six-week time frame. The kit, as the first commercially approved product of the Indian FDA, is called "Mylab PathoDetect COVID-19" Qualitative PCR kit. The kit is the first to be given commercial approval by the CDSCO. Besides, Mylab was the only Indian company in the ICMR assessment to reach 100% sensitivity and 100% specificity ([CDSCO, 2020](#)).

In addition, CDSCO published a list of approved PCR Kits for testing of COVID-19 recently on 23-April 2020 ([Public Notices, 2020](#)).

#### **CONCLUSION**

The current healthcare infrastructure and delivery system have already faced accessibility and affordability problems in a developing nation like India, with a population of 1.34 trillion people. So far, the Indian Health Care Committee, Regulatory Authorities, and the government of India adopted a step-by-step model that will bring many favorable developments to tackle the COVID -19 bio-war. Also, the Indian Government is taking all appropriate measures to ensure that everyone is well prepared for the challenge and the threat posed by the growing

COVID-19 pandemic. They have been able to prevent the spread of the virus in our country with active support from the people of India.

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The authors declare that they have no conflict of interest for this study.

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