

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 894
TO BE ANSWERED ON 23RD JULY, 2021**

RESEARCH CELL TO STUDY POST COVID-19 COMPLICATIONS

**894. SHRI RAHUL RAMESH SHEWALE:
SHRI GIRISH BHALCHANDRA BAPAT:
DR. PRITAM GOPINATHRAO MUNDE:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Indian Medical Association (IMA) has requested the Government to set up a separate research cell to study post COVID-19 complication come out with multi-faceted treatment guidelines in all disciplines of medicine;
- (b) if so, the response of the Government thereto;
- (c) whether post COVID-19 complications of lung fibrosis, increased thrombotic events and fungal infections are on the rise, if so, the details thereof;
- (d) whether drugs needed for the mucormycotic fungal disease are not available with ease; and
- (e) if so, the details thereof and the steps taken by the Government to augment indigenous production?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) to (c): The Indian Medical Association vide letter dated 7th June 2021 addressed to the Hon'ble Prime Minister has mentioned that post-COVID-19 complications of lung fibrosis, thrombotic events and fungal infections are on rise and there is a need to prepare for the same. It also urged Government to set up a separate research cell to study post COVID-19 complication come out with multi-faceted treatment guidelines in all disciplines of medicine.

In this regard the following activities have already been initiated:

Expert group consultations under Director General of Health Services are ongoing to review emerging evidence on organ system specific (respiratory system, renal system, cardiovascular and gastro-intestinal) sequelae of COVID-19.

ICMR has established a National Clinical Registry on COVID with the following objectives:

- To develop National Clinical COVID-19 registry to collect data regarding clinical and laboratory features, treatments, and outcomes of hospitalized COVID-19 patients in India.

- To study the frequency, clinical and laboratory features, treatments, and outcomes of COVID-19 related multisystem inflammatory disorder in children and adolescents by analyzing the national COVID-19 registry.
- To utilize data to answer research questions on COVID -19 including natural course of disease, spectrum of disease, prognostic factors, outcomes data, medications, health systems and context specific questions such as COVID-19 in Tuberculosis, Malnutrition etc.
- To serve as a platform for additional clinical research studies in selected sites.
- To collect follow-up data of discharged COVID 19 patients, if possible.

The registry follows a hub and spoke model with primary data being collected in the electronic data capture form by satellite centres (dedicated COVID-19 hospitals) which are being trained, mentored, and supervised by medical institutes of national repute chosen region-wise. In the first phase, 50 satellite centres and 14 registry sites have been included.

In addition, all AIIMS like institutions have been requested to undertake research to study long term impact of COVID.

It may be premature to conclude that complications like lung fibrosis and increased thrombotic events directly due to COVID-19 infection are on rise. However, a larger number of cases of fungal infections have been noted linked with COVID-19 during the recent surge.

(d) & (e): Although Mucormycosis is not a new disease, its true incidence was unknown as it was not a notifiable disease. Ministry of Health & Family Welfare in May 2021 requested states to declare Mucormycosis a notifiable disease under Epidemic Disease Act, 1897 to get an objective assessment of Mucormycosis in the community.

Since early May 2021 the details of production, stock, supplies made and purchase orders were obtained from the manufacturers and their co-operation was sought to overcome the gap between supply and demand. Both first- and second-line drugs used for managing Mucormycosis cases i.e. Amphotericin B Deoxycholate and Posaconazole are currently amply available in Indian markets.

Union Government has taken various measures to improve the availability of Amphotericin B (liposomal) through a multipronged approach of augmenting production and import and ensure equitable distribution to States/UTs. The various measures adopted include:

- Union Government is continuously engaging with the manufacturers to resolve their issues related to raw materials.
- Department of Pharmaceuticals and the Drug Controller General of India (DCGI) have actively coordinated with the industry for identification of manufacturers, alternate drugs and expeditious approvals of new manufacturing facilities.
- The 5 existing manufacturers have also been called upon to increase production of Liposomal Amphotericin-B. DCGI, after consultation with the association of Drugs manufacturers, has issued manufacturing / marketing permission of Amphotericin B Liposomal Injection to six additional firms.
- Various concerns of manufacturers and importers, including those related to licensing and availability of raw material issues, import license are being speedily addressed.

- Ministry of External Affairs (MEA) is reaching out to various manufacturers abroad to identify new sources of Amphotericin B/ Liposomal Amphotericin B injections and alternative drugs for treatment of Mucormycosis. MEA has also been actively working on ensuring supplies of key excipients from sources abroad for production of Liposomal Amphotericin B in India.
- For equitable distribution, allotments are being made to the States/ UTs in accordance with the proportion of their reported case load in respect of the entire country.
- Supply arrangements are being monitored by the National Pharmaceuticals Pricing Authority (NPPA) to ensure expeditious availability of the drug.