

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

**LOK SABHA  
UNSTARRED QUESTION NO. 819  
TO BE ANSWERED ON 23<sup>RD</sup> JULY, 2021**

**INTEGRATED ACTION PLAN TO TACKLE FUNGAL OUTBREAKS**

**819. ADV. ADOOR PRAKASH:  
DR. AMAR SINGH:  
SHRI BENNY BEHANAN:  
SHRI GAURAV GOGOI:  
SHRI T.N. PRATHAPAN:  
DR. MOHAMMAD JAWED:  
SHRI D.K.SURESH:  
SHRI ANTO ANTONY:**

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

- (a) whether the Government has formed an integrated plan of action to tackle the fungal infection outbreaks consisting of the black, white and yellow variants;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) whether the Government has taken cognizance of the shortage in the supply of Amphotericin-B injections used for the treatment of Mucormycosis;
- (d) if so, the details thereof and the manner in which the Government proposes to meet the demand, and if not, the reasons therefor;
- (e) whether the Government intends to assist the healthcare system with identification and treatment of these diseases; and
- (f) if so, the details thereof and if not, the reasons therefor?

**ANSWER**

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

- (a) & (b): In the wake of second wave of COVID-19 in the country, an increased number of Mucormycosis cases were reported from many States/UTs. Ministry of Health & Family Welfare after thorough gap analysis and expert consultations took several steps to address the problem arising out of Mucormycosis and other fungal infections. The main actions initiated are as under:
- Although Mucormycosis is not a new disease, but its true incidence during the beginning of second wave 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.

- Taking cognizance of association between elevated blood sugar levels (whether in patients with preexisting diabetes mellitus, or hyperglycemia due to steroid therapy) and Mucormycosis, an updated “Clinical Guidance on Diagnosis and Management of Diabetes at COVID-19 Patient Management facility” was issued by Ministry of Health & Family Welfare on 1<sup>st</sup> June 2021.
- After expert deliberations in the National Task Force on COVID-19 comprising of experts drawn from NITI Aayog, ICMR, AIIMS (Delhi), NIV, WHO (India), eminent public health advocacy groups, a detailed advisory on treatment and management of COVID-19 associated Mucormycosis (CAM) was formalized and disseminated to all States and UTs on 7<sup>th</sup> June 2021.
- Amphotericin-B has been prescribed as a drug of choice. The drug is available in two formulations (i) Liposomal Amphotericin B and (ii) Amphotericin B Deoxycholate, which are similar in efficacy, however the latter needs to be used with greater caution with respect to its effects on kidney function test and electrolyte imbalance. Second drug of choice is Posaconazole which may be used in cases with compromised renal function, drug reaction to Amphotericin B, electrolyte imbalance or in non-availability of Amphotericin B.
- Similarly realizing the multi-disciplinary approach required to manage patients suffering from Mucormycosis and other fungal infections, a checklist for managing Mucormycosis and other fungal infections was also circulated to all States/UTs on 11<sup>th</sup> June 2021.
- The clinical management guidelines for managing COVID-19 cases by Ministry of Health & Family Welfare advocates rational use of steroids for managing moderate to severe cases of COVID-19 under strict medical supervision. Further noting relationship between use of steroids and other immunosuppressive drugs, “Advisory for rational use of Steroids and Tocilizumab in the treatment of Covid-19 patients” was issued by Directorate General of Health Services.
- For the reporting of cases and deaths due to Mucormycosis, Union Ministry of Health has requested the States and UTs to submit the details on COVID-19 India portal. States were asked to update the data on the portal which helped Union Health Ministry to analyze and keep a track of evolving nature of problem across the country.

(c) to (f): 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.

Department of Pharmaceuticals (DoP), Central Drugs Standard Control Organization (CDSCO) & National Pharmaceutical Pricing Authority (NPPA) have been jointly monitoring the production and availability of critical (COVID) drugs including Amphotericin-B injections. Accordingly, 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.
- Five existing manufacturers were 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.
- Ramping up production of alternative drugs/forms for treating the disease is also being actively pursued with the manufacturers.
- 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. Through its missions all over the world, MEA has identified 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.
- Department of Pharmaceuticals and the Indian Embassy in the USA are working continuously with the Mylan Labs for increasing import and ensuring early delivery from M/s Gilead Inc. USA.
- 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.
- NPPA has put in place a strongly responsive system to ensure timely supplies of allocated volumes and maintains continuous contact with States/UTs and suppliers to trouble shoot any issues in reaching the drugs to the Health Departments of States/ UTs.