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

# LOK SABHA UNSTARRED Q. No 2032 TO BE ANSWERED ON 30<sup>th</sup> JULY, 2021

#### BLACK FUNGUS DUE TO STEROID USAGE

#### 2032 SHRI SUDARSHAN BHAGAT:

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

- (a) whether number of cases of the black fungus disease is on the rise in people due to excessive use of steroids during the Corona pandemic;
- (b) if so, the details thereof, State/UT-wise; and
- (c) if not, the steps taken by the Government to put a check on the fungal infection/disease?

#### **ANSWER**

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

(a) to (c): Mucormycosis or Black Fungus disease, although not a new disease, was not a notifiable disease till May 2021 when Ministry of Health & Family Welfare requested states to declare Mucormycosis a notifiable disease under Epidemic Disease Act, 1897 to get an objective assessment of Mucormycosis in the community.

Mucormycosis has been found to be causally associated with hyperglycemia (due to new onset or pre-existing diabetes or steroid induced), irrational use of broad-spectrum antibiotics, co-morbidities such as hematological malignancies, use of immunosuppressants, etc.

Mucormycosis cases being reported by the states/UTs peaked in later half of May 2021 and are now showing a declining trend.

State/UT wise details of Mucormycosis cases as reported by the States/UTs till 28<sup>th</sup> July 2021 is at **Annexure**.

Ministry of Health & Family Welfare has taken a number of measures to address the issue of Mucormycosis. Some of the initiatives to prevent occurrence of such cases are detailed below:

- Taking cognizance of association between elevated blood sugar levels (whether in patients with preexisting diabetes mellitus, or hyperglycemia due to steroid therapy), 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.
- 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 immune-suppressive drugs "Advisory for rational use of Steroids and Tocilizumab in the treatment of Covid -19 patients" was issued by Directorate General of Health Services.
- 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 Organisation (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) actively coordinated with the industry for identification of manufacturers, alternate drugs and expeditious approvals of new manufacturing facilities.

- Department of Pharmaceuticals and the Drug Controller General of India (DCGI) actively coordinated with the industry to enhance availability of Amphotericin B through identification of manufacturers, alternate drugs and expeditious approvals of new manufacturing facilities.
- Besides, the existing five manufacturers, DCGI had issued permissions to manufacturing/marketing of Amphotericin B to six additional firms.
- This led to the increase in production capacity from 0.62 lakhs in April 2021 to 1.4 lakhs in May 2021 and was augmented further to 3.57 lakhs in June 2021.
- 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.
- 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) so as 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.

Annexure

### State/UT wise details of Mucormycosis cases as reported by the States/UTs till 28<sup>th</sup> July 2021

S. No.	State/UT	Total Cases
1	Andhra Pradesh	4209
2	Assam	10
3	Bihar	783
4	Chandigarh	644
5	Chhattisgarh	398
6	Delhi	1815
7	Goa	30
8	Gujarat	6846
9	Haryana	1705
10	Himachal Pradesh	31
11	Jammu and Kashmir	47
12	Jharkhand	132
13	Karnataka	3648
14	Kerala	128
15	Madhya Pradesh	2276
16	Maharashtra	9654
17	Manipur	7
18	Nagaland	1
19	Odisha	164
20	Puducherry	199
21	Punjab	666
22	Rajasthan	3536
23	Tamil Nadu	4075
24	Telangana	2578
25	Tripura	1
26	Uttar Pradesh	2351
27	Uttarakhand	555
28	West Bengal	275