Steps taken by Government to ensure drug availability for treatment of Mucormycosis

Government continuously engaged with the manufacturers to resolve their issues related to raw materials

MEA identified new sources of Amphotericin B/ Liposomal Amphotericin B injections and alternative drugs

Government continues to monitor manufacturing, import, supplies and availability of drugs used for treatment of Mucormycosis.

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A sudden increase in the demand has been observed in some States for Amphotericin-B, which is being actively prescribed by the physicians to the patients suffering from Mucormycosis, which has been seen as a post COVID complication. Through active measures to augment production, and import and ensure equitable distribution, Government has been able to mobilise over 6.67 lakh vials of the Amphotericin B for patients in the states and UTs and Central Health Institutes, in addition to other drugs such as Amphotericin Deoxycholate and Posaconazole being used for treatment of this disease.

The Department of Pharmaceuticals (DoP) along with inputs from CDSCO has been continuously assessing the availability of drugs for treating Mucormycosis - both through domestic manufacturing and import. Since early May, 2021 the details of production, stock, supplies made and purchase orders were obtained from the manufacturers and their co-operation sought to overcome the gap between supply and demand. An inter-departmental meeting was held on 10th May, 2021 with Department of Pharmaceuticals, Ministry of Health & Family Welfare (MoHFW), *Central Drugs Standard Control Organisation (*CDSCO) and *Directorate General of Health Services (*DGHS)to take stock of the situation. A view emerged that allocation of limited stocks among the States/UTs would ensure that all States get a fair chance of accessing a share of the available supplies, till the supply demand gap is overcome.

Production enhancement

In order to augment the domestic manufacture, the 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 manufacturing firms were contacted and have been sensitized about the need to increase production. The existing manufacturers have also been called upon to increase production of Liposomal Amphotericin-B. 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.

The existing five manufacturers of Liposomal Amphotericin B are Bharat Serums and Vaccines Limited, Cipla, Sun Pharma, BDR Pharmaceuticals and Lifecare Innovations. The expected release by them for the month of June is about 2.63 lakh vials. Manufacturing of liposomal formulation involves a complicated process and can only be done by industries having advanced technology. DCGI, after consultation with the association of Drugs manufacturers, has issued manufacturing / marketing permission of Amphotericin B Liposomal Injection to six firms, viz., Emcure, Gufic, Alembic, Lyka, Natco Limited and Intas Pharma. The expected release by the six new manufacturers for the month of June is about 1.13 lakh vials.

The domestic production capacity of Amphotericin B Liposomal Injection has increased from about 62000 in April 2021, to 1.63 lakh vials in May 2021 and is expected to cross 3.75 lakh vials in June, which is a fivefold increase in a short time span.

Regular Monitoring of production is being carried out by the Government and several meetings held with the manufacturers to identify the issues involved in the augmentation of the production. Companies manufacturing APIs have also been contacted by the Government and asked to ensure increased and continuous supplies for augmenting production.

Import facilitation

Ministry of External Affairs (MEA) is playing an important role in reaching out to various players 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. Out of the identified sources, the MoHFW has called upon MEA to take steps to procure Liposomal Amphotericin-B from Australia, Russia, Germany, Argentina, Belgium and China. MEA has also been actively working on ensuring supplies of key excipient, HSPC and DSPG-NA 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. Out of total Orders placed with Gilead for 9,05,000 vials, the stocks of 5,33,971 vials have already been received till 16th June by M/s Mylan, the main importer. The remaining deliveries are being expedited.

Making allocation

In order to ensure equitable distribution of the limited stocks, it was decided to make allocation of limited stocks among states, which would ensure that all states with patients of Mucormycosis would get a fair chance of accessing a share of the supplies. The allocation by the Central Government is being done only in respect of Lyposomal Amphotericin-B, barring one manufacturer Bharat Serum, which produces Lyposomal, Lipid and emulsion form of the drug. The allocation of Conventional Amphotericine is also being done since 14th June 2021, after assessing the demand and availability.

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. The number of patients in a particular State is derived from the portal of Ministry of Health and Family Welfare, in which the States themselves enter the figures of patient load in their respective states. This allocation regime is an interim arrangement till the supply of the drug stabilises *vis a vis* the demand.

Physical distribution and availability of the drug in a particular city/ hospital is managed by the State Governments concerned. Liposomal Amphotericin-B is directly procured by State Governments from the manufacturers based on the allocation made and the drug is subsequently made available to the Hospitals.

Through allocations made till 14th June, 2021, a total 6,67,360 vials have been allocated by Department of Pharmaceuticals to States / UTs. In addition, 53,000 vials of Conventional Amphotericin B were also allocated to States / UTs on 14th June.

Ensuring supply

Supply arrangements are being monitored by the National Pharmaceuticals Pricing Authority (NPPA) under the Department so as to ensure expeditious availability of the drug to the needy. 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.

On 7th June, 2021, MoHFW has circulated the advisory of the National Task Force on COVID-19 for treatment and management of Covid related Mucormycosis (CAM), which explains in detail, the manner and conditions under which various Mucormycosis drugs like Amphotericin B lipid complex, liposomal Amphotericin B, Amphotericin deoxycholate form, Posaconazole etc. are to be used. Department of Pharmaceuticals has also on 10th June, 2021 issued an advisory to the Health Secretaries of all State governments/UTs reiterating the need of ensuring judicious use of allocated drugs and efficient distribution within their State/UTs.

Government continues to closely monitor in contact with state governments and manufacturers, the production, import, supplies and availability of the drugs required for treatment of Mucormycosis.

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