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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **W.P.(C) 3031/2020 & C.M. Nos. 15227-29/2021, 15358-363/2021, 15481-482/2021, 15652-653/2021, 15845/2021, 15869/2021, 15962-963/2021 & 16081-85/ 2021**

RAKESH MALHOTRA Petitioner

versus

GOVERNMENT OF NATIONAL CAPITAL
TERRITORY OF INDIA AND ORS Respondents

+ **W.P.(C) 5256/2021 & C.M. Nos.16155/2021 & 16156/2021**

MANISHA CHAUHAN Petitioner

versus

GOVERNMENT OF NCT OF DELHI & ANR. Respondents

+ **W.P.(C) 5050/2021 & C.M. Nos. 15464-66/2021 & 15694/2021**

BHAVREEN KANDHARI Petitioner

versus

GOVT OF NCT OF DELHI & ORS. Respondents

+ **W.P.(C) 5100/2021 and C.M. No. 15623/2021**

MANISHA GUPTA Petitioner

versus

GOVT. OF N.C.T OF DELHI & ANR. Respondents

+ **W.P.(C) 5241/2021**

SH. MANJIT SINGH Petitioner

versus

GOVT. OF N.C.T OF DELHI Respondent

MEMO OF APPEARANCE

For Petitioners:

Petitioner in person in W.P.(C) 3031/2020

Mr. Sanjeev Sagar and Ms. Nazia Parveen, Advocates in W.P.(C) 5256/2021.

Mr. Krishnan Venugopal, Senior Advocate with Mr. Manan Verma,

Mr. Aditya N Prasad, Mr. Kaushik Mishra & Ms. Anmol Srivastava, Mr.

Piyush Sharma, Mr. Shivendra Singh, Advocates in W.P.C No. 5050/2021.
Mr. Sacchin Puri, Senior Advocate with Mr. Praveen K. Sharma and
Mr.Dhananjay Grover, Advocates in W.P.(C) Nos. 5100/2021
Ms. Karuna Nundy, Mr. Sarthak Maggon & Ms. Upasana, Advocates in
W.P.(C.) No. 5102/2021.
Mr. Vivek Sood, Senior Advocate with Mr. Anish Chawla, Advocate in
W.P.(C) No. 5241/2021

For Respondents:

Mr. Tushar Mehta, SGI, Mr. Chetan Sharma, ASG, Ms. Aishwarya Bhati,
ASG along with Ms. Monika Arora, Mr. Amit Mahajan, Mr. Anil Soni &
Mr. Kirtiman Singh, CGSCs, Mr. Syed Husain Adil Taqvi, GP, Mr. Jivesh
Kr. Tiwari, Ms. Nidhi Parashar, Mr. Kanu Aggarwal, Mr. Kritagya Kumar
Kait, Mr. Shriram Tiwary, Mr. Amit Gupta, Mr. Akshay Gadeock, Mr. Sahaj
Garg & Mr. Vinay Yadav, Mr. Vidur Mohan, Mr. Waize Ali Noor and Mr.
Taha Yasin, Advocates for UNION OF INDIA in all the matters.

Mr. Anurag Ahluwalia, CGSC with Mr. Abhigyan Siddhant & Mr. Nitnem
Singh, Advocates for respondent/ UOI/ MOHFW/ ICMR.

Dr. U.B. Das, Senior Chief Medical Officer in the Directorate General of
Health Services, Ministry of Health, GOI.

Mr. Rahul Mehra, Senior Advocate along with Mr. Satyakam, Mr. Santosh
Tripathi, SC Mr. Gautam Narayan, Mr. Anuj Aggarwal & Mr. Anupam
Srivastava, ASCs with Mr. Aditya P. Khanna, Ms. Dacchita Sahni, Ms.
Ritika Vohra and Mr. Chaitanya Gosain, Ms. Aayushi Bansal, Advocates for
GNCTD in all the matters.

Mr. Rajshekhar Rao, Senior Advocate (Amicus Curiae), Mr. Anandh
Venkataramani, Mr. Vinayak Mehrotra, Ms. Mansi Sood, Mr. Karthik
Sundar, Ms. Sonal Sarada, Mr. Areeb Y Amanullah, Advocates in all the
matters.

Mr. Anil Grover, Senior Additional Advocate General for Haryana along
with Ms. Bansuri Swaraj, Additional Advocate General for Haryana and Mr.
Siddhesh Kotwal, Ms. Manya Hasija & Ms. Ana Upadhyay, Advocates.

Mr. Divya Prakash Pande, Advocate for respondent/ North Delhi Municipal
Corporation & South Delhi Municipal Corporation.

Mr. Tushar Sannu, Standing Counsel, IHBAS and EDMC with Mr. Ankit
Bhadouriya and Mr. Subham Jain, Advocates

Ms. Sakshi Popli, Additional Standing Counsel for NDMC.

Ms. Malvika Trivedi, Senior Advocate with Mr. Tanmay Yadav,

Ms. Abhisree Saujanya, Ms. Nihaarika Jauhari, Ms. Eysha Marysha, Ms. Vidhi Jain, Advocates along with Ms. Kritika Gupta, applicant in person. Ms. Garima Prashad, Senior Advocate with Mr. Abhinav Agrawal, Advocate for respondent in W.P.(C.) No. 3031/2020.
Mr. Ankur Mahindro & Ms. Sanjoli Mehrotra, Advocates for intervener.
Mr. Om Prakash & Mr. Pradeep Kumar Tripathi, Advocates for the applicant in C.M. No. 15651/2021.
Ms. Himanshi Nailwal with Mr. Ambuj Tiwari, Mr. Ankur Garg, Mr. Akhil Mitta, Advocates in C.M. No. 15922/21
Ms. Nitya Ramakrishnan, Sr. Adv. with Mr. Prasanna S, Ms. Vinoothna Vinjam and Mr. Ritesh D, Advocates in C.M. No. 15962/2021.
Mr. Anand Grover, Senior Advocate with Mr. Talha Abdul Rahman, Mr. M. Shaz Khan & Mr. Irshaan Kakkar, Advocates for the intervenors in W.P.(C) 5050/2021.
Mr. Aseem Chaturvedi & Mr. Ajay Bhargav, Advocates for M/s INOX.
Mr. Abhinav Tyagi, Advocate for M/s Seth Air Products.
Mr. Rohit Priya Ranjan, Advocate for M/s Goyal Gases.
Ms. Shweta Kabra, Advocate for M/s India Glycols Limited.
Ms. Prabhsahay Kaur, Advocate for Bachpan Bachao Andolan.
Mr. Abhishek Nanda, Advocate for IRDAI.
Ms. Urvi Mohan, Advocate for DBOCWW Board.

CORAM:

HON'BLE MR. JUSTICE VIPIN SANGHI

HON'BLE MR. JUSTICE JASMEET SINGH

ORDER

01.06.2021

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1. Vide order dated 28.05.2021, we had taken note of the consolidated status report filed by the Union of India (UOI), which, *inter alia*, disclosed that out of the sources that have been presently identified abroad, the Ministry of Health & Family Welfare on 24.05.2021 has called upon the Ministry of External Affairs (MEA) to take steps to procure 2,30,000 Vials of *Liposomal Amphotericin B* from Australia, Russia, Argentina, Belgium

and China. The MEA had also been called upon to procure 50,000 Tablets of *Isavuconazole*. It was stated by the UOI that steps in that regard are being taken by the MEA. We had called upon UOI to place on record the detailed current status of the said imports, which was to be considered on 31.05.2021. The UOI was directed to indicate as to how the figure of 2,30,000 Vials for import was arrived at, and whether there is greater availability of the drug which could be imported.

2. The UOI has filed two status reports in this regard – one dated 31.05.2021 and the other dated 01.06.2021, which have been perused by us. What transpires from a reading of the said status reports is that, in fact, most of the probable sources from which 2,30,000 Vials of *Liposomal Amphotericin B* were to be sourced, have proved to be of no avail, and it appears that there are hardly any Vials coming from the sources from which it was expected that 2,30,000 Vials would be received. The UOI has, instead, disclosed a few other sources from which it is trying to procure small quantities of the said drug.

3. Mr. Mehra – learned senior counsel appearing for the GNCTD, has referred to the List of Documents (LOD) filed today. From the said LOD, it appears that as on today, there are 792 active cases of *Mucormycosis* (Black Fungus) in Delhi, out of which 191 cases are being treated at Central Government Hospitals in the NCT of Delhi. The allocation of the drug, i.e. *Liposomal Amphotericin B* for the Central Government Hospitals is made by the UOI separately. So far as the GNCTD is concerned, it has been made allocation of the drug for distribution for treatment of patients suffering from the said disease, who are in the Hospitals of GNCTD, or in the Private

Hospitals. As on 01.06.2021, there are 601 active cases of *Mucormycosis* (Black Fungus) in the NCT of Delhi (other than those being treated at hospitals of the Central Government). The break-up of the said cases is: in the Hospitals of the GNCTD – 209, and, – those being treated in Private Hospitals are 392.

4. The GNCTD has also disclosed the allocation of *Liposomal Amphotericin B* by the UOI for the said 601 patients, which is 1230 Vials. On this basis, the GNCTD has issued an order making the allocation on pro-rata basis. The distribution factor of 2.04658902 has been applied considering the allocation made by the UOI. Thus, it is seen that per patient, about 2 Vials have been made available. The said allocation is made by the GNCTD Hospital-wise, and it is left to the Hospitals to administer the said drug to the patients according to their own discretion.

5. Dr. U.B. Das, Senior Chief Medical Officer in the Directorate General of Health Services, Ministry of Health, Govt. of India has also joined the proceedings. He has informed us that *Liposomal Amphotericin B* is the drug of choice to treat *Mucormycosis* (Black Fungus) and the recommended dosage is 5 mg per Kg (of the body weight) of the said drug. Therefore, for a person weighing 60 Kgs, the patient would require about 300 mg of *Liposomal Amphotericin B* per day, which translates to six Vials of 50 mg each. The number of Vials administered on the patients could vary depending on the body weight, more or less. However, the average comes to about six Vials per patient per day. He also states that there is an alternate, namely, *Amphotericin B*, which has been used to treat *Kala Azar* for a couple of decades. However, he also states that plain *Amphotericin B*

is Nephrotoxic, i.e. it adversely affects the Kidneys and, therefore, the Kidney function of the patient – who has been administered *Amphotericin B*, needs to be monitored. He also states that there is yet another medicine, namely, *Posaconazole* – which can also be used to treat the patients of *Mucormycosis* (Black Fungus).

6. Mr. Venugopal, learned senior counsel, however, submits that according to his information – which he has gathered, there are limitations on the use of the aforesaid medicines, and adverse effects are reported on use of either plain *Amphotericin B*, or *Posaconazole*.

7. In the aforesaid background, some important questions which arise, and which can only be answered by the medical experts are the following:

- (i) Whether it is medically prudent to administer, to a patient suffering from *Mucormycosis* (Black Fungus), two Vials of the said medicine on a daily basis, if the advised dosage is six Vials per day, i.e. 300 mg per day;
- (ii) If a patient – due to shortage of the said medicine, is allocated only two Vials per day, what are the other medications which he could be administered in combination, if at all, to tide over the shortage, and cure the disease;
- (iii) Whether a patient – who is not administered the full required dosage of *Liposomal Amphotericin B*, is exposed to progress of the disease leading to loss of one, or the other, body part such as eyes and jaws, and possibly, eventual death;

(iv) Whether it would be medically prudent to identify patients who should be given the full doses of *Liposomal Amphotericin B*, so that their lives could be saved, even if it is to be at the expense of denying the said drug to another patient who may need the same? If so, what should be the basis for medical categorisation/ prioritization of the patients?

8. These and other related medical issues – which arise for consideration, can only be answered by an expert body like the ICMR. The shortage of *Liposomal Amphotericin-B* – not only in the NCT of Delhi, but even in the country has been continuing for over two weeks now. It is high time that the ICMR – which is statutory body constituted to lay down policy guidelines with regard to the medical treatment of patients suffering from various diseases, comes out with clear guidelines on the use of *Liposomal Amphotericin-B*, *Plain Amphotericin-B*, *Posaconazole*, etc. for treatment of *Mucormycosis* (Black Fungus), and also advises the Central Government on the classification of cases which should be prioritized for the purpose of administration of the various drugs, such as *Liposomal Amphotericin-B*, *Plain Amphotericin-B*, *Posaconazole* .

9. We take cognizance of the fact that on account of non-availability of the drug of choice, i.e. *Liposomal Amphotericin-B*, and lack of information with regard to other drugs which could be used for treatment of the said disease, if at all, a large number of mortalities are taking place all over the country, including in the NCT of Delhi. Despite best efforts, the availability of the said drug in the country remains acutely short as is evident from the facts and figures taken note of hereinabove. If the data placed before us

today is anything to go by, there is a shortage of about 66% even as per the present day requirement. The cases of *Mucormycosis* (Black Fungus) are showing an upward trend. The number of active cases of *Mucormycosis* (Black Fungus) as on 31.05.2021 was 753 in the NCT of Delhi, and the same has been registered at 792 today, i.e. increase of 39 cases in the last 24 hours.

10. From the status reports placed before us, it appears that the UOI has been making efforts to procure the said drug by getting in touch with the primary manufacturer of the said drug and patentholder Gilead through its associate/ subsidiary i.e. Mylan. The manufacturing capacity of several manufacturers in India has also been augmented, and fresh licenses have also been issued. There are issues with regard to availability of basic raw-material used for manufacture of the said drug and efforts are being made to source the same from abroad. However, the requirement of the *Liposomal Amphotericin-B* is far in excess of the availability of the said drug, and it is absolutely clear that the acute shortage of the said medicine shall continue for some time, at least, during which period many more lives would be lost to the said disease.

11. In this situation, in our view, the responsibility has fallen on the shoulders of the UOI to take a policy decision with regard to the manner in which the said drug should be made available to the suffering patients, till such time as the shortage of *Liposomal Amphotericin-B* continues, or an alternate equally effective and safe medicine is found for treatment of the said disease. If all patients suffering from the said disease cannot be treated on account of non-availability of the said drug in sufficient quantity, the

responsibility falls on the UOI to spell out its policy with regard to the priority of patients who should be administered the said drug, to maximize the lives that could be saved, amongst patients suffering from *Mucormycosis* (Black Fungus). Any such policy decision necessarily has to be taken with sufficient inputs from medical and legal experts. Administration of the said drug on patients who have better chances of survival may have to be prioritized. Similarly, within the group of patients who have same or similar chances of survival, patients who are younger and who hold the promise to run the nation in future, may have to be prioritised in comparison with the older generation which has lived its life and on whom others may not be as dependent financially. While so observing, we are, not for a moment, discounting the emotional and psychological support that the older generation provides to families, particularly, the Indian families who are so closely bonded. However, in times like these, practical choices have to be made, and should be made by the State. The learned Amicus has prepared a tabulation of how other countries have approached similar situations and prioritized patients falling in different categories for the purpose of treatment. The said tabulation shall be shared with both the GNCTD and the UOI as the same may assist the Central Government in creating the categories and priorities for the purpose of treatment of the disease in question.

12. We, therefore, direct the UOI to frame a policy with regard to administration of *Liposomal Amphotericin-B* and other drugs as aforesaid, amongst the patients who are suffering from the said disease and once the policy is made, on the basis of the said policy, allocation should be made by

the UOI since it is calling for information on its portal from all over the country of all the patients who are suffering from the said disease.

13. We may also observe that there may be a category of persons who are serving the nation in high positions and whose safety and security may be necessary in view of the pivotal role that they play in the administration of the country. While formulating its policy, the UOI should carve out such exceptional cases for good reasons. Looking to the urgency of the situation, we direct the UOI to place their status report in this regard, which shall be considered on Friday, i.e. 04.06.2021.

14. Mr. Ahluwalia – who appears on behalf of the ICMR, takes note of the order passed and states that he shall ensure that the order is placed before the ICMR for compliance. The ICMR shall also place its report which shall be considered on 04.06.2021.

15. List on 02.06.2021.

VIPIN SANGHI, J

JASMEET SINGH, J

JUNE 01, 2021

B.S. Rohella/ K.D.