
IN THE HIGH COURT OF JUDICATURE AT BOMBAY NAGPUR BENCH : NAGPUR

Suo-Motu P.I.L. No.4 of 2020

(Court on its own motion vs. Union of India and Ors.)

with P.I.L. No.10 of 2020

(Subhash Jainarayan Zanwar vs. Union of India and Ors.)

with

P.I.L. No. 25 of 2020

(Advocate Kamal s/o. Lakhmichand Satuja .vs. Union of India and Ors.)

office Notes, Office Memoranda of Coram, ppearances, Court's orders of directions nd Registrar's orders	, Court's or Judge's orders
	 Mr.S.P.Bhandarkar, amicus curiae for petitioner. Mr.U.M.Aurangabadkar, ASGI for respondent no.1. Mrs. Ketki Joshi, G.P. Mr. D.P. Thakare, Add G.P. & Mr. N.S. Rao, A.G.P for respondent nos. 2, 5, 6, 8 9. Mr.S.M.Puranik, Advocate for respondent no.4. Mr.B.G.Kulkarni, Advocate for respondent no.10. Mr.C.S.Samudra, Advocate for Intervenor/applicant (C No.5775 of 2021 & 692 of 2020 in PI.L. No.4 of 2020). Dr. Tushar D. Mandlekar with Mr. Rohan Malviya, Advocat for respondent No.13 - Dr. Shishir Kolhe – Intervenor. Dr.PK.Arora, in-person in CAO No.723 of 2021. Mr.Nam Heda, Advocate for Railways. (Ms Sushma Advocate for Respondent No.1 & Mr.J.B.Kas Advocate for Respondent No.4 in PI.L. No.25 of 2020). Mr. Nitin P. Lambat, Advocate for Intervenor. Mr. Vaibhav Bhure, Advocate for Intervenor. Mr. Aditya Goyal, Advocate for Intervenor. Mr. S.S. Sanyal, Advocate for Maharashtra Pollution Con Board. Mr. V.R. Bhute, Law Officer, Collector Office, Nagpi present. Mrs. Mugdha Chandurkar with Mr. Rohan Chandurka Advocates for W.C.L. Mr. Arun Agrawal, Advocate for intervenor.
	CORAM : SUNIL B. SHUKRE & AVINASH G. GHAROTE, JJ. DATE : 2.5.2021.

Heard.

2. Add all the seven pharmaceuticals companies, through their respective Directors and Vidarbha Industries Association, Nagpur through its President as necessary party / respondents and notices be issued to them forthwith through e-mail and also through their local agents, distributors and stockists.

3. We direct the Joint Commissioner, F.D.A., that notices Nagpur ensure to these to pharmaceuticals companies are served upon them through the local agents, distributors, dealers and stockists with a further direction to place on record compliance report. In the notices, it should be mentioned that Vidarbha Industries Association, Nagpur shall submit to this Court all details about the names of the companies having in their possession number of oxygen cylinders and also other infrastructural facilities necessary for production, storage, distribution and supply of oxygen to various hospitals in Vidarbha region.

4. In the order dated 1st May, 2021, in paragraph 12, we had directed the Collector, Bhandara to send the request letter to Tirora Thermal Power Station for making available CSR funds for Covid cause. Since this thermal power station is situated within the jurisdiction of Gondia District, the direction is modified and now it is directed that such request shall made by District Collector, Gondia. The request to be made by Collector, Gondia shall be for making available CSR funds of said company for the districts of Gondia, Bhandara and Nagpur. The order dated 1st May, 2021 stands modified accordingly.

5. The Central Government, by fresh order issued on 1st May, 2021, made state-wise allocation of Remdesivir vials for next 10 days effective from 1st May to 9th May, 2021, which appears to be in continuation of such state-wise allocation made earlier as per the order dated 24th April, 2021, which was effective from 21st April, 2021 to 30th April, 2021. On going through the fresh allocation order, we find that for the period of next 10 days i.e. from 1st May 2021 to 9th May, 2021, there is actually reduction in of Remdesivir vials allocation to State of Maharashtra. In the earlier period of 10 days, the allocation was of 435000 vials and in the new period of 10 days the allocation is 374500. This means there is reduction of allocation of Remdesivir vials by 60500 to State of Maharashtra.

6. According to us, such reduction of Remdesivir vials to State of Maharashtra is not consistent with the reduction in number of active cases in the State of Maharashtra. On 30th April, 2021, the number of active cases in Maharashtra was 672000 and as of 1st May, 2021, the number of active cases was 664000. That means there is a reduction of number of active cases by hardly about 1.2% and

whereas the reduction in allocation of the vials to State of Maharashtra for the aforestated period is by about 14.5%. This mismatch needs to be reconsidered and removed by the Central Government.

7. We have heard Shri Aurangabadkar, learned A.S.G.I. on this issue. He has stated that he would seek instructions from the Central Government about this matter and he will get back to the Court on receiving of the information on the next date. Of course, instructions of the Central Government on this issue would have to be sought and we request the learned A.S.G.I. to do the same and revert back to the Court on the next date of hearing.

8. Meanwhile, we would request the Central Government to reconsider it's decision making state-wise allocation for the aforestated period of 10 days and increase the allocation so as to make it consistent with the reduction of number of active cases in the State of Maharashtra.

9. Shri T.D. Mandlekar, learned Advocate for respondent No.13 and Shri S.P. Bhandarkar, learned *Amicus Curiae* submits that the Central Government needs to give its second thought to the considerations which are presently weighing with it while making the state-wise allocation of Remdesivir vials. According to them, one of the most important considerations that must be taken into account by the

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Central Government is of percentage of share of each of the States in the national figure of active case load. They submit that if at a given point of time, as for example, share of State of Maharashtra in active case load of nation-wise cases is say about 20%, the State of Maharashtra should be getting 20% of the total Remdesivir vials produced in a period of 10 days by these 7 manufacturing companies. According to them, the state-wise allocation made by the Central Government, for the present, does not reflect consideration of this important aspect of the issue.

10. Shri Mandlekar, learned Advocate for respondent No.13 further submits that even if the direction is issued to the Central Government for allocation of Remdesivir vials to the State of Maharashtra by taking into consideration the share of State of Maharashtra in nation-wise case load, it is not necessary that granting more allocation to State of Maharashtra would result in reducing the allocation already made to the other States for the that production capacity of all 7 reason manufacturing companies is much more than what has been reflected in the order dated 1st May, 2021.

11. As of now, we do not have any figures of the actual production of Remdesivir vials by all the 7 manufacturing companies. Besides, if any direction as is suggested is to be passed by this Court at this juncture, there is a possibility of the direction having it's trans-border impact, and that too, without knowing anything about the larger scenario. Therefore, we are of the view that this issue can be best decided only by the Central Government and at the apex level of judicial system of India and as such we do not think it appropriate to issue any such direction. At the most, we can make a request and which we do make to the Central Government to appropriately consider the submissions which are reproduced above.

12. The primary purpose of holding this emergency hearing today was to ensure compliance with our directions regarding supply of Remdesivir vials by way of interim relief to Nagpur city and districts of Akola and Bhandara, as per the order dated 30th April, 2021.

13. Now, a pursis has been placed on record on behalf of respondent No.2. It shows that in all 19128 Remdesivir vials have been actually received by Nagpur till this time and 960 more vials are going to be received from Zydus Cadila company by today evening. If these 960 vials are received by today evening, it would complete the compliance with our order dated 30th April, 2021. About 19128 Remdesivir vials which are already received, we direct respondent No.2 to ensure that these vials are distributed amongst Nagpur city, Bhandara and Akola districts, as per our specific directions issued by order dated 30th April, 2021 and this shall be done immediately and forthwith.

14. We have also noticed that everyday the vials that are being sent to different districts of Maharashtra are almost always in short supply of the number of vials that should have been delivered to each of the districts as per district-wise allocation made by Commissioner, vide order dated 30th April, 2021.

15. Today Shri Parimal Singh, Commissioner, F.D.A., State of Maharashtra is virtually present. He informs the Court that F.D.A. is making all out efforts to ensure that pharmaceutical companies fulfill their quota of supply on daily basis to the State of Maharashtra, but somehow or the other, there invariably remains a shortfall in the supply that all the pharmaceutical companies make. He further informs the Court that as per the billed quantity of the supplies as of 1st May, 2021 the shortfall in so far as State of Maharashtra is concerned is 143034 vials. He submits that these pharma companies are required to clear this backlog of vials and also continue to supply vials in accordance with the quota already fixed by the Central Government by it's two orders dated 24th April, 2021 and 1st May, 2021. In addition, submits that the Department of Disaster he Management, Relief and Rehabilitation has also issued an Expression of Interest, dated 27th April, 2021 for supply of 1000000 vials of Remdesivir and from out of such EOI dated 27th April, 2021, so far that Department has received, as per the information given to him, 20500 vials.

16. S.P. Bhandarkar, learned Amicus Mr. Curiae, on instructions, submits that actually the EOI was a global tender issued for inviting bids to supply 1000000 Remdesivir vials, 25000 metric tons of oxygen and 40000 oxygen concentrators. If this is so, it would clearly lead to two conclusions. Firstly, there is no need to mix up the Remdesivir vials which would be supplied eventually under the EOI with those that must be supplied as per orders of the Central Government. Secondly, the EOI being about a global tender should not come in the way of the State Government in it's effort to implement the order of this Court to centralize the whole system of procurement from Seven Indian Pharmaceutical Companies, and then the allocation, distribution and supply of Remdesivir drug within the State, which would be based upon the orders issued from time to time by the Central Government, if any. For this purpose, there is a need for the State Government to take urgent steps in the matter, which have not been done so far. We, therefore, we direct the Chief Secretary, State of Maharashtra to take immediate steps in this regard and centralize the whole process and whole system of procurement from seven pharmaceutical companies of Remdesivir vials and their distribution among all districts in accordance

with the orders of the Central Government. In fact, we have already directed the State to do so earlier, and when done there would be induced in the system a strong element of order which would go a long way in removing the chaos that is prevailing in the system as of now.

17. Now that a fresh order has been received from the Central Government, issued on $1^{\,\rm st}$ May, 2021 making a fresh State wise allocation in which, as already stated, the share of State of Maharashtra for a period of ten days is of 3,74,500 vials, it would be necessary for the State to issue district-wise allocation order afresh effective for next ten days starting from 1st May, 2021 and ending on 9th May, 2021. The earlier district-wise allocation order was issued by the F.D.A., State of Maharashtra. But considering the responsibility of Health Ministry and the control that it exercises and also the fact that at present there is no centralized procurement of Remdesivir drug, it would be necessary, just to avoid confusion and chaos that the district wise allocation order is issued by the Health department in consultation with the F.D.A., State of Maharashtra and the present procurement agency, if any. Accordingly, we direct the Health Secretary/respondent no.2 to issue a fresh district wise allocation order of Remdesivir vials based upon the order of the Central Government dated 1.5.2021 which should be effective for a period from 1st May, 2021 till 9th May, 2021. The order shall be issued within 24 hours from today and it shall be uploaded on the website of Health Ministry and also on the website of F.D.A., State of Maharashtra. This system would be in operation till the whole process of procurement, allocation and distribution of Remdesivir vials is centralized by the State of Maharashtra. Once such centralization takes place, the State of Maharashtra would have to consider modifying this system appropriately.

18. We would also direct that now no pharmaceutical company which is duty-bound to supply Remdesivir vials in accordance with the orders of the Central Government dated 24th April, 2021 and 1st May, 2021 to State of Maharashtra, shall supply Remdesivir vials to private purchasers in the State unless the daily quota of the supply allocated to each of the pharmaceutical companies for Maharashtra is first fulfilled by every pharmaceutical company and if there remains any balance of Remdesivir vials thereafter, then only the concerned pharmaceutical company shall supply those vials to the private purchasers in the State in fulfillment of the orders that they have received from them. We further direct the Secretary, Health of the State of Maharashtra and Commissioner, F.D.A., State of Maharashtra to ensure that these directions are scrupulously followed by every pharmaceutical company and in case it is seen that there is any violation committed by any of the pharmaceutical companies, we further direct that the erring company shall be prosecuted under the relevant provisions of law for violating the directions of this Court and jeopardizing the precious human life. For this purpose, it would also be necessary that each of the pharmaceutical companies submits on daily basis it's production figures to State of Maharashtra and also upload those production figures on their respective websites. We direct all the 7 pharmaceutical companies to send their production figures to Commissioner, F.D.A., State of Maharashtra and also upload the same on their respective websites. Any violation committed in this regard would be viewed seriously and would be liable for prosecution under appropriate criminal law.

19. We request Commissioner, F.D.A., State of Maharashtra to send copy of the order to each of the pharmaceutical companies for the information and due compliance and on receipt of copy of this order, acknowledgment of the receipt thereof shall be issued by each of the pharmaceutical companies.

20. We further direct the F.D.A., State of Maharashtra to:-

(a) Upload on daily basis all the figures pertaining to production of Remdesivir drug and also other drugs received by it from all the pharmaceutical companies.

(b) Upload on it's website the order making ten days or weekly district wise distribution of Remdesivir vials.

(c) Upload on it's website the number of vials actually received by it and the backlog on a given date.

All this information shall be uploaded on daily basis.

21. We may remind here the State that when it implements our direction to centralize the whole process of procurement, allocation and distribution of Remdesivir vials, it shall ensure that there is only one single entity which is responsible for the entire process starting from procurement and ending with distribution and delivery of Remdesivir vials. This is necessary to avoid confusion, creation of backlog and misuse of Remdesivir vials.

22. As regards compliance with our order dated 30.4.2021 directing the State to supply 20000 vials to Nagpur City, Akola and Bhandara, we find that same has been substantially complied with and it would be fully complied with by today evening. But, we must say it here that such compliance is only in respect of an order which was in the nature of an interim relief. The backlog nevertheless continues to trouble these places and also other districts of Vidarbha region and therefore, it is necessary that further direction is issued to the State as well as F.D.A., State of Maharashtra and seven Pharmaceutical Companies to ensure that there is supply and delivery of Remdesivir vials on daily basis for catering to the needs of the Covid patients in Vidarbha region and of course in the entire State of Accordingly, we direct the State of Maharashtra. Maharashtra, in particular the Secretary of Health and F.D.A., State of Maharashtra to ensure that every day the seven Pharmaceutical companies supply and actually deliver Remdesivir vials, by removing the backlog, in accordance with the supply quota earmarked for each of them on daily basis for a period from 21.4.2021 to 9.5.2021. We further direct the State of Maharashtra to hold responsible the Pharmaceutical Companies if they or any of them commit any default in fulfilling the supplies as fixed for each of them on daily basis by covering the aforesaid period, by the Central Government and if necessary, to take coercive action against the concerned Pharmaceutical Company. We also direct all the seven Pharmaceutical Companies to adhere to the daily quota of supplies fixed for them by the Central Government as regards the State of Maharashtra and if we find that any default is committed by any of the Pharmaceutical companies without any proper justification, serious coercive action would be taken against the defaulting company. If there is any difficulty in making delivery of Remdesivir vials on daily basis and also in removing backlog on account of transportation, same shall be taken care of adequately by the State of Maharashtra. If necessary, the State of Maharashtra

shall make arrangement for air-lifting of Remdesivir vials from the production facilities of the Pharmaceutical companies and then their delivery to every district through fastest mode of transportation. We further direct the State to see that henceforth no gap is created in the demand and supply in terms of the Central Government Order dated 24th April, 2021 and 1st May, 2021 in this regard.

23. If any of the pharmaceuticals companies difficulty in sending Remdesivir vials has in accordance with the aforestated Central Government orders, on account of non-placing of supply orders by the State of Maharashtra with the pharmaceuticals companies, we would direct them to not wait for receipt of any such supply orders from the State Government for the reason that placing of supply order is a part of completion of the formalities and the formalities can always be completed even after have made actual supplies been by the pharmaceuticals companies. Nevertheless, we would direct the State of Maharashtra, through Health Ministry and also F.D.A., State of Maharashtra to immediately place supply orders with all the pharmaceuticals companies to enable them to send the vials in accordance with the quota of supply fixed for each of them by the Central Government. For this purpose, the State of Maharashtra may exercise its power under Section 2 of the Epidemic Disaster Act, 1987 read with Section 65 of the Disaster Management Act, 2005 and may also do away with tender procedure. As regards the purchase price of the Remdesivir vials, an appropriate decision must be taken by the State of Maharashtra, which may include the decision to purchase these vials at the permissible MRPs. This shall be done within 48 hours from today.

As regards setting up of Central Control 24. Room, we had already issued necessary directions in the matter. In continuation of those orders, now we direct that the Central Control Room should be set up jointly by the District Collector, Nagpur and the Commissioner, Nagpur Municipal Corporation by exercising their powers under Section 2 of the Epidemic Diseases Act, 1897 read with Section 65 of the Disaster Management Act, 2005. The order that would be issued jointly by these authorities shall name the members of the Central Control Room, which could be officers from different department of Government and doctors enlisted from IMA and VHA. These members shall be divided into different teams, with each team overseeing and deciding on every aspect of Covid management in Nagpur city and District, from bed allocation in every hospital, private or Government, through distribution of all essential drugs including such as Remdesivir and Tocilizumab to distribution of oxygen and Covid essentials. The Central Control Room would be manned by these teams 24 hours X 7 days. The order to be issued shall also include the scope of work of the teams that

would be forming part of Central Control Room. The teams working at the Central Control Room shall be assisted by officers and men deployed in the field and a decision in this regard would also have to be taken jointly by both these authorities. The names of the officers and other persons deployed in the field to assist the Central Control Room on 24 hours X 7 days basis shall also be mentioned in the joint order. Both these authorities may adopt the model devised by Mumbai Municipal Corporation under the leadership of its Commissioner Mr. Iqbal Singh Chahal. For issuance of this order, assistance may be sought from the legal experts including the learned Government Pleader. Once such a common order is issued, we make it clear that it would be mandatory for all hospitals, whether Government, Zilla Parishad or private or Society or Trust hospital, to abide by the same and any reluctance or disobedience shown in respect of this order shall be viewed seriously by this Court.

25. Stand over to 5th May, 2021 at 12:00 Noon.

<u>JUDGE</u>

JUDGE