(2023) 03 DEL CK 0043

In the Delhi High Court

Case No : CONT.CAS(C) No. 415 Of 2022, Civil Writ Petition No. 11610 Of 2017, 2943, 5315, 10782 Of 2020, 322, 1491, 1511, 1611, 3662, 3682, 3689, 3706, 3707, 3729, 3737, 3859, 4045, 4067, 4259, 4304, 4551, 4812, 5394, 5395, 9684, 14317 Of 2021, 1182 Of 2022 , 1054,

Master Medhansh Jhawar @ Madhav Through His Natural Guardian — APPELLANT

Vs

Rajesh Bhushan & Ors. — RESPONDENT

Date of Decision : 06-03-2023

Acts Referred:

Citation : (2023) 03 DEL CK 0043

Hon'ble Judges : Prathiba M. Singh, J

Bench : Single Bench

Advocate : Rahul Malhotra, Tanya Kumari, Shyel Trehan, Rohan Poddar, Shivalika Rudrabatla, Kirtiman Singh, Vidhi Jain, Rajiv Manjhi, Divyam Nandrajo, Mayank Kamra, Tanveer Oberoi, Jaswinder Singh, Dr. Madhulika Kabra, Dr. Shefali Gulati

Judgement

Prathiba M. Singh, J

1. This hearing has been done through hybrid mode.

2. The present batch of petitions has been filed by the Petitioners who are mostly children suffering from Rare Diseases. The case of the Petitioners is that medicines and therapies for the said diseases are exorbitantly expensive. These matters have been heard by the Court from time to time and various directions have been issued for enabling treatment and making medicines available to the Petitioners.

3. On the last date of hearing, Mr. Rajiv Manjhi, Joint Secretary, Ministry of Health and Family Welfare and a team of doctors from AIIMS had appeared before the Court and various submissions were made about clinical trials and the amount that can be released per patient. Since the hearing was inconclusive on the said date, the Court had issued the following directions:

"8. Today, the hearing was inconclusive. In order to have an effective further hearing the following directions are issued:

(i) The team from AIIMS who is present before the Court today shall place on record a complete chart of all the clinical trials in which AIIMS is involved for the two medical conditions i.e. DMD and Gaucher. The said chart shall deal with the feasibility of enrolment of all the Petitioners in the said clinical trials.

(ii) The DCGI shall also place on record a complete chart of all the trials which have been approved or are pending approval in respect of DMD and Gaucher.

(iii) The Ministry of Health and Family Welfare, Union of India shall specifically consider the case of Alishba Khan who has already started treatment for DMD but her treatment has been stopped due to non-release of further funds and place its stand on record on the next date of hearing.

(iv) All officials from DCGI, Ministries, lawyers and doctors from AIIMS shall appear physically on the next date of hearing as due to the large number of issues and the number of lawyers appearing, a virtual hearing is not feasible."

4. In view of the directions passed on the last date, today, a Report dated 4th March, 2023 has been handed over to the Court by ld. Counsel for AIIMS. The Report states that the following studies/ trials are currently being undertaken in relation to rare diseases in India:

1. By Sarepta Therapeutics pertaining to Duchenne Muscular Dystrophy (DMD).

2. By PTC Therapeutics pertaining to DMD.

3. By Shaare Zedak Medical Center, Israel pertaining to Gaucher disease.

5. The Report, thereafter, goes on to assess the eligibility of children before the Court in participating in the said clinical trials. Dr. Kabra and Dr. Shefali Gulati, who are present in Court, submit that, the four candidates who were found to be eligible to be included on a preliminary assessment are Aviraj Garg, Shourya Maru, Chirag and Aarav Garg.

6. It is the submission of Dr. Gulati that insofar as Aviraj Garg is concerned, he has already been included in the clinical trials of Sarepta. Insofar as the other three candidates are concerned, Dr. Gulati submits that they have been preliminary examined over video conferencing and assures the Court that they would be physically examined and the requisite tests shall be conducted on 9th March, 2023.

7. On the said date, the said Petitioners shall also be informed of the fact that if they are agreeable to participate in the trials, then the medication for the duration of the trial cannot be administered upon them. Let the three candidates appear before Dr. Gulati on 9th March, 2023.

8. Let the assessment be carried out and upon being counselled of the above-mentioned fact, the parents and candidates who give their consent may be

accommodated in the trials.

9. On behalf of the Drug Controller General of India (DCGI), Mr. B.K. Samantrai, Deputy Drug Controller submits that approval for 19 further subjects for the Sarepta clinical trial for DMD has been given by the DCGI on 2nd March, 2023. It is further submitted on behalf of DCGI that in respect of trial subjects who are enrolled in the trials, post-trial access shall be continued to be provided by Ms. PPD Pharmaceuticals Development (India) Ltd., which is the clinical research organization of Sarepta. As per the Additional Affidavit dated 6th March, 2023 filed on behalf of the DCGI, the permission that has been granted by the Central Licensing Authority to conduct clinical trials to Sarepta has been granted subject to Post-Trial Access being granted as per the provisions of New Drugs and Clinical Trial Rules, 2019.

10. At this stage, it is submitted on behalf of Master Ayushman Chaturvedi, Petitioner in W.P.(C) 5395/2021 that he may be physically examined and his candidature may be considered for the clinical trials as the preliminary assessment had been carried out on a video call. Dr. Gulati to do the needful qua Master Ayushman Chaturvedi as well.

11. Mr. Rajiv Manjhi, Joint Secretary, Ministry of Health and Family Welfare, who is present in Court, submits that as per the OM dated 19th May, 2022, cap of Rs.50 lakhs has been fixed for patients in respect of anyone suffering from rare diseases. On the other hand, from the submissions made by Dr. Kabra and Dr. Gulati, it appears to the Court that the expenses that would be required for the treatment per patient per year would range anything between 20 lakhs to around Rs.7 crores per year.

12. Considering the large number of children who are before the Court, this Court had by previous orders directed BIRAC to hold a meeting with DART in order to explore the possibility of government funding for clinical trials for the development of indigenous therapies qua rare diseases. On 15th February, 2023, the Court was informed that no consensus could be reached between BIRAC and DART in respect of funding of clinical trials. Accordingly, the Court had referred the matter to the Secretary, Ministry of Health and Family Welfare. The relevant portion of the order reads as under:

"4. Today, minutes of the meeting held on 2nd February, 2023 have been handed over to the Court. Unfortunately, the minutes of the meeting show that there has been no progress whatsoever in respect of the directions issued by the Court. A perusal of the minutes shows that BIRAC is bound by the Biotechnology Industry Partnership Programme (BIPP) under which the Grant-in-aid Letter Agreement was entered into with Hanugen Therapeutics Pvt. Ltd. The stand taken by BIRAC is that it is mandatory for Hanugen to contribute 50% of the total project cost.

5. In view of this position, the Court is of the opinion that the matter would have to be now referred to the Secretary, Ministry of Health and Family Welfare (MH&FW) to take a decision in respect of clinical trials that are to be conducted

for testing the therapies for rare diseases including DMD."

13. In view of the order passed by the Court on 15th February, 2023, an OM dated 28th February, 2023, has been issued which states as under:

"2. In this regard, it is stated that as per para 12(b) of the National Policy for Rare Diseases(NPRD), 2021, National Consortium can be provided with an expanded mandate to include research & development, technology transfer and indigenization of therapeutics for rare diseases. It will be convened by Department of Health Research (DHR) with ICMR as a member. As envisaged in the policy, Department of Health Research has established the National Consortium for Research and Development on therapeutics for Rare Diseases vide Order dated 08.10.2021 (Copy enclosed). The National Consortium has the National Apex Committee with the Secretary, DHR & DG, ICMR as the Chairperson, Prof. IC Verma, Advisor, Ganga Ram Hospital Delhi and Dr. Madhulika Kabra, Dept. of Paediatrics, AIIMS, Delhi as Clinical Geneticist, representatives from scientific Departments as the members, experts, and other stakeholders. The Secretariat of the Consortium is housed under Basic Medical Sciences Division which is responsible for the data management and coordinate various activities under the Consortium. The Terms of Reference of the Consortium inter alia include the following:

i. The National Consortium for Research and Development on therapeutics for Rare Diseases (NCRDTRD) shall have the mandate to include research & development, both basic and translation, technology transfer and indigenization of therapeutics for rare diseases.

ii. Ensure facilitation of an integrated research pipeline to promote the development of new drugs, for which pharmaceutical companies would be encouraged and research organizations as well as funding agencies would be involved in this important endeavour.

iii. Seek outputs and outcomes from Nidan Kendras & Centre of Excellence (COE) under the various activities in rare diseases wherever funding has been provided.

iv. Collaborate with concerned departments to promote local development and manufacturing of the drugs for rare diseases.

3. As may be seen above, the subject matter of clinical trials and its funding pertain to ICMR, DHR. In view of the aforesaid, the matter regarding clinical trial alongwith all the relevant Orders of the Hon'ble Court is referred to the Secretary, Department of Health Research (DHR) to take a decision in respect of clinical trials that are to be conducted for testing the therapies for rare diseases including DMD."

14. Mr. Manjhi also submits that the Department of Health Research (DHR) would be the appropriate department to take a decision in respect of funding for the clinical trials qua developing indigenous therapies for rare diseases in India.

15. As per the above OM, one National Consortium for Research and Development on Therapeutics for Rare Diseases, is stated to have been established by Department of Health Research vide order dated 8th October, 2021.

16. Since the DART trial has already been approved by the DCGI, considering the earlier arrangement which was there between BIRAC and Hanugen, it is deemed appropriate to refer the entire matter to the National Consortium which shall hold a meeting on clinical trials for developing indigenous therapies for rare diseases including DMD and Gaucher with DART/ Hanugen and place its recommendations before the Court in respect of the following issues:

i. Funding of clinical trials for development of indigenous therapies in respect of DMD and other rare diseases.

ii. The manner in which the order of this Court, directing releases of funds for treatment, dated 14th December, 2021 is to be implemented.

iii. The manner in which therapies have to be arranged for children with rare diseases, suffering either from DMD or other Lysosomal Storage Disorders.

iv. Let an affidavit be filed by the next date of hearing as to the various research and development activities carried out by the National Consortium/DHR till date in respect of rare diseases and their current status.

17. The National consortium is free to call any other entity or person, whom it deems appropriate and whose participation would be required to make effective recommendations. The recommendations would be comprehensive in nature and shall consider the following aspects:

i. The age of the children, whose life may be curtailed if the treatment is not commenced on priority.

ii. The expenses, which may be incurred if the medicines are to be provided to all the children which have approached the Centres of Excellence seeking treatment.

iii. The possibility and feasibility of exploring indigenous therapies in the already approved trials.

iv. Any negotiations or arrangements to be entered into with the companies, who already have approved therapies for administration to children with rare diseases in India.

18. In the said meeting of the National Consortium, other Centres of Excellence under the National Policy for Rare Diseases (NPRD) shall also be consulted on the estimate of candidates who may be requiring medicines and therapies across India and not just restricted to Delhi.

19. The meeting of the national consortium shall be held on or before 20th March, 2023 and a report shall be put up by the next date of hearing.

20. Insofar as AIIMS, New Delhi is concerned, since all the candidates who are Petitioners before this Court, have been called to AIIMS for commencing their treatment, let a status report as to the status of treatment of all the Petitioners be also filed by the next date of hearing.

21. Insofar as Ms. Alishba Khan, the Petitioner in W.P.(C) 2943/2020 is concerned, the Court on 15th February, 2023 was informed that her treatment has been stopped due to paucity of funds. On the said date, the Court had passed the following order:

"15. In the case of Ms. Alishba Khan, who is suffering from Gaucher, it is submitted by the ld. Counsel that medicines were being provided by AIIMS till January, 2023. However, thereafter, the treatment has been stopped. In response, it is submitted by ld. Counsel for AIIMS that the treatment had to be stopped as the funds received in respect of the said patient were exhausted.

16. Considering the fact that AIIMS, Delhi is recognised as a Centre of Excellence for treating rare diseases and is also the nodal centre of the Consortium of Centres of Excellence under the National Policy for Rare Diseases, 2021, and bearing in mind the large number of patients who have filed petitions before this court, for whom medicines are needed, it is directed that a sum of Rs.5 crores shall be immediately released by the Union of India to AIIMS, Delhi so as to ensure that the treatment of children, where it has already commenced, is not stopped due to lack of funds.

17. The said funds shall be released within a period of two weeks from today."

22. As can be seen from the order extracted above, the Ministry was earlier directed to release a sum of Rs.5 crores. On the last date of hearing, Mr. Manjhi had submitted that as per the Ministry's policy, only Rs.50,00,000/- can be released per patient. Today also, Mr. Manjhi reiterates his submission that since Rs.50 lakhs limit has reached, further amounts cannot be released.

23. Vide orders dated 14th December, 2021 and 1st February, 2022, directions were given by the Court to release funds for the medicines of the Petitioners. Relevant portion of the order dated 14th December, 2021 reads as under:

"5. In the light of the aforesaid stand taken by the respondent no.1 which shows that they have every intention to ensure that the children covered under the 'National Policy for Rare Diseases, 2021' get all the medical assistance they require, I am of the view that once it is an admitted position that petitioners are covered under the said policy promulgated by the respondent no.1 itself for the welfare of persons like the petitioners, they cannot be made to suffer. Any delay in commencement of their treatment may prove to be fatal and defeat the very purpose for which the abovementioned policy was created. I am therefore of the considered opinion that interim directions for commencement of treatment of at least the petitioners before this Court deserve to be issued. It is accordingly directed that the treatment be started forthwith by AIIMS or any of the other

Centres of Excellence, as the case may be, details of which Centres have been furnished by the Union of India in it's affidavit dated 28.09.2021. The names of these Centre of Excellence are also duly noted in the policy itself. The direction to AIIMS and the other Centres of Excellence to commence treatment of these children would also include a direction to them to provide the necessary medicines to these children, the cost whereof will be borne by the Union of India. It will be the responsibility of the Union of India to ensure that necessary funds are provided to all the Centres of Excellence, including AIIMS as and when demanded."

24. Relevant portion of the order dated 1st February, 2022, reads as under:

9. On the last submission of Mr. Luthra, Mr. Oberoi would submit that AIIMS is not in a position to utilise the annual budget sanctioned to the AIIMS, for the treatment of petitioners herein. He also states that insofar as the petitioners who are suffering from Non-DMD disease, they can be directed to report to the Chairman of Rare Diseases, Dr. Madhulika Kabra day after tomorrow, on which date they shall be attended to and the treatment shall be started. I must state here that the submissions made by Mr. Oberoi are not at all appealing. The order passed on December 14, 2021 is very clear that the treatment of the petitioners i.e., children must start immediately. It is surprising that even after a period of one month no treatment has yet started. Insofar as funds are concerned, the Court in the said order has clearly stated that it is the responsibility of the Union of India to ensure necessary funds are provided to all Centres of Excellence including AIIMS as and when demanded for treatment of these children."

25. These orders have also been upheld by the Supreme Court vide order dated 11th July, 2022, passed in SLP(C) Nos.10152-10174/2022 titled Union of India v. Master Arnesh Shaw.

26. Accordingly, Rs.5 crores as directed in order dated 15th February, 2023, shall now be released within one week, as an ad hoc amount subject to further orders. The treatment of Ms. Alishba Khan shall be commenced by the AIIMS immediately thereafter.

27. List on 13th April, 2023.

W.P.(C) 2614/2023

28. Issue notice.

29. The child in this matter, Master Karan, is suffering from DMD. Accordingly, it is directed that he also be examined on 9th March, 2023 i.e., Thursday by AIIMS along with other Petitioners. Insofar as his case is concerned, if the Board at AIIMS is of the opinion that his treatment ought to be commenced, let requisite steps in this regard be taken and recommendation be sent to the Ministry.

30. The status report to be filed by AIIMS in view of the directions given above shall be filed in his respect as well.

31. List on 13th April, 2023.

32. These are part heard matters.

