
(2023) 05 DEL CK 0205

In the Delhi High Court

Case No : 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, 1079, 2614, 4495, 4502, 4526,

Master Arnesh Shaw

APPELLANT

Vs

Union Of India & Anr.

RESPONDENT

Date of Decision : 29-05-2023

Acts Referred:

Citation : (2023) 05 DEL CK 0205

Hon'ble Judges : Prathiba M. Singh, J

Bench : Single Bench

Advocate : Rahul Malhotra, Shyel Trehan, Shivalika Rudrabatla, Asif Ahmed, Kirtiman Singh, Vidhi Jain, Ripudaman Bhardwaj, Kushagra Kumar, Ripu Daman Bhardwaj, Tanveer Oberoi, Dharmender Verma, Vishal Singh, Sheffali Gulati, Vishal Singh, Shantanu Garg

Judgement

Prathiba M. Singh, J

1. This hearing has been done through hybrid mode.
2. On the last date of hearing, the Court was informed that the second tranche of payment as per the Grant-in-aid Letter Agreement (GLA) has been arranged by Hanugen. In view of said submission, the Court had directed a meeting to be held between Hanugen, BIRAC, and the representatives of ICMR to decide the time table for the clinical trials for therapies for rare diseases in terms of the approved protocols.
3. Furthermore, in order to ensure that there is optimal coordination between the medical community, the providers of therapies and the governmental agencies, and to ensure that the Rare Diseases Policy, 2021 is implemented in an efficient manner, the Court had constituted the National Rare Diseases Committee (hereinafter "Committee"). The first meeting of the Committee was also fixed by the Court.

4. Ms. Vidhi Jain, Id. Counsel appearing on behalf of Union of India submits that meetings in view of the order passed by the Court were held and has placed on record the minutes of the following two meetings:

? Meeting between ICMR, BIRAC and Hanugen Therapeutics

? Meeting between National Rare Diseases' Committee

5. As per the minutes of the meeting dated 23rd May, 2023 involving ICMR, BIRAC and Hanugen, ICMR has, in principle, agreed to fund four clinical trial sites for the stages to be conducted by Hanugen. The said funding would include support for data monitoring, data management, quality assurance and regulatory support for Hanugen. The tentative timelines for the same, as stated in the minutes, are as under:

1. ICMR will complete review of the project through Project Review Committee and hold a meeting with site PIs by 30th June, 2023.

2. Hanugen will manufacture adequate amount of investigational drug manufactured in GMP approved site by 3rd week of July, 2023.

3. ICMR will release 1st year funds to the trial sites by 30th September, 2023.

6. A perusal of the minutes of meeting dated 25th May, 2023 of the National Rare Disease Committee, would show that the Committee has extensively discussed the manner in which rare diseases should be dealt with in India. The Committee has framed short-term goals, mid-term goals and long-term goals as also action points. For the present purposes, action points identified by the Committee are relevant and the same are set out below:

“(i) Dr. Madhulika Kabra was entrusted to collate list (similar to AIIMS, Delhi) of all patients of rare diseases treated under CoE. She was also asked to provide a comprehensive List of diseases, effective drugs, Drug cost, manufacture by 5th June, 2023.

(ii) M/s. Sarepta may be called for discussions before the Committee to chalk out ways as to how the drugs can be made available in the country.”

7. The next meeting of the Committee is scheduled to be held on 13th June, 2023 at 10:00 am.

8. In addition to the above, Ms. Jain, Id. Counsel submits that the Government has also contacted M/s Sarepta on 27th May, 2023. The Under Secretary to the Rare Disease Cell has written an email to the Senior Vice President of M/s. Sarepta stating that the Committee would like to have a meeting with Sarepta. She further submits, under instructions, that a reply dated 29th May, 2023 has been received to this email to the effect that Sarepta has agreed to have a virtual meeting with the Committee on 13th June, 2023.

9. Paragraph 22 of the order dated 15th May, 2023 highlights the urgency required in treatment in respect of those patients whose treatment has been

stopped due to lack of funding. The said paragraph shall be brought to the attention to the members of the Committee on the next date of meeting. For the purpose of ready reference, paragraph 22 of the order dated 15th May, 2023 is reproduced hereinunder:

“22. In addition to the above mandate, the immediate requirement of the patients whose treatment has been stopped due to lack of funding, and whose details have been captured in paragraph 16 of the order dated 3rd May, 2023 shall be taken up by the Committee on an urgent basis, so that the treatment can be re-commenced. The Committee would be free to contact the providers or manufacturers or distributors of the DMD therapies as also other therapies, in a manner to ensure immediate commencement of providing adequate doses for the said patients.”

10. Considering the urgency involved in the matter for patients who have already been provided treatment by AIIMS after procuring medicines from Sarepta, the Committee may discuss the best possible measures during its discussion with Sarepta in relation to the manner in which the treatment can be resumed for all these patients.

11. Accordingly, the Committee shall hold deliberations with M/s Sarepta for urgent procurement of the medicines and also the timelines by which the supplies can be made for the same.

12. Ld. Counsel for the Petitioner in W.P.(C) 2943/2020, i.e., Ms. Alishba Khan submits that she suffers from Gaucher disease, and treatment to the extent of Rs.50 lacs has already been provided to her.

13. The Committee shall also consider her case for continuation of further treatment and for the said purpose may also contact, Sanofi India if it deems necessary.

14. Issue notice in W.P.(C)s 7549/2023, 7553/2023 & 7644/2023. These are the petitions filed by children who are suffering from DMD. Let the said petitioners be examined under the supervision of Dr. Kabra and a report be placed on record as to the feasibility of providing them any treatment.

15. List for receiving of further reports on 10th July, 2023 at 3:30 pm.