

\$~18, 17 & 19 to 44

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
Date of Decision: 22nd December, 2022

+ **W.P.(C) 5315/2020 & CM APPL. 19189/2020**

MASTER ARNESH SHAW Petitioner

Through: Ms. Anchal Tiwari and Ms. Tripti Kapoor, Advocates. (M:9755427204)
Ms. Shyel Trehan, Amicus Curiae with Mr. Rohan Poddar, Adv (M:7044065747).
Mr. Asit Ahmed Advocate (M-9560995495)

versus

UNION OF INDIA & ANR. Respondents

Through: Ms. Nidhi Raman CGSC with Mr. Rudra Paliwal, Advocates
Mr. Ripu Daman Bhardwaj & Mr. Kushagra Kumar, Advocates
Mr. Tanveer Oberoi, Advocate for (AIIMS).
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor, Ms. Vidhi Jain, Ms. Kunjala Bhardwaj, Mr. Madhav Bajaj
Ms. Durge Shandini

(17) WITH

+ **CONT.CAS(C) 415/2022 & CM APPL. 18280/2022**

MASTER MEDHANSH JHAWAR @ MADHAV THROUGH HIS
NATURAL GUARDIAN Petitioner

Through: Ms. Anchal Tiwari and Ms. Tripti Kapoor, Advocates.
Ms. Shyel Trehan, Amicus Curiae with Mr. Rohan Poddar, Adv.
Mr. Jaswinder Singh Advocate (M-9811232066)
Mr. Rahul Malhotra Advocate

versus

RAJESH BHUSHAN & ORS. Respondent

Through: Mr. Kirtiman Singh, CGSC, Mr.
Waize Ali Noor, Ms. Vidhi Jain, Ms.
Kunjala Bhardwaj, Mr. Madhav Bajaj
Ms. Durge Shandini
Mr. Tanveer Oberoi, Advocates
(M:9958935556) Mr. Jaswinder
Singh, Advocate (M:9811232066)

(19)

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WITH
W.P.(C) 11610/2017 & CM APPL. 27637/2018, 44016/2022
FSMA INDIA CHARITABLE TRUST Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA AND ANR. Respondents

Through: Mr. Sameer Vashisht, ASC, Civil
GNCTD with Ms. Sanjana Nangia,
Advocates (M:8287936603).
Mr. Vijay Joshi, Sr. Panel Counsel of
UOI with Mr. Kuldeep Singh,
Advocate.
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(20)

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WITH
**W.P.(C) 2943/2020 & CM APPLs. 10227/2020, 10228/2020,
6633/2022**
ALISHBA KHAN Petitioner

Through: Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.
Mr. Rahul Malhotra Advocate

versus

UNION OF INDIA AND ORS. Respondents

Through: Mr. Anuj Aggarwal, ASC, GNCTD,
Ms. Ayushi Bansal, Mr. Sanyam Suri
and Ms. Arshya Singh, Advocates for

respondents no.2 and 4
(M:9891363718).

Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(21)

WITH

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W.P.(C) 10782/2020 & CM APPL. 33828/2020

AVIRAJ GARG, AGE 4 YEARS, THROUGH HIS NEXT FRIEND
AND NATURAL FATHER SH. ABHINAV GARG..... Petitioner

Through: Mr. Ashok Agarwal, Mr.Kumar
Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Amrita Prakash, CGSC and Mr.
Vishal Ashwani Mehta, Advocates
(M:9818667963).

Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(22)

WITH

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W.P.(C) 322/2021 & CM APPL. 812/2021

KESHAV SHARMA AGE 12 YEARS THROUGH HIS NEXT
FRIEND AND NATURAL FATHER
SANJEEV KUMAR Petitioner

Through: Ms. Archana Sachdeva, Advocates
(Mob No. 9818758576), Mr. Ashok
Agarwal, Mr.Kumar Utkarsh & Mr.
Manoj Kumar (M:9811101923)

Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Ajay Dignpaul and Mr. Kamal
Dignpaul with Ms. Swati Kwatra,
Advocates for UOI.

Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS)

(23)

WITH

+ **W.P.(C) 1491/2021 & CM APPLs. 4291/2021, 8671/2022**
MASTER MEDHANSH JHAWAR @ MADHAV Petitioner
Through: Ms. Anchal Tiwari and Ms. Tripti Kapoor, Advocates.
Ms. Shyel Trehan, Amicus Curiae with Mr. Rohan Poddar, Adv.
Mr. Rahul Malhotra Advocate

versus

UNION OF INDIA & ANR. Respondents
Through: Mr. Kirtiman Singh & Ms. Vidhi Jain, Advocates (M: 9999359235)
Mr. Tanveer Oberoi, Advocate for respondent (AIIMS).

(24)

WITH

+ **W.P.(C) 1511/2021 & CM APPL. 4331/2021, 8616/2022**
MASTER KENIT JHAWAR @ KESHAV Petitioner
Through: Ms. Anchal Tiwari and Ms. Tripti Kapoor, Advocates.
Ms. Shyel Trehan, Amicus Curiae with Mr. Rohan Poddar, Adv.
Mr. Rahul Malhotra Advocate

versus

UNION OF INDIA & ANR. Respondents
Through: Mr. Ghanshyam Mishra, Advocates (M: 9899794006)
Mr. Tanveer Oberoi, Advocate for respondent (AIIMS).

(25)

WITH

+ **W.P.(C) 1611/2021 & CM APPL. 4600/2021**
LAKSHYA KUMAR GOYAL, 8 YRS OLD, THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. VIPIN KUMAR Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae with Mr. Rohan Poddar, Adv.

versus
UNION OF INDIA & ANR. Respondents
Through: Mr. Bharathi Raju, Sr. Panel Counsel
UOI.
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(26) WITH
+ **W.P.(C) 3662/2021 & CM APPLs. 11103/2021, 25590/2021,
32504/2021**

PAYEL BHATTACHARYA Petitioner
Through: Mr. Ishaan Karki, Advocate.
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.
Mr. Aditya Chatter SEF with Mr.
Ishan Kanki, Advocates (M-
9582812402)

versus
UNION OF INDIA & ORS. Respondents
Through: Mr. Anuj Aggarwal, ASC, GNCTD,
Ms. Ayushi Bansal, Mr. Sanyam Suri
and Ms. Arshya Singh, Advocates for
respondents no.2 (M:9891363718).
Mr. Ripu Daman Bhardwaj (CGSC)
for UOI.
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(27) WITH
+ **W.P.(C) 3682/2021 & CM APPL. 11153/2021**
HARSHIT SONI, 16 YEARS OLD, THROUGH HIS NEXT
FRIEND AND NATURAL FATHER
SH. TIKAM CHAND SONI Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar.
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus
UNION OF INDIA & ANR. Respondents
Through: Mr. T.P. Singh, Sr. Central Govt.

Counsel for respondent no.1
(M:9971579687).

Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS)

(28)

WITH

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W.P.(C) 3689/2021 & CM APPL.11179/2021

DHANANJAY BHARDWAJ, 11 YEARS OLD, THROUGH
HIS NEXT FRIEND ND NATURAL FATHER
SH. AMIT KUMAR Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).

Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Sanjeev Uniyal, Mr. Dhawal
Uniyal, Mr. Sachin Chandela,
Advocates for R-1 (M:9560806614).

Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS)

(29)

WITH

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W.P.(C) 3706/2021 & CM APPL. 11229/2021

KHUSHWANT BHARDWAJ, 7 YEARS OLD,
THROUGH HIS NEXT FRIEND AND NATURAL
FATHER SH. NIKHIL BHARDWAJ Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar

Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS)

(30)

WITH

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W.P. (C) 3707/2021 & CM APPL. 11230/2021

AARAV GARG, 5 YEARS OLD, THROUGH HIS
NEXT FRIEND AND NATURAL

FATHER SH. VIVEK Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents
Through: Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS)
Mr. Siddharth Khatana R1/UIO (M-
9811132326)

(31)
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WITH
W.P.(C) 3729/2021 & CM APPL. 11269/2021
MANISH, 8 YEARS OLD, THROUGH HIS
NEXT FRIEND AND NATURAL FATHER
SH. PHOOL CHAND JAT & ANR. Petitioners
Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents
Through: Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS)

(32)
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WITH
W.P.(C) 3737/2021 & CM APPL. 11277/2021
SHOURYA MARU, 7 YEARS OLD,
THROUGH HIS NEXT FRIEND AND NATURAL
FATHER SH. KAMAL KUMAR MARU Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents
Through: Mr. Ranvir Singh (CGSC) for R-1.
Mr. Tanveer Oberoi, Advocate for

respondent (AIIMS).

(33)

WITH

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W.P.(C) 3859/2021 & CM APPL. 11647/2021

SIDDHARTH SWARNKAR, 9 YEARS OLD,
THROUGH HIS NEXT FRIEND AND NATURAL
FATHER SH. DINESH KUMAR SWARNKAR Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Anuj Aggarwal, ASC, GNCTD
with Ms. Ayushi Bansal, Mr. Sanyam
Suri and Ms. Arshya Singh Advocates
for R-1 to 5 (M:9891363718).
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(34)

WITH

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W.P.(C) 4045/2021 & CM APPL. 12213/2021

UTKARSH INDRAJIT PAWAR, 10 YEARS OLD, THROUGH HIS
NEXT FRIEND AND NATURAL FATHER SH. INDRAJIT
DAMAR PAWAR Petitioner

Through: Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.
Mr. Ashok Agarwal, Mr. Kumar
Utkarsh & Mr. Manoj Kumar

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Sanjeev Sabharwal, Sr. Panel
Counsel with Ms. Shweta, Advocate
for UOI.
Mr. Harish Kumar Garg, Advocate
for UOI (M:9810150029).
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(35)

WITH

- + **W.P.(C) 4067/2021 & CM APPL. 12306/2021**
ANSHU, 10 YEARS OLD, THROUGH HIS NEXT FRIEND
AND NATURAL FATHER
SH. NARENDRA KUMAR YADAV Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.
- versus
UNION OF INDIA & ANR. Respondents
Through: Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).
Mr. Sanjeev Sabharwal, SPC, (UOI)
Advocate (M-9810031680)
- (36) **WITH**
+ **W.P.(C) 4259/2021 & CM APPL. 12948/2021**
ISHAAN, 10 YEARS OLD, THROUGH HIS NEXT FRIEND AND
NATURAL FATHER SH. RAJVIR SINGH Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.
- versus
UNION OF INDIA & ANR. Respondent
Through: Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).
- (37) **WITH**
+ **W.P.(C) 4304/2021 & CM APPL. 13108/2021**
TANAV HANDOO, 6 YEARS OLD, THROUGH HIS NEXT
FRIEND AND NATURAL FATHER SH. AMIT
HANDOO Petitioner
Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar.

versus
 UNION OF INDIA & ANR. Respondents
 Through: Mr. Satya Ranjan (Sr. Panal Counsel)
 with Mr. Kautilya Birat, Advocates
 for UOI.
 Mr. Tanveer Oberoi, Advocate for
 respondent (AIIMS).

(38) WITH
 + **W.P.(C) 4551/2021 & CM APPL. 13949/2021**
 SHAURYA DAHIYA, 7 YEARS OLD, THROUGH HIS NEXT
 FRIEND AND NATURAL FATHER SH. SATBIR
 DAHIYA Petitioner
 Through: Mr. Ashok Agarwal, Mr. Kumar
 Utkarsh and Mr. Manoj Kumar,
 Advocates (M:9662778086).
 Ms. Shyel Trehan, Amicus Curiae
 with Mr. Rohan Poddar, Adv.

versus
 UNION OF INDIA & ANR. Respondents
 Through: Mr. Avnish Singh, (SCGC) and Mr.
 Aditya Vikram Dembela, Advocates
 Mr. Tanveer Oberoi, Advocate for
 respondent (AIIMS).

(39) WITH
 + **W.P.(C) 4812/2021 & CM APPL. 14844/2021**
 NIKHIL YOGENDERSINGH CHOUDARY, 17 YEARS OLD,
 THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH.
 YOGENDERSINGH P CHOUDARY Petitioner
 Through: Mr. Ashok Agarwal, Mr. Kumar
 Utkarsh and Mr. Manoj Kumar,
 Advocates (M:9662778086).
 Ms. Shyel Trehan, Amicus Curiae
 with Mr. Rohan Poddar, Adv.

versus
 UNION OF INDIA & ANR. Respondents
 Through: Mr. Ranvir Singh (CGSC) for R-1.
 Mr. Tanveer Oberoi, Advocate for
 respondent (AIIMS).

(40) WITH
+ **W.P.(C) 5394/2021 & CM APPL. 16683/2021**
UDAYVEER SINGH GULERIA, 7 YEARS OLD, THROUGH HIS
NEXT FRIEND AND NATURAL FATHER SH. RAMESH
GULERIA Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR. Respondents

Through: Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(41) WITH
+ **W.P.(C) 5395/2021 & CM APPL. 16686/2021**
MASTER AYUSHMAN CHATURVEDI Petitioner

Through: Mr. Anurag Ojha, Mr. Gautam
Barnwal & Mr. Kumar Abhishek,
Advocates (M-8969011590)
Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ORS. Respondents

Through: Mr. Niraj Kumar, Sr. Central Govt.
Counsel for UOI.
Mr. Jawahar Raja, ASC (C), GNCTD
for respondent no.2.
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).
Mr. G.D. Sharma, Advocate for
Respondent no.4.

(42) WITH
+ **W.P.(C) 9684/2021**
AADHYAN JAISWAL 11 YEARS OLD THROUGH HIS NEXT

FRIEND AND NATURAL FATHER SH ANIL KUMAR
JAISWAL

..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ORS.

..... Respondents

Through: Mr. Divyam Nandrajog, Panel
Counsel, GNCTD, Mr. Mohd. Shahid
Khan, Mr. Bhriugu Pamidi Ghantam,
Advocate.
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).

(43)

WITH

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W.P.(C) 14317/2021 & CM APPL. 45148/2021

SHREYANSH AARAV, 11 YEARS OLD, THROUGH HIS NEXT
FRIEND AND NATURAL MOTHER SMT. KANCHAN
KAMINI

..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar
Utkarsh and Mr. Manoj Kumar,
Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Ripu Daman Bhardwaj (CGSC)
for UOI.
Mr. Tanveer Oberoi, Advocate for
respondent (AIIMS).
Mr. Lakshay Kumar Goyal v/s VOI &
ORS Ms. Bharathi Raju SPO with
Mr. Yogesh Panwar Advocates (M-
9868895906)

(44)

WITH

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W.P.(C) 1182/2022 & CM APPL. 3442/2022

INSHA MINOR THROUGH HER NEXT FRIEND AND

NATURAL FATHER SH IRSHAD AHMAD SOFI..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh and Mr. Manoj Kumar, Advocates (M:9662778086).
Ms. Shyel Trehan, Amicus Curiae with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ORS.

..... Respondent

Through: Mr. Sanjeev Uniyal, Mr. Dhawal Uniyal and Mr. Sachin Chandela, Advocates for R-1.
Mr. Tanveer Oberoi, Advocate for respondent (AIIMS).
Mr. Kirtiman Singh, CGSC, Mr. Waize Ali Noor, Ms. Vidhi Jain, Ms. Kunjala Bhardwaj, Mr. Madhav Bajaj
Ms. Durge Shandini

**CORAM:
JUSTICE PRATHIBA M. SINGH**

Prathiba M. Singh, J. (Oral)

1. This hearing has been done through hybrid mode.
2. The present batch of petitions have been filed by the Petitioners who are mostly children suffering from Rare Diseases. The case of the Petitioners is that the medicines and therapies for the said Rare Diseases are exorbitantly expensive, and directions ought to be issued to the Respondents i.e., the Union of India and its Ministry of Health and Family Welfare, All India Institute of Medical Science (hereinafter, "AIIMS"), as well as, the GNCTD, to provide continuous and uninterrupted treatment to the Petitioners, free of cost.
3. These matters have been heard by the Court from time to time and various directions have been issued for enabling treatment and for making

available medicines for the Petitioners.

4. Vide previous order dated 9th December, 2022, this Court had recorded the developments that have taken place to date in the matter. Ld. CGSC was also directed to obtain further instructions on the various aspects captured in the order dated 9th December, 2022.

5. Today, Mr. Kirtiman Singh, Id. CGSC has obtained instructions on the said aspects. A short note dated 22nd December, 2022 has also been handed over by the Id. CGSC covering the various aspects of the matter which are being continuously monitored by the Court. This Court has heard the Id. Counsels and perused the said short note. Let the same be brought on record.

Digital Crowdfunding Platform

6. Vide previous order dated 9th December, 2022, it was submitted that the crowdfunding platform is now operational. However, a need was felt for the said platform to be publicized in order to attract funding from the general public and corporate entities, including Public Sector Undertakings (“PSUs”). Accordingly, the following direction was issued by this Court, vide order dated 9th December, 2022:

“9. Accordingly, it is directed that the details of the crowdfunding platform be communicated by the Respondent No.1 to all the Navratna PSUs, as also, at least ten of the top business houses / private companies in India, so as to enable them to consider contribution to the said platform as part of CSR (corporate social responsibility) endeavours. There shall be proper follow up to this communication by the Respondent No.1. Any responses received to the said communication shall be placed on record.”

7. As per the short note dated 22nd December, 2022, it is submitted that the crowdfunding platforms are being publicized using proper and effective channels, in the following manner:

- A virtual meeting was held on 17th June, 2021 by the Ministry of Health and Family Welfare (hereinafter, “*MoH&FW*”), with the representatives of various Ministries, industrial associations, PSUs, etc., to sensitize them about the rare diseases and the need for voluntary donations for the treatment of patients with rare diseases;
- This Court is informed that, at the request of representatives of the various PSUs and industries, a clarification has been sought by the MoH&FW vide DO Letter dated 3rd August, 2021 and 13th June, 2022 in respect of the inclusion of the subject “Donation for Rare Diseases” in Schedule VII of the Companies Act, 2013, in order to facilitate industries/corporates to contribute easily under the Corporate Social Responsibility (CSR) provision contained in Section 135 of the Companies Act, 2013. The Ministry of Corporate Affairs is yet to revert on this aspect.

8. This Court is of the opinion that, in order to ensure that there is a specific recognition of voluntary donations for rare diseases, the subject “*Donation for Rare Diseases*” ought to be included in Schedule VII of the Companies Act, 2013, as requested by the MoH&FW.

9. Insofar as sensitization of PSUs, industry associations, etc. is concerned, it is submitted that, vide DO letter dated 30th September, 2022 addressed by the MoH&FW, the Department of Public Enterprises (hereinafter, “*DPE*”) has been requested to create such a programme to sensitize PSUs and regarding resource mobilization for rare diseases under

CSR fund of the companies. It is submitted that, in response to the said DO letter dated 30th September, 2021, the DPE vide its DO letter dated 10th October, 2022, has further requested the Ministry of Corporate Affairs to process the said proposal.

10. Accordingly, let the Ministry of Corporate Affairs file an affidavit as to the status of the request dated 3rd August, 2021 and 13th June, 2022 made by the MoH&FW, as also, the request dated 10th October, 2022 made by the DPE, by the next date of hearing.

11. Let the Department of Public Enterprises also file an affidavit as to the request dated 30th September, 2022 made by the MoH&FW, by the next date of hearing.

12. Ld. CGSC to communicate the present order to the Ministry of Corporate Affairs and the Department of Public Enterprises, to facilitate compliance.

13. In view of the submissions made today, it is clear to this Court that the efforts in respect of the digital crowdfunding platform have not yielded much result so far, as the issue of rare diseases does not appear to have gained enough importance in the society in general. Thus, MoH&FW shall consider publicizing the crowdfunding platform by alternative means, including through television and radio platforms, as also, social media platforms, in order to attract voluntary donations for the purpose of rare diseases. Any other steps which the Ministry deems fit, may also be taken.

Financial Assistance to Patients with Rare Diseases

14. It is submitted that the guidelines and procedure for providing financial assistance to patients suffering from rare diseases have also issued on 11th August, 2022 and communicated to all the Centres of Excellence

(hereinafter, “CoEs”). As per the said guidelines, the COEs have the option to explore the possibility of getting financial assistance from other agencies/drug manufacturers/corporate sector under CSR by signing an MoU. The content of the said MoU may be finalized by the Committee of the COE and approved by the Director of the COE.

Indigenous Development of Treatment, Therapies & Medicines for Rare Diseases

15. Vide previous order dated 9th December, 2022, this Court had recorded as under:

“15. Insofar as the indigenous development of treatment, therapies and medicines for rare diseases, especially DMD, is concerned, it has been pointed out that a Memorandum of Understanding dated 8th January, 2021 has been signed between the Biotechnology Industry Research Assistance Council (BIRAC) and M/s. Hanugen Therapeutics Private Limited (hereinafter, “Hanugen”). As per the said MoU, Hanugen was to conduct a multi-centric study for therapeutic evaluation in respect of DMD patients. In terms of the agreement, 50% of the fund for this study was to be contributed by the Government and the other 50% was to be contributed by Hanugen itself. The total approved amount was Rs.9.24 crores.

16. It is submitted by Ms. Trehan, the Ld. Amicus that the first tranche of Rs.1.41 crores was released. The same was matched by Hanugen. However, for the remaining tranches, there is shortage of funds.

17. The representatives of Hanugen have appeared before the Court virtually. They have stated that Phase 2-3 trials of the therapy have been approved by DCGI, and they have enrolled 54 patients for conducting the said trials. However, the commencement of the said trials has been delayed due to lack of funds.

18. In the opinion of this Court, DMD is a rare

disease which is prevalent in a considerable number of patients in India. The indigenous development of therapies for DMD is extremely crucial in order to avoid import of expensive medication. The medication for DMD is currently not manufactured and also not easily available in India. The same is, in fact, imported from the USA. Thus, the trials, which have already been approved, ought to be allowed to be completed. If the same prove to be successful, there could be the possibility of a solution for patients suffering from DMD in India.

19. Under such circumstances, it is directed as under:

i. The officials from M/s. Hanugen Therapeutics Private Limited, who have joined the proceedings virtually today, shall place on record an affidavit giving the details of requirements of funding, patient enrolment, DCGI approval, and the manner in which the Phase 2-3 trials are to be conducted. The said affidavit shall be filed by M/s. Hanugen Therapeutics Private Limited, within one week.

ii. **Ld. CGSC shall seek instructions as to whether a sum of Rs.5 crores could be released from the Rare Diseases Fund in favour of M/s. Hanugen Therapeutics Private Limited, on an urgent basis, in order to enable the commencement of the clinical trials.**

16. Pursuant to the previous order dated 9th December, 2022, an affidavit dated 17th December, 2022, deposed by Dr. Arun Shastry, has been filed on behalf of Hanugen. A perusal of the said affidavit shows that the total budget for the clinical trials involving 54 patients would be Rs.13.15 crores. The breakdown of costs as specified in the said affidavit has been extracted below:

***Breakup for Clinical Trial Budget
Cost per Patient***

S.No.	Head	Amount (INR)
1.	Drug	20,00,000
2.	CRO	2,00,000
3.	Hospital	2,00,000
5	Overheads	1,00,000
Total		25,00,000/-

For 54 Patients

S.No.	Head	Amount (INR)
1.	Drug	10,80,00,000
2.	CRO	1,08,00,000
3.	Hospital	1,08,00,000
4.	Overheads	54,00,000
Total		13,50,00,000/-
<i>Subtracting the sum already released by BIRAC and also put in by Hanugen (Rs.1,41,37,500/- each)</i>		<i>10,67,25,000/-</i>

17. At this point in time, the clear position of Hanugen and DART is that they are unable to fund their portion of the amount as per the Memorandum of Understanding dated 8th January, 2021 signed between the Biotechnology Industry Research Assistance Council (BIRAC) and M/s. Hanugen Therapeutics Private Limited (hereinafter, "*Hanugen*"). It is submitted that if the clinical trial is conducted by administering the medicines in respect of half of the total of 54 patients, the total budgetary requirement for commencing the said trial, would be a sum of approximately Rs.5.35 crores that would be required by Hanugen. It was in this background that the Court had issued the directions relating to release of Rs.5 crores, as extracted hereinabove.

18. Upon a query put by the Court, insofar as the direction for disbursement of Rs.5 crores to Hanugen is concerned, it is submitted that a sum of Rs.1.41 crores has already been released by BIRAC, in favour of Hanugen. The remaining amount which is to be released by BIRAC, in terms of the said MoU, would be approximately Rs.3.2 crores.

19. Keeping all the above factors in mind, it is directed that the clinical trials, in the manner as specified in its affidavit dated 17th December, 2022, ought to be commenced and conducted by Hanugen. Under such circumstances, considering the part funding which has already been disbursed, as also, the lack of funds with Hanugen at this point in time, it is deemed appropriate to direct that an amount to the tune of Rs.5.35 crores shall be released by BIRAC in favour of Hanugen, subject to the intellectual property rights in the data, therapies, products/processes, vesting with the Government/BIRAC.

20. On the issue of intellectual property rights in the therapy/drug

proposed to be developed, it is noticed that in the MoU dated 8th January, 2021, the ‘Intellectual Property Governing Framework’ for the said project is defined as under:

**“ INTELLECTUAL PROPERTY GOVERNING
FRAMEWORK**

**1. SCOPE OF IP GENERATED DURING THE
CONDUCT OF THE PROJECT**

a) *The New Intellectual Property (IP) rights belong to company*

Provided this Project is not determined as a “Nationally Important Project” to be governed through specific ‘Order of BIRAC’. Such cases of “Nationally Important Project” shall have specific terms of licensing, pricing or March-in-rights for the purpose of public interest demand of Government of India.

b) *It is the responsibility of the Fund Recipients to protect the New Intellectual Property (IP). They shall bear the expenditure involved in protecting the New IP”*

21. This Court is of the opinion that the said MoU dated 8th January, 2021 was executed at a point in time when the magnitude of the issue concerning rare diseases was yet to be fully taken cognisance of by this Court. The Court has been monitoring and supervising the treatment of children suffering from rare diseases, with involvement of the Department of Biotechnology, MoH&FW, AIIMS etc. The enormity of the issues faced by the children with rare diseases leaves no doubt in the mind of the Court that the development of treatment for children with rare diseases ought to be considered as a “Nationally Important Project”. Ordered accordingly.

22. Upon a query from the Court, Dr. Shastry who is duly authorized on behalf of M/s. Hanugen Therapeutics Private Limited/DART, submits that

M/s. Hanugen Therapeutics Private Limited would have no objection, if the entire intellectual property, both in the data as also in any therapeutics/treatment that may be developed in the course of this project, would vest with the Government of India, subject to the terms being negotiated with BIRAC.

23. In view of the above statement of Dr. Shastry, as also, the fact that the project is now being declared as a “Nationally Important Project”, a fresh agreement shall now be entered into between BIRAC and M/s Hanugen Therapeutics Private Limited, laying down the framework of intellectual property rights which shall vest in the parties to the said agreement, in line with the above observations.

24. For the said purpose, the first meeting between the BIRAC and M/s Hanugen Therapeutics Private Limited for finalizing the said agreement shall be held on 12th January, 2023. Ms. Trehan, Id. Amicus Curiae may also assist the parties in finalizing the said agreement, if required. Mr. Amit Kumar, Legal Officer of BIRAC, who is present in Court today, shall also remain present in the said meeting. Let the draft agreement in this regard be placed before this Court, on the next date of hearing.

Commencement of Treatment

25. On the last date of hearing, this Court was apprised that, despite repeated orders, the patients of Duchenne Muscular Dystrophy (“DMD”) have yet not started receiving treatment. In this regard, the order dated 9th December, 2022 records as under:

“13. Mr. Oberoi, Id. Counsel for AIIMS submits that there is substantial development in this regard. The fund had been received qua few patients. Tenders have been called and the purchase orders have also been

placed on the concerned manufacturers.

14. Let the expected timelines for receiving of the medicines and for the starting of administration of the medicines upon the DMD patients, be also provided by AIIMS, by way of affidavit on the next date of hearing. AIIMS to file a detailed status report of the working of the Rare Diseases Committee functioning in the hospital and the work done till date.”

26. Mr. Oberoi, Id. Counsel for AIIMS submits that the affidavit pursuant to the order dated 9th December, 2022 has been filed by AIIMS, however, the same is not on record. Let the same be brought on record.

27. Mr. Oberoi, Id. Counsel further submits that the medicines for DMD which are being imported, are likely to be received in India by 10th February, 2022 from the United States and AIIMS is taking all the required steps for expediting the receipt of the medicines, so that treatment of the patients can be commenced.

28. In *W.P.(C) 1491/2021* and *W.P.(C) 1511/2021*, Id. Counsel for the Petitioners submits that AIIMS has not complied with the statement made on its behalf, vide order dated 23rd February, 2022, to the effect that the requisition for the medicines for MPS II (Hunter's Syndrome) shall be received by 25th February, 2022, and the treatment of the Petitioners would start thereafter. However, he submits that the said medicines have not been received to date.

29. Let Id. Counsel for AIIMS do the needful to ensure that the said timelines placed before this Court, are strictly adhered to.

Rare Diseases Fund

30. Vide previous order dated 9th December, 2022, this Court was informed that the 'Rare Diseases Fund' is currently being managed by the MoH&FW. Accordingly, it was directed as follows:

“11. Let a status report be filed, jointly by the Ministry of Health and Family Welfare and the Department of Biotechnology, on the following aspects:

i. Compliance of the directions issued under paragraph 21 of order dated 23rd March, 2021, which has been reproduced hereinabove.

ii. Data shall be provided to the Court as to the number of patients in respect of whom Centres of Excellence have been granted the funding, as also, the number of patients in respect of whom the treatment has been commenced.

iii. Timelines being followed by the Ministry of Health and Family Welfare in approving the recommendations for grant of funding and treatment.”

31. Today, ld. CGSC submits that the said status report is yet to be filed, and seeks further time to do so. Let the status report be now filed positively by the next date of hearing.

32. List these matters on 30th January, 2023.

33. These are part-heard matters.

**PRATHIBA M. SINGH
JUDGE**

DECEMBER 22, 2022

Rahul/AD