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\* **IN THE HIGH COURT OF DELHI AT NEW DELHI**  
*Date of Decision: 30<sup>th</sup> January, 2023*

+ **CONT.CAS(C) 415/2022 & CM APPL. 18280/2022**  
MASTER MEDHANSH JHAWAR @ MADHAV THROUGH HIS  
NATURAL GUARDIAN ..... Petitioner

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

versus

RAJESH BHUSHAN & ORS. .... Respondent

Through: Mr. Kirtiman Singh, CGSC, Ms.  
Vidhi Jain, Advocate for UOI.  
Mr. Tanveer Oberoi (M:9958935556)  
and Mr. Jaswinder Singh, Advocate  
(M:9811232066)

(48) WITH

+ **W.P.(C) 5315/2020 & CM APPL. 19189/2020, 4237/2023**  
MASTER ARNESH SHAW ..... Petitioner

Through: Mr. Rahul Malhotra, Advocate.  
Ms. Shyel Trehan, Amicus Curiae  
with Mr. Rohan Poddar, Adv  
(M:7044065747).

versus

UNION OF INDIA & ANR. .... Respondents

Through: Ms. Nidhi Raman CGSC with Mr.  
Rudra Paliwal, Advocates.  
Mr. Kirtiman Singh, CGSC, Ms.  
Vidhi Jain, Advocate for UOI.  
Mr. Ripu Daman Bhardwaj, CGSC  
for UOI.  
Mr. Tanveer Oberoi, Advocate for  
(AIIMS).  
Mr. Dharmender Verma & Mr.  
Abhishek Yadav, Advocates for  
BIRAC. (M: 9171856779)

(49) 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. Shubham Chaturvedi,  
Advocate.  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).

(50) 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.

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  
R-2 and 4 (M:9891363718).  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).

(51) WITH  
+ **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).

(52) WITH  
+ **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)

(53) WITH  
+ **W.P.(C) 1491/2021 & CM APPLs. 4291/2021, 8671/2022**  
MASTER MEDHANSH JHAWAR @ MADHAV .... Petitioner

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

versus

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

(54) WITH  
+ **W.P.(C) 1511/2021 & CM APPL. 4331/2021, 8616/2022**

MASTER KENIT JHAWAR @ KESHAV ..... Petitioner

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

versus

UNION OF INDIA & ANR. .... Respondents

Through: Mr. Ghanshyam Mishra, Advocate for  
R-1. (M: 9899794006)  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).

(55)

WITH

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**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  
with Mr. Rohit Singh, Advocate for  
UOI. (M:9868895906)  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).

(56)

WITH

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

PAYEL BHATTACHARYA

..... Petitioner

Through: Mr. Aditya Chatterjee and Mr. Ishaan  
Karki, Advocates.  
Ms. Shyel Trehan, Amicus Curiae  
with Mr. Rohan Poddar, Adv.

versus

UNION OF INDIA & ORS. .... Respondents

Through: Mr. Anuj Aggarwal, ASC, GNCTD,  
Ms. Ayushi Bansal, Mr. Sanyam Suri

and Ms. Arshya Singh, Advocates for R-2 (M:9891363718).

Mr. Ripu Daman Bhardwaj (CGSC) for UOI.

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

(57)

WITH

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**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 R-1 (M:9971579687).

Mr. Tanveer Oberoi, Advocate for respondent (AIIMS)

(58)

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 and Mr. Dhawal Uniyal, Advocates for R-1 (M:9560806614).

Mr. Tanveer Oberoi, Advocate for respondent (AIIMS)

(59)  
+ WITH  
**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)

(60)  
+ WITH  
**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. Siddharth Khattna, Advocate for  
UOI. (M:9811132326)  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS)

(61)  
+ 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)
- (62)  
+ 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.  
(M:9818071061)  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).
- (63)  
+ WITH  
**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).
- (64)  
+ WITH  
**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..

versus

UNION OF INDIA & ANR. .... Respondents

Through: Mr. Sanjeev Sabharwal, Sr. Panel  
Counsel with Ms. Shweta, Advocate  
for UOI.

Mr. Harish Kumar Garg and Ms.  
Khushboo Sharma, Advocates for  
UOI (M:9810150029).

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

(65)

WITH

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**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).

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WITH

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**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).
- (67)  
+ 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).
- (68)  
+ 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.  
(M:8826437138)  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).

(69)  
+ 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).

(70)  
+ 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).

(71)  
+ WITH  
**W.P.(C) 5395/2021 & CM APPL. 16686/2021**  
MASTER AYUSHMAN CHATURVEDI ..... 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. Niraj Kumar, Sr. Central Govt.  
Counsel for UOI.  
Mr. Jawahar Raja, ASC (C) with Ms.  
Moksha Sharma, Adv. for GNCTD.  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).  
Mr. G.D. Sharma, Advocate for R-4.

(72)  
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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. Mayank Kamra, Advs.  
Mr. Tanveer Oberoi, Advocate for  
respondent (AIIMS).

(73)  
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WITH

**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).

(74)

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, Advocates for R-1.

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

(79)

WITH

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**W.P.(C) 1054/2023 and CM APPL. 4164/2023**

MASTER TUSHAR THROUGH HIS NEXT FRIEND AND NATURAL FATHER SH. JAI PRAKASH ..... 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. Ripu Dhawan Bhardwaj, CGSC with Mr. Hardik GP for UOI.

Mr. Tanveer Oberoi, Advocate for respondent (AIIMS)

(82)

AND

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**W.P.(C) 1079/2023 and CM APPL. 4248/2023**

MASTER RUDRA PAWAR THROUGH HIS NEXT FRIEND AND NATURAL MOTHER SMT. ANU VISHNOI ..... 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. Ripu Dhawan Bhardwaj, CGSC  
with Mr. Hardik GP for UOI (M:  
9818030700).

Mr. Tanveer Oberoi, Advocate for  
(AIIMS)

**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 has 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 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 to the Petitioners.

**Indigenous Development of Treatment, Therapies & Medicines for Rare Diseases**

4. In terms of the Memorandum of Understanding dated 8<sup>th</sup> January, 2021 signed between M/s Hanugen Therapeutics Private Limited (*hereinafter 'Hanugen'*) and the Biotechnology Industry Research

Assistance Council (*hereinafter 'BIRAC'*), Hanugen was to conduct a multi-centric study for the therapeutic evaluation in respect of DMD patients. The total approved amount for the project was Rs.9.24 crores. As per the MoU, 50% of the said amount was to be provided by BIRAC and the other 50% was to be contributed by Hanugen.

5. On 9<sup>th</sup> December, 2022, this Court was apprised that the commencement of clinical trials was delayed due to lack of funds. In view of the said submission, the Court had directed the Id. CGSC to seek instructions as to whether a sum of Rs. 5 crores can be released from the Rare Diseases Fund in favour of Hanugen in order to enable the commencement of clinical trial.

6. Thereafter, an affidavit dated 17<sup>th</sup> December, 2022 was filed on behalf of Hanugen stating that the total budget for clinical trial involving 54 patients would be Rs.13.50 crores. Out of the said amount, Rs.1.41 crore each was already put in by Hanugen and BIRAC. Thus, the total outstanding amount was Rs.10.67 crores. The affidavit further stated that for the first 6 months only 50% of the patients would receive the drug, so to begin the trial, an amount of Rs.5.35 crores was needed by Hanugen.

7. Upon hearing the parties, the Court had passed the following order on 22<sup>nd</sup> December, 2022:

*“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.

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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, ld. 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.”*

8. As per the above order, Rs. 5.35 crores were directed to be released by BIRAC to Hanugen. An agreement was also to be negotiated between BIRAC and Hanugen for vesting of all intellectual property in the data, therapies, products/processes.

9. Further to the previous order dated 22nd December, 2022, it appears that there is a complete stalemate between Hanugen and BIRAC. No effective meeting has taken place between BIRAC and Hanugen in terms of the order dated 22<sup>nd</sup> December, 2022.

10. Today, **CM No.4237/2023** filed by Hanugen is listed before the Court. The said application has been filed by Hanugen seeking orders from the Court clarifying that the amount of Rs.5.35 crores directed to be released is only the first tranche of payment for the commencement of the clinical trial. Hanugen's cause of anxiety are the following two emails sent by BIRAC on 13<sup>th</sup> January, 2023:

*"Dear Dr. Arun,*

*With reference to the High Court Order, an amount of Rs.5.35 crores is to be released by BIRAC in favour of Hanugen. The order also states that the total cost of the study (after subtracting the sum already released by BIRAC and also put in by Hanugen) is Rs. 10.6725 Cr.*

*With reference to this, kindly clarify the source of the remaining funds... "*



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*"Dear Dr. Arun,*

***In continuation to the trail mail, Project Division and the fund recipient (Hanugen) may please note that the total cost of the project will remains Rs. 936.70 Lakhs as per the GLA.***

*The Court had directed BIRAC to consider further funding of Rs. 5.35 Cr. over and above the already released amount.*

***Hence, the company shall ignore the total project cost as mentioned in trail mail. and the company may please do the following needful: (by 14th January 2023)***

*1. to arrange a meeting on top priority as directed by the Hon'ble Court. BIRAC had already requested for that, and now the meeting may be arranged in upcoming week on top priority i.e., from 16 January 2023 to 18 January 2023.*

*2. to provide revised Clause 7 of the GLA."*

11. The above emails show that order dated 22<sup>nd</sup> December, 2022 has been completely misinterpreted by BIRAC. Vide the said order, the Court had acceded to the request of Hanugen to release the payment of Rs.5.35 crores to it in order to ensure that the trial is commenced. The said amount was computed by the Court upon a submission of Hanugen that the total estimated cost of the clinical trial was to the tune of Rs.13.5 crores, out of which 10.67 crores was yet to be paid. Since, Hanugen had submitted that for the first six months only 50% of the patients would receive the drug, the Court had directed that half of the project amount, i.e., 5.35 crores be released to Hanugen.

12. There are a large number of writ petitions filed by children suffering from DMD. The Government has agreed to release a maximum of Rs. 50 lakhs per patient. The intention was that the entire research for the indigenous therapy for DMD could be funded by BIRAC/Government,

which would also own IP rights in the data and therapy/drug that may be developed. Considering the total cost of Rs.13.50 crores as against the allotted amount of Rs. 50 lakhs being invested into each patient for medicines from the US, the indigenous development of therapies for DMD ought to be explored, in the opinion of the Court. A similar view had been expressed by the Court vide order dated 5<sup>th</sup> August, 2022, in the following words:

**“5. The Court is of the considered view that the financial support which is envisaged in the Office Memorandum of 19 May 2022 and its terms which speak of financial aid “for treatment” could be considered as covering the expenses likely to be incurred in the course of administration of the trial drug by the competent authority in the Union Government. The imperatives for favorable consideration and exploration of this line would be guided by the stark difference in the price of the trial drug when compared to that of other experimental remedies currently available as well as the possibility of the drug which has been indigenously developed then being adopted for treatment of many more DMD afflicted children in our country and across the globe. Apart from the evident benefits of cost saving, the trials may perhaps lead to the rollout of a readily accessible drug for DMD in the country itself.**

6. While the Court is conscious that the drug is to presently go through a rigorous clinical trial in order to gauge and ascertain its efficacy, it also bears in mind and weighs in consideration the opinion of AIIMS which had informed the Court that the drugs currently being adopted for treatment “may help in attenuating the decline in cardiac and respiratory functions”. That expert body had further submitted before the Court that presently there is a dearth of evidence which may suggest or establish that the administration of those drugs would

*help in stopping the progress of the degenerative disorder. Admittedly, even for those exorbitantly priced drugs there are no long-term clinical studies available and they thus all so remain in the realm of experimental therapies. All of the aforesaid factors would thus merit consideration of the competent authority in the Union Government which may examine whether the expenses which are likely to be incurred in the course of administering the drug to the 54 enrolled patients would stand covered under Office Memorandum of 19 May 2022.*”

13. Let the present order along with order dated 22<sup>nd</sup> December, 2022 be placed before Ms. Alka Sharma, Managing Director, BIRAC and Mr. Rajesh Gokhale, Secretary, Department of Biotechnology (DBT). Ms. Alka Sharma and Mr. Rajesh Gokhale, or any senior official from DBT nominated by Mr. Gokhale, are requested to hold a meeting with the representatives of Hanugen in order to explore the framework in which funding for clinical trial for DMD can be done, in the larger interest. Previous orders passed by this Court would show that the budgets which were kept aside for rare diseases have not even been completely utilised. Relevant portion of the order dated 23<sup>rd</sup> March, 2021 reads as under:

“14. Insofar as the Ministry of Health and Family Welfare, Union of India, is concerned, in terms of the order dated 2<sup>nd</sup> March 2021, a short affidavit in respect of the budget that was allocated for Health and specifically directed for Rare Diseases has been filed. The relevant extract from the said affidavit which has been deposed by Mr. Pulkesh Kumar, Deputy Secretary, Ministry of Health & Family Welfare, are set out below:

3. That the name of the scheme under which assistance is being provided is by the name "Assistance for Hospitalization of Poor Patients

*Suffering from Rare-Diseases" which is a component of the scheme namely Rashtriya Arogya Nidhi (RAN) which was specifically introduced in RE 2018-19.*

4. *That further, the details of BE, RE and expenditure in respect of rare diseases component under the Umbrella Scheme of Rashtriya Arogya Nidhi (RAN) are as under:*

*(in Rs. crore)*

<i>Sr. No.</i>	<i>Year</i>	<i>Budget Estimate (BE)</i>	<i>Revised Estimates (RE)</i>	<i>Expenditure</i>
<i>1</i>	<i>2018-19</i>	<i>Nil</i>	<i>7.50</i>	<i>Nil</i>
<i>2</i>	<i>2019-20</i>	<i>100.00</i>	<i>25.00</i>	<i>1.30</i>
<i>3</i>	<i>2020-21</i>	<i>77.32</i>	<i>10.00</i>	<i>5.90</i>
<i>4</i>	<i>2021-22</i>	<i>25.00</i>	<i>Nil</i>	<i>Nil</i>

5. *It may be seen from the above table that:*

- i. In the year 2018-19, allocation for the component for rare diseases was 7.50 crore at RE stage. However, no expenditure was made;*
- ii. In the year 2019-20, allocation for the rare diseases was 100.00 crore at BE, 25.00 crore at RE stage and the expenditure was 1.30 crore;*
- iii. In the year 2020-21, allocation for the rare diseases was 77.32 crore at BE, 10.00 crore at RE stage and the expenditure till date is 5.90 crore;*
- iv. In the year 2021-22, allocation for the rare disease is 25.00 crore under BE."*

*XXX*

*18. Secondly, the affidavit of Ministry of Health and Family Welfare, Union of India, also reveals that almost Rs. 200 crores were budgeted for the purpose of expenditure in respect of Rare Diseases. The affidavit shows that the expenditure that has already been incurred is only to the tune of Rs.7 crores over*

*the last three years.*

**19. Considering the fact that budgets have already been sanctioned for dealing with Rare Diseases, it is directed that such budgets ought to be now utilized efficiently for the purposes of both funding of treatments, as well as Research and Development activities.**

14. The Government thus has an obligation to invest in this research to enable development of indigenous therapies.

15. The officials ought to bear in mind that there are 28 writ petitions which have been filed before the Court seeking funding for medicines and therapies. As per the Rare Diseases policy of the Government itself, a sum of Rs.50 lacs per patient has to be set aside for providing medicines per patient. This would involve a substantial amount of money being spent.

**16. In this background, let the meeting for negotiating an agreement for the development of indigenous therapies for DMD and vesting the intellectual property and other rights with the Government be held on 2<sup>nd</sup> February, 2023 at 5:00 pm.**

17. The representatives of DART/Hanugen, who are present in Court, shall also attend the said meeting.

18. In order to enable effective discussions, Ms. Shyel Trehan, Id. Counsel and Mr. Kirtiman Singh, Id. CGSC shall also join the said meeting.

19. Mr. Amit Kumar from BIRAC, who is present in Court today shall brief the concerned officials about the events that have transpired in these proceedings in order to ensure that effective deliberations can take place.

20. It is made clear that the amount of Rs.5.35 crores, which was directed to be released to M/s. Hanugen vide order dated 22<sup>nd</sup> December, 2022 for the purpose of conducting phase-2/3 trials is not the upper limit and the

terms and conditions of the agreement are still to be negotiated between the parties. Further directions for release of funds to each of the patients would be passed, if no progress is made, by the next date of hearing.

**Commencement of Treatment**

21. Mr. Oberoi, Id. counsel for AIIMS had submitted under instructions that purchase orders have already been placed on M/s Sarepta. This submission of the Id. Counsel is controverted by Id. Counsel appearing for the Petitioner.

22. At this stage, Dr. Kanika from AIIMS, who has joined the Court virtually, has revealed that the supply orders have not been placed on M/s Sarepta yet. She submits the funds were released in respect of few patients in September, 2022, however, the tender process took time. The earlier tender had to be cancelled and a fresh tender had to be placed.

23. On 9<sup>th</sup> December, 2022, the Court was informed that, in respect of DMD patients, tenders have been called and purchase orders have also been placed, which is completely contrary to what is being submitted today in Court by Dr. Kanika. The relevant portion of the order reads as under:

*“12. This Court is informed that the treatment for patients of Gaucher Disease is stated to have commenced. However, despite repeated orders, the patients of Duchenne Muscular Dystrophy (“DMD”) have yet not started receiving treatment.*

*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.”*

24. Since the inception of these cases, it is well known to all the parties and stakeholders concerned that for DMD, M/s Sarepta is the only one

company which is supplying therapeutics across the world.

25. The amount having been released by the Ministry of Health & Family Welfare way back in September, 2022, the non-placing of purchase orders/supply orders on M/s Sarepta would be a grossly negligent attitude adopted by the concerned persons at AIIMS. There cannot be any justification for this attitude.

26. Let an affidavit be filed by AIIMS within one week explaining its position.

27. Mr. Oberoi, Id. Counsel also seeks a clarification in respect of the constitution of the Rare Disease Committee. Let an application be filed if any clarification is needed.

28. Dr. Kanika to remain present in Court on the next date.

29. List on 15<sup>th</sup> February, 2023.

**W.P.(C) 1054/2023 & W.P.(C) 1079/2023**

30. These are writ petitions filed by two minors, who are suffering from Duchenne Muscular Dystrophy (DMD). The prayer in the petitions is to consider the case of the Petitioners for treatment through administration of Antisense Oligonucleotide (AON) therapy and other treatment free of cost.

31. Issue notice.

32. Ld. counsel for the Union of India to take instructions for release of funds in respect of these patients to AIIMS.

33. List on 15<sup>th</sup> February, 2023.

**PRATHIBA M. SINGH  
JUDGE**

**JANUARY 30, 2023/dk/mr/sk**  
(corrected & released on 1<sup>st</sup> February, 2023)