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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of Decision: 15th February, 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)

(30) **WITH**

+ **W.P.(C) 5315/2020 & CM APPL. 19189/2020, 4237/2023, 7519/2023**

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, Adv. for (AIIMS).
Mr. Dharmender Verma & Mr.
Abhishek Yadav, Advocates for
BIRAC. (M: 9171856779)
Dr. Kanika, AIIMS in person.

(31) **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, Adv. for (AIIMS).

(32)

WITH

+ **W.P.(C) 2943/2020 & CM APPLs. 10227/2020, 10228/2020,
6633/2022, 7534/2023**

ALISHBA KHAN Petitioner

Through: Mr. Rahul Malhotra, Advocate.
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, Adv. for (AIIMS).

(33)

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, Adv. for (AIIMS).

- (34)
+ 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, Adv. for (AIIMS).
- (35)
+ 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, Adv. for (AIIMS).
- (36)
+ 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, Adv. for (AIIMS).
- (37)
+ 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
with Mr. Rohit Singh, Advocate for
UOI. (M:9868895906)
Mr. Tanveer Oberoi, Adv. for (AIIMS).

(38)

WITH

+ **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, Adv. for (AIIMS).

(39)

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 R-1 (M:9971579687).
Mr. Tanveer Oberoi, Adv. for (AIIMS).

(40)
+ WITH
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, Advs for R-1 (M:9560806614).
Mr. Tanveer Oberoi, Adv. for (AIIMS).

(41)
+ 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, Adv. for (AIIMS).

(42)
+ 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, Adv. for (AIIMS).

(43)
+ 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, Adv. for (AIIMS).

(44)
+ 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, Adv. for (AIIMS).

(45)
+ 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, Adv. for (AIIMS).

(46)
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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, Adv. for (AIIMS).

(47)
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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, Adv. for (AIIMS).

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+

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, Adv. for (AIIMS).
Mr. Ripudam Bhardwaj, CGSC with
Mr. Vinod Tiwari, Adv. for R-1 & 3.
- (49)
+ 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, Advs for UOI.
Mr. Tanveer Oberoi, Adv. for (AIIMS).
- (50)
+ 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, Adv. for (AIIMS).
- (51)
+ 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, Adv. for (AIIMS).

(52)

WITH

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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, Adv. for (AIIMS).

(53)

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).

Mr. Anurag ojha & Deepak Somani, Advocate.

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, Adv. for (AIIMS).

Mr. G.D. Sharma, Advocate for R-4.

- (54)
+ 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, Adv. for (AIIMS).
- (55)
+ 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, Adv. for (AIIMS).
- (56)
+ WITH
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, Advs for R-1. (M:9560806614)
 Mr. Tanveer Oberoi, Adv. for (AIIMS).

(7)
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WITH
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, Adv. for (AIIMS)

(8)
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AND
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.
 Mr. Tanveer Oberoi, Adv. 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 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.

Indigenous Development of Treatment, Therapies & Medicines for Rare Diseases

3. On the last date of hearing, the Court had directed Ms. Alka Sharma, Managing Director, BIRAC and Mr. Rajesh Gokhale, or any senior official from the Department of Biotechnology (DBT) nominated by Mr. Gokhale, to hold a meeting with the representatives of Hanugen to explore the framework under which funding for clinical study for therapeutic evaluation of indigenous treatment in respect of DMD patients can be done. The relevant portion of the said order reads as under:

*“13. Let the present order along with order dated 22nd 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 23rd March, 2021 reads as under:*

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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 2nd 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, ld. Counsel and Mr. Kirtiman Singh, ld. 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.”

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.

6. Let the orders passed by this Court dated 18th October, 2022, 29th November, 2022, and 9th December, 2022 be communicated by Mr. Kirtiman Singh, Id. CGSC to the Secretary, MH&FW who shall file the stand of the Ministry on record by way of an affidavit by the next date of hearing.

7. MH&FW shall also depute a senior official, at least of the level of Joint Secretary, to join the Court proceedings on the next date of hearing.

Commencement of Treatment

8. Each of the Petitioners may approach AIIMS, New Delhi or the respective Centres of Excellence, closer to their locations, for the commencement of their treatment in terms of the order dated 14th December, 2021, which contains the following directions:

*“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 its 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.

6. It is expected that by the next date, the Union of India will iron out the remaining issues in the working of the policy, so that all other persons covered by the policy are also provided the necessary treatment at the earliest. Needless to state, as assured by the learned ASG, the Union of India shall pursue its application before the Kerala High Court for transfer of the amount of about Rs. 53 crores lying before the said Court, which amount was collected, as already noted in the orders previously passed by this Court for treatment of a child suffering from a rare disease who unfortunately succumbed to the said disease before the said amount could be utilized. This Court also hopes that in the light of the facts emerging from the compilation of extracts of the Annual Returns of PSUs handed over by learned senior counsel for the petitioner in Court, will endeavour to impress upon the PSUs, the importance of diverting at least a part of their CSR contributions towards the fund set up on the online crowd funding website i.e., <http://rarediseases.nhp.gov.in/> created for treatment of the children suffering from rare diseases.

7. Needless to state that this amount spent by the Union of India for treatment of these children including the

amount for procurement of medicines for the petitioners herein would be adjustable from the funds which are received in the account set up on the specially dedicated portal, or any other appropriate fund created for the said purpose as may be available with the Union of India.”

9. Vide order dated 30th January, 2023, the Court had directed AIIMS to file an affidavit in respect of non-placing of purchase order/supply order of medicine on M/s Sarepta.
10. An affidavit dated 30th January, 2023 has been filed on behalf of AIIMS placing on record a copy of the invoice dated 31st January, 2023 issued upon M/s My Tomorrows Headquarters, Sarepta's distributor for DMD medicines. Ld. Counsel for AIIMS, under instructions, submits that though the supply order notes the date of delivery as 17th March, 2023, the delivery of the medicines is expected by 28th February, 2023 on the basis of their correspondence with Sarepta.
11. At this stage, the Court has been informed that M/s Sarepta has registered for clinical trials in India for the same medicines which are being procured by AIIMS. Furthermore, AIIMS Delhi is stated to be one of the centres of Sarepta's clinical trial.
12. In view of the same, let the DCGI file an affidavit as to the details of M/s Sarepta's trial or any other trial which has been approved by it in respect of DMD, Gaucher, or Hunter's Syndrome therapies.
13. A competent official from the office of the DCGI shall also remain present in Court on the next date of hearing.
14. Let the present order be communicated by Mr. Kirtiman Singh, Id. CGSC to the DCGI for compliance.

W.P.(C) 2943/2020

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.

18. Complete account of the manner in which the funds are being expended shall be maintained by AIIMS, Delhi under the direct supervision of Dr. Kabra who is heading the Rare Diseases Committee, AIIMS, New Delhi. Upon funds being received, the medicines shall be immediately procured by AIIMS and the treatment shall be recommenced.

19. In respect of the Petitioners in ***W.P.(C) 1491/2021*** and ***W.P.(C) 1511/2021***, ld. Counsel submits that the treatment in respect of Petitioners, who are both suffering from Hunter Syndrome, is yet to commence.

20. Dr. Kanika, who is present in Court today, submits that orders have been placed with Takeda Pharmaceuticals and upon receiving the medicines, the treatment shall be commenced without delay.
21. Let the Union of India place on record an affidavit within a period of one week giving the complete information of the funds released from the Rare Diseases Fund to various Centres for Excellence and the number of patients for whom treatment has been approved till date.
22. Prof. (Dr.) Madhulika Kabra, is requested to join the proceedings virtually on the next date of hearing.
23. List on 1st March, 2023.

FEBRUARY 15, 2023

Rahul/dj/SK

**PRATHIBA M. SINGH
JUDGE**

सत्यमेव जयते