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

\+ **W.P.(C) 11610/2017 & CM APPL. 27637/2018**

FSMA INDIA CHARITABLE TRUST ..... Petitioner

Through: Mr. Ashok Agarwal, Mr. Kumar Utkarsh & Mr. ,Manoj Kumar, Advocates for Petitioner. (M: 9811101923)

Ms. Shyel Trehan with Ms. Shivalika Rudrabatla, Advs. amicus curiae. (M: 6370344354)

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Kirtiman Singh, CGSC with Ms. Vidhi Jain, Adv. for UOI. (M: 9999359235)

Mr. Vijay Joshi, Adv. for R-1. (M: 9873677817)

Mr. Anand Grover, Sr. Adv. with Mr. Saurabh Chauhan, Mr. Varun Jain, Mr. Rohin Bhatt, Advs. with along with Ms. Archana Panda for Intervenors. (M: 9971540730)

Mr. Pravin Anand, Mr. Shrawan Chopra, Ms. Prachi Agarwal, Mr. Achyut Tewari, Advocates for assisting the Court. (M: 8604633567)

CORAM:
JUSTICE PRATHIBA M. SINGH

O R D E R

% 21.07.2023

1. This hearing has been done through hybrid mode.

2. The present writ petition has been filed by FSMA India Charitable Trust, which is stated to be a body formed by family members of patients

suffering from Spinal Muscular Atrophy (SMA) and is registered under the Societies Registration Act, 1860. According to the Petitioner, 122 families are members of the Petitioner organization. SMA is a rare, neuromuscular, progressive genetic disease, which effects the nervous system and requires medication intervention on a regular basis and continuous medication. According to the Petitioner, the treatment for the patients suffering from SMA is very expensive. As per the Petitioner, SMA affected individuals are also substantial in number and various drugs, which are available as on today in India, are not readily available at reasonably affordable prices.

3. Mr. Anand Grover, ld. Senior counsel appearing for Cure SMA India - Respondent No.6, submits that it is a similarly placed body working for the benefit of SMA patients. He further submits that the impleadment application of the said Respondent was allowed by the Court vide order dated 11th October, 2019. Mr. Grover, has handed over a note setting out the pricing of medicines for SMA in India and other countries.

4. Mr. Grover, ld. Senior Counsel submits that three medications which are available for SMA are manufactured by Biogen, Novartis and Roche. He points out that insofar as the medication called Evrysdi-Ridisplam manufactured and marketed by Roche is concerned, the same costs Rs.6,23,000/- per bottle in India of which a patient weighing more than 20 kgs need roughly 36 bottles in a year. However, it is his submission that the same is available at a much more reasonable price in other countries such as China and Pakistan where the company the same are made available at less than 1/10th of the prices in India i.e., Rs.44,692/-, and 41,002/- per bottle respectively. The prayer in this petition is for making available medication and treatment for children with rare diseases SMA at an affordable price.

5. On the last date of hearing, considering the submissions made on the said date, Court notice was issued to Mr. Pravin Anand, ld. Counsel who regularly appears for some of these pharmaceutical companies, to appear for assistance of the Court. Today, Mr. Pravin Anand, ld. Counsel has appeared for assisting the Court.

6. This Court has been dealing with a batch of writ petitions filed by the family members of patients suffering from rare diseases such as DMD, Gaucher, Hunter's syndrome. As part of the said batch of the petitions this Court had appointed a National Rare Disease Committee vide order dated 15th March, 2023 with the following mandate:

> *21. The mandate of the Committee would broadly be to take all steps needed for implementation of the National Rare Disease Policy, 2021. The mandate of the Committee shall include:*
>
> *(i) **Procurement of therapies & drugs and creation of associated logistical framework for administration of treatment for patients with rare diseases**;*
>
> *(ii) Recommending necessary steps for the indigenisation of therapies, medicines for rare diseases and identify the manner in which the same can be made accessible to the lakhs of patients who, as per the Policy, are suffering from rare diseases;*
>
> *(iii) The Committee, while working broadly under the umbrella of the Policy, would undertake a periodic review of the Policy and recommend to the Ministry of Health and Family Welfare, the changes needed in the Policy if the same is deemed necessary.*
>
> *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*.

7. Ms. Vidhi Jain, ld. Counsel submits that the Committee is currently holding deliberations with various companies including Sarepta, Sanofi etc., in order to explore the possibility of obtaining medications at a more reasonable price for children affected with rare diseases.

8. In addition, Mr. Pravin Anand, ld. Counsel who is present Court, submits that he would seek instructions as to whether any solution could be found for the issues raised in this petition.

9. After perusing the note which has been handed over today, by Mr. Grover, it seems that there is a possibility of the National Rare Diseases Committee speaking to these companies in order to source medication for SMA patients.

10. Accordingly, it is directed that the National Rare Diseases Committee shall look into the note, which has been today submitted by Mr. Anand Grover, ld. Sr. Counsel and invite companies manufacturing and marketing medicines for SMA in order to explore the possibility of procuring the medication at a reasonable cost.

11. It is emphasized that effective deliberations between the companies as also the National Rare Diseases Committee as also a positive response from the Companies would have substantial impact on the lives of children who are suffering from rare diseases.

12. Mr. Anand, ld. Counsel would also seek instructions as to whether the said companies would be willing to make available medications at

reasonable prices, for these children, who are suffering from rare diseases, as part of their overall Corporate Social Responsibility (CSR).

13. The note, which has been handed over by Mr. Anand Grover shall be placed before the Committee by Mr. Kirtiman Singh's office. Let a status report be filed by the Committee by the next date of hearing on the progress made by it in negotiation with companies manufacturing and marketing medicines for rare diseases.

14. List on 3rd August, 2023.

PRATHIBA M. SINGH, J.

JULY 21, 2023/*dk/sk*