

IN THE HIGH COURT OF KARNATAKA AT BENGALURU

DATED THIS THE 18TH DAY OF JULY 2022

PRESENT

THE HON'BLE MR. ALOK ARADHE
ACTING CHIEF JUSTICE

AND

THE HON'BLE MS.JUSTICE J.M. KHAZI

W.P. NO.19061 OF 2015 (GM-RES)

BETWEEN:

LYSOSOMAL STORAGE DISORDERS SUPPORT SOCIETY
A SOCIETY REGISTERED UNDER THE PROVISIONS
OF SOCIETIES REGISTRATION ACT, 1860
DEPARTMENT OF GENERIC MEDICINE
GROUND FLOOR, NEAR EMERGENCY BLOCK
SRI. GANGARAM HOSPITAL, OLD RAJENDRA NAGAR
NEW DELHI 110060
AND REPRESENTED BY ITS PRESIDENT
MR. MAJIT SINGH.

... PETITIONER

(BY MS/MRS. VARSHA MANOJ, ADV.,)

AND:

1. STATE OF KARNATAKA
THROUGH ITS CHIEF SECRETARY
VIDHANA SOUDHA, VIDHANA VEEDHI
BANGALORE.
2. MINISTRY OF HEALTH WELFARE
GOVERNMENT OF KARNATAKA
THROUGH ITS PRINCIPAL SECRETARY
HEALTH AND FAMILY WELFARE
VIDHANA SOUDHA, VIDHANA VEEDHI
BANGALORE.

3. INDIRA GANDHI INSTITUTE OF CHILD HEALTH
SOUTH HOSPITAL COMPLEX
DHARMARAM COLLEGE POST
BANGALORE 560029
REP. BY ITS DIRECTOR.
4. THE UNION OF INDIA
REP. BY ITS SECRETARY
MINISTRY OF HEALTH AND FAMILY WELFARE
NIRMAN BHAWAN, C-WING, NEW DELHI.
5. SANOFI HEALTHCARE INDIA PRIVATE LIMITED
FORMERLY SANOFI INDIA LTD.
THROUGH ITS SUBSIDIARY
SANOFI-SYNTHELABO INDIA PVT. LTD.
SANOFI HOUSE, CTS NO.117
B L & T BUSINESS PARK
SAKI VIHAR ROAD, POWAI, MUMBAI-400072
REP. BY ITS GENERAL MANAGER.

... RESPONDENTS

(BY MR. VIJAY KUMAR A. PATIL, AGA FOR R1 & R2
MR. N.K. RAMESH, ADV., FOR R3
MR. M.B. NARGUND, ASG A/W
MR. KUMAR M.N. CGC FOR R4
MR. M.G. NANJAPPA, ADV., FOR R5)

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THIS W.P. IS FILED UNDER ARTICLE 226 AND 227 OF THE CONSTITUTION OF INDIA, PRAYING TO DIRECT THE RESPONDENTS JOINTLY AND SEVERALLY TO TAKE ALL STEPS NECESSARY TO PROVIDE TO MEMBERS OF THE PETITIONER OR ANY OTHER SUCH SIMILARLY SITUATE PATIENT, CONTINUOUS, UNINTERRUPTED TREATMENT FREE OF COST AT THE INDIRA GANDHI INSTITUTE OF CHILD HEALTH OR ANY OTHER INSTITUTE HAVING REQUISITE MEDICAL FACILITIES OR TO BEAR THE ENTIRE EXPENSES OF SUCH TREATMENT. DIRECT THE RESPONDENT TO MAKE NECESSARY AMENDMENTS TO EXISTING POLICIES SUCH AS THE RASHTRIYA BAL SWASTHYA KARYAKRAM [RBSK] SCHEME AND OTHER SUCH HEALTH CARE BENEFIT

SCHEMES BEING RUN BY THE GOVERNMENT TO FACILITATE THE TREATMENT OF RARE DISEASES INCLUDING LSDs AT THE EXPENSE OF THE RESPONDENT & ETC.

THIS W.P. COMING ON FOR ORDERS, THIS DAY, **ACTING CHIEF JUSTICE** MADE THE FOLLOWING:

ORDER

This petition, which has been filed pro bono publico, raises an issue with regard to rights of children suffering from debilitating and potential rare disease called Lysosomal Storage Disorders (LSDs), which is a rare genetic disease. The petitioner seeks a writ of mandamus to the respondents to jointly and severally take all necessary steps to provide members of the petitioner or any other patient continuous uninterrupted treatment free of cost at Indira Gandhi Institute of Child Health (hereinafter referred to as 'the Institute' for short) in Bangalore. The petitioner further seeks a direction to the respondents to make necessary amendments to existing policies such as Rashtriya Bal Swasthya Karyakram (RBSK) Scheme

and other such health care benefits being run by the Government to facilitate treatment of rare diseases including LSDs. The petitioner also seeks appointment of a committee to enquire into the issue pertaining to non-allocation of funds to the institute towards treatment of rare diseases.

2. The petitioner claims to be a registered Pan-India non-profit organization, which aims to create awareness about LSDs, amongst the medical practitioners as well as public in general. In State of Karnataka, the treatment to patients of LSDs is provided in the Institute, which is an autonomous institute established by the State Government. Cost of treatment of a patient suffering from LSDs is expensive and most of the families of the patients suffering from such disease are not able to afford the cost of medical treatment, which is approximately Rs.40 Lakhs for a child weighing about 10 Kgs. The

petitioner, therefore, approached the State Government seeking treatment of the patients suffering from LSDs and made a request to provide for financial assistance. Thereafter, this petition was filed seeking the reliefs as stated supra.

3. A division bench of this court by an order dated 23.04.2020 directed the State Government to pay an amount of Rs.595.1 Lakhs to the Institute for a four-month block period from 01.03.2020 to 30.06.2020. The institute was directed to provide treatment to 25 children and the remaining amount was directed to be kept in a separate account. The State Government was also granted the liberty to approach the Central Government seeking to release a substantial contribution for making payment of the same to the Institute. Thereafter, on 12.02.2021, this court noted that a sum of Rs.5 Crores has already

been released to the Institute and the amount would be sufficient to treat the patients till end of March, 2021. Thereafter, on 23.04.2021 also, a direction was issued to the Government of India to pay a sum of Rs.3 Crores to the Institute whereas, the State Government was directed to pay a sum of Rs.2 Crores to the Institute. It is not in dispute that the aforesaid amounts have been paid to the institute and the institute has sufficient funds to treat the patients upto December, 2022.

4. Learned counsel for the petitioner submitted that the policy framed by the Government of India in the year 2021 does not apply to the petitioner and the directions issued by this court on 24.02.2020 are final in nature. However, it is not disputed that the patients are treated in the institute and the financial assistance has been extended to them.

5. On the other hand, learned Additional Solicitor General of India as well as learned Additional Government Advocate, at the outset, fairly stated that the Government of India as well as the Government of Karnataka have not treated this litigation as an adversarial one and have ensured that treatment is given to the patients suffering from the rare disease. It is submitted that every possible effort is being made to extend the treatment to the patients who are suffering from the rare disease. Our attention has also been invited to the National Policy for Rare Diseases, 2021 and it has been stated that the aforesaid Policy shall be implemented in letter and spirit. It is also pointed out that in the budget for the period from April 2022 to March 2023, a provision for Rs.10 Crores has been made and the aforesaid amount shall be released to the institute for the treatment of the patients on demand by the institute. Learned counsel

for respondent No.5 submits that it shall provide treatment to three patients for a period of three months on their identification by the institute.

6. We have considered the submissions made on both sides and have perused the record. Admittedly, in compliance of the interim orders passed by this court from time to time, the amounts have been released in favour of the institute. It is also not in dispute that the institute has sufficient funds to treat the patient till December, 2022. A provision for a sum of Rs.10 Crores, has been made by the State Government for the period from April 2022 to March 2023 and the aforesaid amount shall be released for the treatment of the patients on demand being made by the institute.

7. During the pendency of the petition, the Government of India has framed a comprehensive

policy which is known as National Policy for Rare Diseases, 2021. The said policy has been framed on the basis of recommendations made by an Expert Committee constituted by Government of India in consultation with the State Governments at the draft stage of formulation of the Policy. The aforesaid policy takes note of the Indian scenario and also takes into account of the experiences from other countries alongside the need to balance competing priorities. The Policy also provides the measures for prevention and control.

8. Eight Centres of Excellence and Nidhaan Kendras have been notified all across the country by the Central Government under the Scheme to facilitate diagnosis prevention and treatment of rare diseases. The policy also makes a provision for addition of more centers of excellence for regional outreach. Para 10 of the Policy provides for the

initiatives, which shall be taken for the patients of rare diseases. It provides that financial support upto Rs.20 Lakhs shall be provided by the Central Government for treatment of the rare diseases. The Policy also provides that State Government may consider providing for special diets of hormonal supplements or other relatively low cost interventions to the patients of such rare diseases. The scheme further provides that the government will endeavor to create alternate funding mechanism through setting up a digital platform for voluntary individuals and corporate donors to contribute for the treatment-cost of patients with rare diseases. The scheme also provides for voluntary crowd-funding for treatment.

9. Thus, the aforesaid Policy governs the need of the treatment to the patients suffering from rare diseases. The aforesaid policy has been framed by the Central Government on the basis of recommendations

made by Committee of Experts. It is not the case of the petitioner that the aforesaid policy is either capricious or is malafide. It is also not the case of the petitioner that treatment to the patients of LSD is not being administered. The Government of India as well as the State Government has categorically stated that they have not treated this petition as an adversarial litigation and has assured this court that all steps will be taken to implement the Policy, which has been framed by the Central Government in Letter an Spirit.

For the aforementioned reasons, the prayer sought for amendment to the existing policy such as RBSK scheme and to enquire into non-allocation of funds does not survive for consideration. In view of the fact that a Policy has already been framed for treatment of the patients suffering from rare diseases, it is directed to the Central Government and State

Government to ensure implementation of the aforesaid policy.

In the result, the writ petition is disposed of.

**Sd/-
ACTING CHIEF JUSTICE**

**Sd/-
JUDGE**

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