

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT

THE HONOURABLE MR. JUSTICE P.B.SURESH KUMAR

FRIDAY, THE 21<sup>ST</sup> DAY OF JANUARY 2022 / 1<sup>ST</sup> MAGHA, 1943

W.P(C) NO. 7984 OF 2021

PETITIONER:

ARIF, S/O.MOHAMMED ASHRAF, KULANGARA PARAMBIL,  
ERANTHODE, VALAMBOOR P.O., MALAPPURAM DISTRICT -  
679325

BY ADV

RESPONDENTS:

- 1 THE STATE OF KERALA, REPRESENTED BY PRINCIPAL SECRETARY TO GOVERNMENT OF KERALA, DEPARTMENT OF HEALTH AND FAMILY WELFARE, GOVERNMENT SECRETARIAT, THIRUVANANTHAPURAM - 695001
  - 2 THE DIRECTOR OF HEALTH SERVICES, DIRECTORATE OF HEALTH SERVICES, GENERAL HOSPITAL JUNCTION, THIRUVANANTHAPURAM - 695035
  - 3 THE DISTRICT MEDICAL OFFICER OF HEALTH, CIVIL STATION, CALICUT - 673001
  - 4 GOVERNMENT MEDICAL COLLEGE CAMPUS, KOZHIKODE - 673008, REPRESENTED BY ITS SUPERINTENDENT
- ADDL.R5 UNION OF INDIA REPRESENTED BY ITS SECRETARY TO MINISTRY OF CORPORATE AFFAIRS, 5TH FLOOR, A-WING, SHASTRI BHAWAN, NEW DELHI - 110001
- ADDL.R6 THE DRUGS CONTROLLER GENERAL OF INDIA, NEW DELHI
- ADDL.R7 THE INDIAN COUNCIL OF MEDICAL RESEARCH, NEW DELHI
- ADDL.R8 THE DRUGS CONTROLLER, OFFICE OF THE DRUGS CONTROLLER, RED CROSS ROAD, PUBLIC LABORATORY COMPOUND, VANCHIYOOR P.O, THIRUVANANTHAPURAM
- ADDL.R9 THE DIRECTOR OF MEDICAL EDUCATION, GOVERNMENT OF KERALA, THIRUVANANTHAPURAM
- ADDL.R10 THE SECRETARY TO GOVERNMENT, FINANCE DEPARTMENT, GOVERNMENT OF KERALA, THIRUVANANTHAPURAM
- ADDL.R11 THE SECRETARY TO GOVERNMENT, TAXES DEPARTMENT, GOVERNMENT OF KERALA, THIRUVANANTHAPURA

- ADDL.R12 THE DIRECTOR GENERAL OF POLICE,  
THIRUVANANTHAPURAM
- ADD.R13 THE KERALA STATE LEGAL SERVICES AUTHORITY,  
REPRESENTED BY ITS MEMBER SECRETARY, ERNAKULAM
- ADDL.R14 SRI.MANJALAMKUZHI ALI, MEMBER OF LEGISLATIVE  
ASSEMBLY, MANKADA CONSTITUENCY, MALAPPURAM
- ADDL.R15 SRI.M.VIJIN, MEMBER OF LEGISLATIVE ASSEMBLY,  
KALLIASERY CONSTITUENCY, KANNUR
- ADDL.R16 UNION OF INDIA, REPRESENTED BY THE SECRETARY,  
MINISTRY OF HEALTH AND FAMILY WELFARE,  
GOVERNMENT OF INDIA, NEW DELHI
- ADDL.R17 CURE SMA FOUNDATION OF INDIA, HAVING ITS OFFICE  
AT 501/D23, IREO VICTOR VALLEY, SECTOR 67,  
GURUGRAM, HARYANA, INDIA.PIN 122018 REPRESENTED  
BY ITS TRUSTEE/STATE COORDINATOR, KERALA CHAPTER  
(DR.RAZEENA.K, AGED 45 YEARS,  
W/O.DR.SETHUNATH.T, THAMBRERI (HOUSE), NEDUVA  
P.O, PARAPPANANGADI, MALAPPURAM DISTRICT)

**P.B.SURESH KUMAR, J.**

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**W.P.(C) No.7984 of 2021**  
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**Dated this the 21<sup>st</sup> day of January, 2022.**

**ORDER**

There cannot be any doubt on the principle that where there is a right, there is a remedy, *ubi jus ibi remedium*, but the facts of this case unfortunately disclose that there is a gap in reality between right and remedy, especially when it comes to the enforcement of rights against State. The attempt of this Court in this matter, therefore, is to bridge the said gap.

2. Coming to the facts, the son of the petitioner Imran Mohammed, a toddler was suffering from a rare disease 'Spinal Muscular Atrophy' (SMA). It was alleged by the petitioner that the life of his son cannot be saved otherwise than by administering the drug "Onasemnogene Apeparvovec (Zolgensma)" which costs approximately Rs.18 crores. The case

of the petitioner was that since he is unable to secure the drug, the State is obliged to secure and administer the same to his son to save his life.

3. An organisation of the parents of children suffering from SMA called 'Cure SMA Foundation of India' has got themselves impleaded as seventeenth respondent in the writ petition. The affidavit filed by them in this matter reveals that SMA is an extremely severe and rare genetically inherited degenerative neuro muscular disease; that SMA results in progressive loss of motor nerve cells in the brain stem and spinal cord that controls essential muscle activity and that those who are affected by SMA at a very early stage of their life may not survive and though persons who are affected by SMA at a later stage would survive, they need supportive care. It is also revealed from the said affidavit that there are about 100 children in the State who are suffering from SMA; that though there are life saving and life altering drugs including Zolgensma for the treatment of SMA, they are prohibitively expensive and no facilities whatsoever have been provided by the Central and

State Governments for treatment of SMA, especially for those who cannot afford the expenses for the treatment.

4. It has come out that since there are no facilities in the State for treatment of rare diseases especially for those who cannot afford the expenses for treatment, a committee was formed under the Chairmanship of a Member of the State Legislative Assembly for raising funds for the treatment of the son of the petitioner and the said committee could collect approximately Rs.16.5 crores. Unfortunately, since the son of the petitioner died in the meanwhile during the pendency of the writ petition, the amount collected could not be utilised for the purpose. The Chairman of the committee which collected funds for the treatment of the son of the petitioner is the fourteenth respondent in the writ petition. Similarly, it has come out in the course of the hearing that a sum of Rs.46,78,72,125.48 has been collected by a committee under the co-ordinatorship of another Member of the State Legislative Assembly for treatment of a similarly placed child. The co-ordinator of the said committee is the fifteenth

respondent in the writ petition.

5. It is seen that since the takers of the drugs for treatment of rare diseases are only a minuscule, they are sold at prohibitively expensive prices, presumably to recoup the cost of its research and development. Since the drugs for treatment of such diseases are prohibitively expensive and since no facilities whatsoever have been provided by the State Government for treatment of rare diseases, as in the case on hand, most of the patients, especially children of tender age are doomed to die. Having noticed the said reality and having found that the inaction on the part of the State Government in not making any facilities for treatment of rare diseases would amount to flagrant violation of the right to life guaranteed under Article 21 of the Constitution, it was felt that as the *sentinel on the qui vive*, this Court is constitutionally obliged to intervene in the matter, despite the fact that the relief sought for in the writ petition has become infructuous, and the matter is retained accordingly for the said purpose.

6. It is seen that in the year 2021, the Central

Government has come out with a national policy for rare diseases, styled as 'National Policy for Rare Diseases, 2021'. In terms of the National Policy, the Central Government has identified and categorised rare diseases into three groups, of which Group-1 are diseases for which one-time curative treatments are available, Group-2 are diseases requiring long term treatment, the cost of which is relatively low and Group-3 are diseases for which treatments are available, but the cost is very high. Since rare diseases place a major economic burden on the country, the National Policy is that interventions that benefit a large number of persons who are unable to afford the treatment expenses with lesser amounts shall be prioritised. It has come out that the Central Government has notified the hospitals referred to in the National Policy with facilities for treatment of rare diseases as Centres of Excellence (COE) and made provision for extending financial support upto Rs.20 lakhs for treatment of rare diseases included in Group-1. It has also come out that in view of the resource constraints and compelling health priorities, in terms of the National Policy, the

Central Government has established a digital platform also for voluntary crowd-funding to raise funds required for the treatment of the diseases, especially to those under Group-3.

7. Sufficient data is not available on record to ascertain whether treatment could be extended for all rare diseases making use of the facilities made in terms of the National Policy. Be that as it may, since none of the hospitals in the State has been notified as a COE and since the nearest COE as far as the State of Kerala is at Bangalore, the facilities, if any, available in the nearest COE are beyond the reach of most of the patients in the State, who are suffering from rare diseases, especially those who belong to the lower strata of the society.

8. Although the Central Government has formulated a policy for treatment of rare diseases and is in the process of implementing the same, it has come out that the State Government does not have a policy for treatment of rare diseases. In the affidavit filed on behalf of the State Government pursuant to the direction issued by this Court to disclose its views and suggestions to tackle the menace of rare



diseases, it is stated, among others, that the State Government is in the process of finalising a concept note for raising crowdfunding for treatment of rare diseases and the Social Justice Department and the Kerala Social Security Mission (KSSM) are in the process of finalising the norms for identification of beneficiaries and also for engaging the services of social media groups for encouraging donations for the treatment of rare diseases. It is also stated in the said affidavit that Kerala Social Security Mission has established a payment gateway styled as 'We Care' and rolled out an online platform for mobilising contributions and the same can be utilised for mobilising public contribution to provide support and for the management of rare diseases. The relevant portion of the affidavit reads thus:

“5. In compliance with the directions of this Hon'ble Court, two meetings were conducted by the Chief Principal Secretary to Chief Minister on 23.07.2021 and 23.09.2021. The discussions were mainly targeting the possibilities for mobilizing the digital crowd funding to provide support to patients with rare diseases. In the meeting convened on 23.07.2021, the following decisions were taken :-

- (i) Develop a Concept Note for raising crowd funding for

SMA, including other rare diseases. Health and Social Justice Departments was directed take further steps in this regard.

(ii) Social Justice Department and Kerala Social Security Mission shall develop proper norms for identification of beneficiaries.

(iii) Social Justice Department and Social Security Mission shall engage the services of PRD accredited social media groups for the State, National and International level campaign for encouraging donations for the treatment of rare diseases.

(iv) Kerala Social Security Mission (KSSM) shall invite Expression of Interests to appoint an agency for State, National and International level campaign in the meantime.

6.As directed in the meeting, a draft concept note was prepared by the KSSM. As per the initiative of the Kerala Social Security Mission, three agencies have come up and they have made the 1<sup>st</sup> stage of presentation. Final presentation is scheduled to next week and after that KSSM will commence the process for final selection of accredited agencies for State, National and International level campaign for social media to encourage donations.

7.The meeting convened on 23.09.2021 observed that Kerala Social Security Mission(KSSM) is in the final stage of fixing norms for identification of beneficiaries, and will be completed at the earliest. In the Meeting, it was decided that, this will form part of the Concept Note along with the details of the fund set apart for rare diseases. National Policy for Rare Diseases, 2021 shall also be considered while finalizing the

concept.”

9. The learned Senior Government Pleader who appeared in the matter submitted that availability of resources is the impediment in extending the treatment for rare diseases and earnest efforts are being taken to tackle the menace. The learned counsel for the additional fourteenth respondent submitted that insofar as the money collected for the treatment of the son of the petitioner could not be utilised for that purpose, the committee is contemplating to make use of the funds for treatment of other similarly placed children. It was however submitted by the learned counsel that if this Court issues any direction as to the utilisation of the funds collected by them, they would abide by the same. The learned counsel for the additional fifteenth respondent submitted that insofar as the money collected by the committee under the co-ordinatorship of additional fifteenth respondent is far more than the amount required, the committee is contemplating to make available the remaining funds to the Government. It was

however submitted that if this Court issues any direction for utilisation of the funds collected by them, the committee would abide by the same.

10. There is no dispute to the fact that although effective treatments are available for most of the rare diseases, only a very few is able to afford the expenses of the treatment and most of the patients, especially children of tender age, are doomed to die for want of affordability to meet the treatment expenses and for want of facilities in the State for the same for those who cannot afford the treatment expenses. The case of the son of the petitioner is one of such instance.

11. Article 24(2)(b) of the United Nations Convention on the Rights of the Child, to which India is a party, casts an obligation upon the State parties to ensure the provision for necessary medical assistance and health care to all children. Article 25.1 of the Universal Declaration of Human Rights, to which India is also a party, affirms that everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and

medical care and necessary social services. As per Article 12.1 of the International Covenant on Economic, Social and Cultural Rights to which India is a party, the State parties have recognized the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. That apart, Article 21 of the Constitution casts an obligation on the State to preserve the life of every citizen. It is now settled by a long catena of decisions that the right to health and medical care is a facet of Article 21. The State is, therefore, duty bound to extend medical assistance to everyone for preserving human life [See **Parmanand Katara v. Union of India**, (1989) 4 SCC 286 and **Paschim Banga Khet Mazdoor Samity v. State of W.B.**, (1996) 4 SCC 37]. Further, our Constitution envisages establishment of a welfare State at the Federal level as also at the State level. All that is done in a welfare State by its Government is for the well being of its citizens. The life of citizens is a matter of paramount importance in a welfare State, for, if the State cannot secure the life of its citizens, the very concept of welfare State would become meaningless. The

Government in a welfare State is obliged therefore, to provide adequate medical facilities for securing the life of its citizens. True, if a class or category of persons can afford to pay or partially pay for their medical treatment because of their economic background, free medical treatment to such class of persons may not be part of the constitutional obligation of the State [See **Confederation of Ex-Servicemen Assns. v. Union of India**, (2006) 8 SCC 399]. But, in so far as persons who cannot afford to pay for their medical treatment, the State is certainly obliged constitutionally to make adequate provision for their treatment, for, no Government can say that it will not treat patients with rare diseases due to financial constraints. That does not mean that the State has to make use of its resources earmarked for the entire community for the said purpose, for, the resources of the State are to be utilised for various other purposes as well. In other words, the Constitutional obligation of the State is to make provisions for the same [See **Brij Mohan Lal v. Union of India**, (2012) 6 SCC 502]. For the said purpose, the Government is free to tap

the resources of the civil society and non-Government and charitable organizations. In other words, the initiative to tackle situations of this nature has to come from the Government and it cannot shirk its responsibility by contending that it has no resources.

12. While countries like United States, Japan, Australia, Israel as also members of European Union have evolved policies to provide affordable treatment to patients suffering from rare diseases and have implemented the same several years back, the Central Government had not even formulated a concrete policy until recently to address the grievances of patients suffering from rare diseases. Although the Central Government has evolved a policy in the year 2021 for treatment of rare diseases and established a few Centres of Excellence for the said purpose, the people in the State, especially people belonging to poor background, are not benefitted by the said policy inasmuch as no Centre of Excellence is established in the State, though it could be said technically that persons suffering from rare diseases in the

State are free to avail treatment from any one of the Centres of Excellence. It is a fact that since the expenditure to be incurred for treatment of rare diseases is one which cannot be afforded fully even by the Central Government, the Central Government has evolved a policy to resort to crowd funding for making up the deficit by setting up online platforms for the same at the designated hospitals. The averments in the affidavit filed on behalf of the State Government in this matter also indicates that even the State Government is contemplating a similar method for raising funds for making arrangements for support and management of rare diseases. Though it is stated in the affidavit filed on behalf of the State Government that steps are being taken for support and management of rare diseases, the averments in the affidavit would indicate that despite having realised several years back that the menace of rare diseases is one to be tackled, the steps stated to have been taken are only at its infancy.

13. It is seen that in W.P.(C) No.21897 of 2016 instituted before this Court earlier by the parent of a child



suffering from a rare disease, having found that the petitioner therein is unable to incur the expenses for securing the drug to be administered for saving the life of the child, this Court directed the State Government to make appropriate arrangements for the treatment. The State Government has challenged the said decision, in W.A.No.2151 of 2017 on the ground that the State Government cannot afford the cost of treatment. Although this Court in the said appeal permitted the State Government to adopt appropriate measures to raise funds by way of donations for the treatment of children suffering from rare diseases including the child involved in that case, the materials on record in the said case indicate that the State Government could not do anything substantial in the matter. The materials indicate that only a sum of Rs.11.5 lakhs could be generated by the State Government for the said purpose during the last almost three years, other than the contribution received from the Central Government and made by the State Government, when amounts required for the purpose is many fold. The materials also indicate that even though the State

Government had undertaken in 2018 that a corpus fund of Rs.50 Lakhs would be set up in the Kerala Social Security Mission for the treatment of rare diseases, the said amount was provided only in the year 2021, that too, after several interventions by the Court. Insofar as it has come out that crores of rupees could be collected in a span of few days at the instance of the representatives of the people for the treatment of two children suffering from SMA, it could be inferred that lackadaisical approach is the cause for inability on the part of the State Government in making arrangements for treatment of rare diseases. It is all the more so since materials in the public domain indicate that crores of rupees are being collected purportedly for treatment, even through digital platforms provided by private business enterprises.

14. That apart, going by the averments in the affidavit filed in this matter, the State Government is contemplating crowdfunding even for the management of rare diseases. When patients suffering from rare diseases are dying on account of their inability to secure the drugs available in the

market, the priority shall be to make use of the resources available for treatment of the rare diseases, and not management. Similarly, since the treatment for rare diseases cannot be afforded even by mighty Governments, as indicated in the National Policy, interventions that benefit more with the available resources shall be prioritised.

15. The credibility of a democratic legal system is intrinsically linked to the enforceability of rights of citizens. Enforcement of socio-economic rights pose a major challenge to the legal system. True, in matters where availability of resources has a material bearing and policy regarding priority is involved, it may not be prudent for constitutional courts to give directions. At the same time, when constitutional courts are convinced that fundamental rights of citizens cannot be enforced without judicial interference, the principle of continuing mandamus which is now an integral part of our constitutional jurisprudence, could certainly be invoked for the purpose of enforcing the fundamental rights of the citizens to bridge the gap between right and remedy [See

**Swaraj Abhiyan v. Union of India**, AIR 2016 SC 2953].

16. Insofar as it is found that facilities for treatment of rare diseases would not be in place in the State in the near future without judicial interference, I am the view that this Court is constitutionally obliged to issue appropriate directions to the State Government to make available facilities for treatment of such diseases so as to enforce the federal rights guaranteed to the citizens under Article 21 of the Constitution.

17. While the fifteenth respondent has indicated in his affidavit unambiguously that the surplus amount collected by the committee of which is the coordinator has no objection in making use of the said amount in accordance with the directions of this court, the fourteenth respondent has filed an affidavit indicating that the committee of which he is the chairman is contemplating to make use of 75% of the amount for the treatment of six children suffering from SMA and the balance for construction of a building in the premises of the Government Hospital, Mankada. Even though

it was pointed out by the counsel for the fourteenth respondent that the committee of which the fourteenth respondent is the chairman is also willing to make use of the funds in accordance with the directions of this court, in the context of the affidavit filed by the fourteenth respondent, it is necessary to mention that the said committee which collected money for the treatment of the son of the petitioner may not be justified to make use of the same for any other purposes, for the amounts available with them which are not claimed back by the donors can only be regarded as made by donors intending to part out and out with their money and in that event, the said amount is liable to be treated as *bona vacantia*.

18. Having regard to the discussions aforesaid, the following directions are issued for the present :

(1) The additional sixteenth respondent is directed to file an affidavit indicating whether the COEs provided for in the National Policy are working as contemplated and also whether amounts sufficient for treatment of rare diseases, especially for those included in Group-3 of the

National Policy could be generated through the digital platform established for crowdfunding and if not, whether any alternative arrangements have been made for treatment of such diseases. The additional sixteenth respondent shall state in the affidavit the criteria, if any, prescribed for admission of patients suffering from rare diseases belonging to other States in the COEs. The additional sixteenth respondent shall also state in the affidavit the impediments, if any, in establishing COEs in all the States and if there are no impediments, the steps, if any, to be taken by the State Governments for the said purpose.

(2) The State Government shall file an affidavit indicating the present stage of development of the Concept Note for raising crowdfunding for treatment of rare diseases as also the steps taken for identification of beneficiaries, and for engaging services of social media groups for encouraging donations for treatment of rare diseases referred to in the affidavit filed by the Principal Secretary to Government, Health and Family Welfare Department dated 1.10.2021.

(3) The State Government shall indicate in the

affidavit, after obtaining the opinion of the experts in the field, the particulars of the rare diseases included in the National Policy for which effective treatments are available and the financial burden of which could be borne by the State Government. The State Government shall also indicate in the affidavit the impediments, if any, in making arrangements in one or more Medical Colleges in the State for treatment of rare diseases included in the National Policy. The State Government shall also state in the affidavit as to whether a digital platform could be established exclusively for crowdfunding for treatment of rare diseases, indicating the details of each and every patient undergoing treatment, the summary of disease, the amount required for treatment, the amount collected etc., with provision for separate campaigns dedicated for each patient, with the participation of the representatives of the people.

(4) The State Government shall forthwith make a provision for receiving the unutilized funds collected at the initiative of respondents 14 and 15 for treatment of children suffering from SMA and issue communication to the said

respondents to transfer the unutilized funds to the State Government.

(5) Insofar as the funds referred to in direction (4) above are funds collected for procurement of drugs for treatment of children suffering from SMA, the State Government shall earmark the said funds exclusively for procurement of drugs for treatment of children suffering from SMA.

(6) The State Government shall forthwith identify the children who are suffering from SMA in the State for whose ailments effective drugs are available, and use the funds received from respondents 14 and 15 exclusively for procuring drugs for the treatment of such children by prioritising interventions that benefit more number of children with the lesser amount available. The State Government shall also make necessary arrangements for the treatment of such children.

List this matter after a month. The affidavits directed shall be filed in the meanwhile. The State Government shall also



W.P.(C) No.7984 of 2021

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indicate in the affidavit compliance of directions (4) to (6) above.

**Sd/-**

**P.B.SURESH KUMAR, JUDGE**