(2021) 04 DEL CK 0167

In the Delhi High Court

Case No : Civil Writ Petition No. 5315, 10782 Of 2020, 322, 1491, 1511, 1611, 3662, 3682, 3689, 3706, 3707, 3729, 3737, 3859, 4045, 4067, 4259, 4304, 4551, 4812 Of 2021 & CM APPL. 19189, 33828 Of 2020, 812, 4291, 4331-4332, 4600, 11103-11105, 11153, 11179, 11229, 1

Utkarsh Indrajit Pawar, 10 Years Old, Through His Next Friend And Natural Father Sh. Indrajit Damar Pawar — APPELLANT

Vs

Union Of India & Anr — RESPONDENT

Date of Decision : 19-04-2021

Acts Referred:
Rights of Persons with Disabilities Act, 2016 — Section 86

Citation : (2021) 04 DEL CK 0167

Hon'ble Judges : Prathiba M. Singh, J

Bench : Single Bench

Advocate : Ashok Agarwal, Kumar Utkarsh, Harish Kumar Garg, Payal Agrawal

Judgement

Prathiba M. Singh, J

1. This hearing has been done through video conferencing.

2. Vide order dated 23rd March, 2021, detailed directions were issued in respect of the further steps to be taken for provision of treatments and indigenisation of treatments for rare diseases. The said directions are as under:

"21. In view of the above, the following directions are issued by this Court:

i) The 'National Policy for Rare Diseases' shall be finalized and notified by the Government of India, on or before 31st March, 2021.

ii) As a part of the said policy, the 'National Consortium for Research and Development on therapeutics for Rare Diseases' shall also be set up.

iii) A Rare Diseases Committee shall be set up at AIIMS consisting of Prof. (Dr.) Madhulika Kabra and Prof. (Dr.) P. Ramesh Menon, who shall examine the applications for treatment and funding, received from any patient suffering from

Rare Diseases. The said Committee can, depending upon the condition of the patient, also co-opt any one member from any specialized field into the said Committee. The Committee would, upon examination, recommend the kind of treatment which would be made available to the patients. Upon the approval of the Committee, the expenses for the treatment involved shall be drawn from the Rare Diseases Fund after approval by the Director, AIIMS.

iv) The entire unspent budget allocated for Rare Diseases, for the years 2018-19, 2019-20 and 2020-21, as per the amounts extracted above, shall be immediately moved into a fund called the 'Rare Diseases Fund', which shall be managed and utilized by AIIMS, which shall serve as a nodal agency for this fund. A separate bank account for the Rare Diseases Fund shall be opened by the Director, AIIMS for this purpose.

v) The digital platform that is created in the Policy, for the purposes of receiving crowdfunding and other kinds of funding, shall be linked to the Rare Diseases Fund. All individuals, organizations, companies etc., who wish to contribute to the said fund, shall make direct contributions. The Rare Diseases Fund shall be under the direct control and supervision of the Director, AIIMS. Periodic reports may be called for, by the Ministry of Health and Family Welfare, UOI, from AIIMS, in respect of the contributions that are received, as well as qua the utilization of the said fund.

vi) The other Institutes which shall be notified under the policy, as centres for excellence, for Rare Diseases shall also be entitled to receive applications from patients who need treatment, and shall forward the same to the Rare Diseases Committee based in AIIMS.

vii) In the case of direct applications being made to AIIMS, a decision shall be taken by the Rare Diseases Committee within a period of two weeks, in respect of the treatment and funding etc. In case, the application is routed through other institutes/ centres of excellence which are notified in the Health Policy for Rare Diseases, a decision upon the treatment and funding shall be taken by the Committee within a period of four weeks.

viii) In the context of Rare Diseases, the Government may consider increasing the budget for the year 2021-22 for the Rare Diseases Fund.

ix) The National Consortium for Research and Development on therapeutics for Rare Diseases shall be the nodal agency for supervising and monitoring the indigenization of treatments and therapies, manufacture of drugs, technology transfer, approvals, etc. for Rare Diseases. The said Consortium, as recommended in the report, shall consist of representatives from DBT, ICMR, DST, CSIR, DCGI, and other related Ministries and Departments. DBT and ICMR shall jointly take the lead.

x) The Consortium shall also make recommendations, if any, as to whether the patients suffering from Rare Diseases ought to be included in any of the clinical

trials currently taking place.

xi) The Consortium, while monitoring Research and Development, shall also approve applications for funding of research projects in respect of treatment and therapies for Rare Diseases. The Amounts from the 'Rare Diseases Fund' may be utilised for the purpose of Research. All projects approved shall have specific deliverables and timelines. The amounts shall be released for this purpose only after the project is approved by the Chairperson of the Consortium or an official, not below the level of Joint Secretary, Ministry of Health and Family Welfare, until the consortium is fully operational. Upon a project being approved by the Chairperson of the Consortium/Joint Secretary, the amount from the Rare Diseases Fund shall be released for the said project.

xii) The National Policy for Rare Diseases shall also deal with any limits/ caps that are to be imposed for various categories of Rare Diseases, only if required.

xiii) Any financial incentives to be given for manufacturing/ Research and Development of therapies for Rare Diseases shall also be explored in the Policy

xiv) The Policy shall also explore as to whether any financial incentives are to be given to the companies, who could contribute for the treatment/ Research and Development relating to Rare Diseases."

3. The Union of India, Ministry of Health & Family Welfare, has emailed to the court master, an affidavit dated 16th April, 2021, stated to be in compliance of the order dated 23rd March, 2021. The affidavit has set out the following compliances, which as per the UOI have been undertaken.

(1) The National Policy for Rare Disease Policy (NPRD), 2021 was notified on 30th March, 2021. A copy of the notified policy has been annexed with the affidavit.

(2) The consortium of Centres of Excellence for the prevention and treatment of Rare Diseases, under the leadership of AIIMS, has also been made a part of the policy as per paragraph 12(a) of the policy. The communication in this regard has already been sent by the Ministry to AIIMS, for constituting the said Consortium. The letter dated 7th April, 2021, in this regard has been annexed with the affidavit.

(3) Insofar as funding is concerned, as per the affidavit, the budgeted estimates from previous years have elapsed as the same were not utilized. However, the current year's available funds, under the Rare Disease Component, i.e. Rs.4.10 crores, under the umbrella scheme of RAN, is stated to have been transferred through RTGS to the AIIMS in the RAN account. The budget estimate for 2021-22 is to the tune of Rs.25 crores. Based on the utilization, the Ministry has deposed that the funds can even be enhanced.

(4) In addition, it is submitted that the option of crowd funding has also been accepted to provide supplementary funding resources.

(5) There are eight centres for excellence, each of which would be managing the

digital platform of crowd funding. The Ministry has written letters to each of centres for excellence for opening bank accounts for the rare diseases fund.

(6) Insofar as research and development, technology transfer and indigenization of therapeutics for rare diseases is concerned, the National Consortium would be convened by the Department of Health Research, with ICMR as a member. CSIR, Department of Science and Technology, Department of Biotechnology and Department of Pharmaceuticals, will be part of the said Consortium and will supplement research efforts. Further, approval for new products in the rare disease category would be provided by the Drugs Controller General of India under the New Drugs and Clinical Trial Rules, 2019.

4. Insofar as AIIMS is concerned, it is submitted by Mr. Oberoi, ld. Counsel appearing for AIIMS, that after the receipt of the letters from the Ministry, the `Rare Diseases Committee' has been constituted within AIIMS. It is further submitted on behalf of AIIMS that all the cases of the Petitioners would be referred to the said Committee, and a status report will be filed in respect of the decisions taken for each of the Petitioners before the next date.

5. It has also been highlighted by ld. counsels that though the amount has been transferred, it having been transferred to the RAN account, a limit of Rs.20 lakhs would be applicable to the use of the said amount qua a single beneficiary. Mr. Bhardwaj, ld. CGSC shall seek instructions in this regard and make submissions on the next date.

6. Mr. Ashok Aggarwal, ld. Counsel for the Petitioners, has brought to the notice of this Court that Duchene Muscular Dystrophy is a recognised form of disability under the Rights of Persons with Disability Act, 2016. He submits that under Section 86 of the said Act, the National Fund for Personal with Disability ("NFPD") has also been set up. Accordingly, in view of the fact that such a fund is a part of the said statute, the Ministry of Health and Family Welfare shall file affidavit as to whether NFPD has been set up and if so, what is the amount which has been allocated for the said purpose and if any amount has been allocated specifically for DMD.

7. It is submitted by Mr. Bhardwaj, ld. CGSC, that the ld. Solicitor General, who would be appearing in this matter, is unavailable today hence he seeks an adjournment.

8. Let status report/ Affidavit be filed by the Ministry of Health and Family Welfare, as well as AIIMS, in respect of the above mentioned issues, by 15th May 2021.

9. List for further proceedings on 20th May, 2021.

