(2021) 03 DEL CK 0025

In the Delhi High Court

Case No : Civil Writ Petition No. 5315, 10782 Of 2020, 322, 1491, 1511, 1611 Of 2021

Aviraj Garg, Age 4 Years, Through His Next Friend And Natural Father Sh. Abhinav Garg — APPELLANT

Vs

Union Of India & Anr — RESPONDENT

Date of Decision : 02-03-2021

Acts Referred:

Citation : (2021) 03 DEL CK 0025

Hon'ble Judges : Prathiba M. Singh, J

Bench : Single Bench

Advocate : Ashok Aggarwal, Kumar Utkarsh, Amrita Prakash, Tanveer Oberoi, Satvik Verma, Rajdeep Bhattacharya,

Judgement

Prathiba M. Singh, J

1. This hearing has been done through video conferencing.

CM APPL. 4332/2021 (for exemption) in WP(C) 1511/2021

2. Allowed, subject to all just exceptions. Application is disposed of.

WP(C) 10782/2020 & CM APPL. 33828/2020 (for interim direction)

WP(C) 5315/2020 & CM APPL. 19189/2020 (for interim direction)

WP(C) 322/2021 & CM APPL. 812/2021 (for interim direction)

WP(C) 1491/2021 & CM APPL. 4291/2021 (for interim direction)

WP(C) 1511/2021 & CM APPL. 4331/2021 (for interim direction)

WP(C) 1611/2021 & CM APPL. 4600/2021 (for interim direction)

3. The Court has perused the two affidavits filed by Central Drugs Standard Control Organisation (hereinafter, â??CDSCOâ?) and the Union of

India. The Court has also heard the submissions of Dr. Shastry from Dystrophy Annihilation Research Trust, Bangalore (hereinafter, â??DARTâ?)

and on behalf of the Institute of Child Health, Kolkata.

4. Firstly, this Court is of the opinion that there ought to have been greater effort by the Ministry of Health by engaging with M/s Sarepta

Therapeutics, which was willing to provide a confidential proposal; by exploring more concrete options for crowdfunding etc. The clear stand of the

Union of India appears to be that until the policy gets notified and the e-platform for crowdfunding is created, there can be no crowdfunding which can

be explored. However, orally Dr. Pulkesh Singh for the Ministry of Health, Union of India, has mentioned that he has written to four organisations to

arrange for funding for treatment of the said patients.

5. From the submissions made by Dr. Shastry from DART as also from the affidavit filed on behalf of CDSCO, it appears that clinical trials are

already underway in India for drugs/therapies for the treatment of DMD. The details of the same are set out in the affidavit filed by CDSCO. The

said affidavit and the submissions made today shows that there are various organisations and companies which are conducting clinical trials in respect

of DMD therapies. The same include :-

(i) M/s Medspace Clinical Research India Private Limited

(ii) M/s Muscular Dystrophy Patients Welfare Society

(iii) M/s Dystrophy Annihilation Research Trust

(iv) Institute of Child Health, Kolkata

(v) Nizamâ??s Institute of Medical Sciences (non sense mutation DMD)

(vi) Child Trust Hospital, Chennai (non sense mutation DMD)

6. In view of the fact that there are various therapies for DMD which are already being researched upon in India and there are several children

suffering from these diseases, the feasibility of accelerated approval processes ought to be examined. Further, the Union of India ought to explore the

confidential proposal which is being put forward by M/s Sarepta Therapeutics for the purpose of making the therapy available for children who are

suffering from DMD. In order to undertake a comprehensive assessment of the issues that have arisen and for recommending a time-line based

solution, this Court constitutes the following Committee:

(i) Chairperson - Dr. Renu Swarup, Secretary of Department of Biotechnology, Govt. of India. (secy@dbt.nic.in)

(ii) Dr. (Prof.) Madhulika Kabra, Division of Genetics, Department of Paediatrics, AIIMS (madhulikakabra@hotmail.com)

(iii) Dr. IC Verma Director, Centre of Medical Genetics, Sir Ganga Ram Hospital (dr_icverma@yahoo.com)

(iv) Dr. P. Ramesh Menon, Associate Professor, Department of Paediatrics, AIIMS (M: 8800997737) (rpmaiims@gmail.com)

(v) Dr. Arun Shastry, Chief Scientific Officer, Dystrophy Annihilation Research Trust (DART) (M:9840219833) (arunshastry@dartindia.in)

(vi) Dr. Apurba Ghosh, Director, Institute of Child Health (apurbaghosh@yahoo.com)

(vii) Dr. Angamuthu Meena Kanikannan, Nizam's Institute of Medical Sciences (M: +914065863509) (meenaak@hotmail.com)

(viii) Dr. V, Viswanathan, Kanchi Karnakoti, CHILDS Trust Hospital (M: 9840100072) (vishneuro@gmail.com)

(ix) Dr. Pulkesh Kumar, Deputy Secretary, Ministry of Health and Family Welfare.

The Chairperson is free to consult or co-opt any other member or organisation, if deemed expedient, into the Committee.

7. The committee shall submit a report on the following major aspects:

(i) How to immediately provide treatment and therapy options to the Petitioners and similarly situated patients suffering from DMD, Hunterâ??s

syndromes and other rare diseases.

(ii) Steps to be taken to indigenize the development of the therapies in India, and reasonable timelines required to be followed thereof.

(iii) Whether accelerated approval processes can be considered especially in view of the research currently being undertaken in India for DMD?

(iv) Immediate concrete proposals for crowdfunding of the costs of treatment for children with rare diseases.

8. The first meeting of the Committee shall be held on 5th March, 2021 at 3.00 p.m. A report be submitted to this Court on or before 12th March,

2021.

9. Further, a specific affidavit shall be filed by the Union of India specifying the budget for health in the last five years, as also whether any part of the

budget has been unused and can be used for the purpose of treatment of the

Petitioners or the indigenous development of therapies for the treatment of rare diseases.

10. List this matter on 15th March, 2021.

