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

\+ W.P.(C) 3737/2019 & CM No.17121/2019

ADITYA BHATIA ..... Petitioner

Through: Mr Chetan Sharma, Sr. Advocate with Ms Mansi Sinha and Mr Amit Gupta, Advocates alongwith petitioner in person.

versus

UNION OF INDIA & ANR ..... Respondents

Through: Ms Maninder Acharya, ASG with Mr Kirtiman Singh, CGSC, Mr Waize Ali Noor, Mr Sahil Sood, Mr Prateek Dhanda, Mr Harshul Choudhary and Mr Viplav Acharya, Advocates for R-1/UOI.

Ms Hetu Arora Sethi, ASC, GNCTD with Mr Siddharth Agarwal, Advocates for R-2.

CORAM:
HON'BLE MR. JUSTICE VIBHU BAKHRU

O R D E R

% 15.04.2019

1. The petitioner has filed the present petition, *inter alia*, praying that the respondents be directed to permit the petitioner to continue to avail "Human Embryonic Stem Cell Therapy", being provided to the petitioner by Nutech Mediworld, Green Park Extension (hereafter 'the said clinic'). The petitioner states that he is suffering from Facioscapulohumeral Muscular Dystrophy (FSHD), and there is no other cure for the said condition. In these circumstances, the petitioner had approached the said clinic and is

being administered the Human Embryonic Stem Cell Therapy. According to the petitioner, the said treatment is helping the petitioner and the discontinuance of the said therapy would severely jeopardise the petitioner's condition. The petitioner is also conscious of the fact that the said therapy may not be a recognised therapy, and the products being administered to the petitioner may not have the approval of the concerned authority. Mr Chetan Sharma, learned senior counsel appearing for the petitioner also states that the petitioner is fully aware of the risks being taken by him.

2. With a view to regulate such novel therapies, the respondent has framed the New Drugs and Clinical Trials Rules, 2019, which define 'New Drugs' as under:

> (w) "new drug" means,—
> (i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority with respect to its claims; or
> (ii) a drug approved by the Central Licencing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or
> (iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or
> (iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the

> Central Licencing Authority; or
> (v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;
> Explanation.— The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licencing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs;

3. The petitioner, essentially, seeks to challenge the validity of the said definition on the assumption that the treatment being administered to him is covered under clause (v) of Rule 2(1)(w) as set out above.

4. Ms Acharya, learned ASG appearing for the respondent, states that there is no clarity as to whether the treatment being provided to the petitioner falls with the said Rules as no particulars of the same have been submitted by the said clinic.

5. In the aforesaid circumstances, this Court considers it apposite to direct, as an interim measure, that the treatment being provided to the petitioner will not be impeded. This is subject to the clinic in question submitting all the information as to the treatment being afforded to the petitioner to the Central Drugs Standard Control Organisation (CDSO), within a period of one week from today. The concerned authority shall examine whether the said treatment or the products being administered to the petitioner, *prima facie*, fall within the scope of the expression 'New Drugs' as defined under Rule 2(1)(w) of New Drugs and Clinical Trials Rules, 2019, and communicate its view to the petitioner and the said clinic.

6. Needless to state that if the said products fall within the scope of the definition ‘New Drugs’, the concerned clinic/entity administering the same would require to take approval as required under the said Rules.

7. It is seen that the petitioner has sought to challenge the constitutional vires of the New Drugs and Clinical Trials Rules, 2019. The petitioner’s contention in this regard are reserved, and the petitioner would be at liberty to apply afresh, if a cause so arises.

8. Order *dasti* under signatures of the Court Master.

9. The petition is disposed of with the aforesaid observations. The pending application is disposed of.

VIBHU BAKHRU, J

APRIL 15, 2019
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