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

% *Date of Judgment: 28th May, 2019*

+ W.P.(C) 6139/2019, CM Appls. 26423-24/2019

DEEPAK KHOSLA

..... Petitioner

Through Mr. Ajay Kohli & Ms. Pooja Vohra,
Advocates.

versus

UNION OF INDIA AND ANR.

..... Respondents

Through Mr. Kirtiman Singh, CGSC for UOI
with Mr. Waize Ali Noor, Advocate.
Mr. Anuj Aggarwal, ASC for R-2
with Mr. Atul Goyal, Advocate.

CORAM:

HON'BLE MR. JUSTICE G.S.SISTANI

HON'BLE MS. JUSTICE JYOTI SINGH

G.S. SISTANI, J. (ORAL)

CM APPL 26424/2019 (Exemption)

1. Exemption is allowed subject to all just exceptions.
2. Application stands disposed of.

W.P.(C) 6139/2019

3. Petitioner claims to be a patient of Glaucoma with Macular Degeneration, which results in damage to the optic nerve and causes vision loss. It is also the case of the petitioner that he visited the clinic 'Nutech Mediworld at Green Park, New Delhi' where stem cell treatments are provided. Since July, 2016 till March, 2019, petitioner claims that he has shown visible improvement since the transplantation

of Embryonic Stem Cells, from July, 2016 onwards as compared to his medical condition prior to the commencement of his treatment.

4. Mr. Kohli, counsel for the petitioner submits that petitioner has been forced to approach this court on account of a notification 'New Drugs and Clinical Rules, 2019 ("New Rules")', which have been notified by respondent no.1, which includes 'stem cell derived products' under the definition of 'new drugs' Clause (v) of sub-clause (w) of Rule 2 of the new Drugs and Clinical Trials Rules, 2019. It is contended that the effect of this notification would be that the medicine prescribed would fall under the definition of 'new drug' and would require approval from the concerned authority in terms of the said rules. Learned counsel submits that in view of the notification, the clinic has stopped providing medical treatment i.e. Embryonic Stem Cell therapy, which is a treatment required by the petitioner for his day to day sustenance of life and basic activities, and in case, this treatment is discontinued further, it would lead to a serious impact on his health. It is further contended that the clinic in question i.e. Nutech Mediworld, which is administering the medicine at present, cannot function under the New Rules, unless the license is obtained. It is pointed out that till the rules fall in place and the marketing license is provided during the intervening period, serious prejudice would be caused to the health of the petitioner i.e. between the application is made under the authority i.e. Drug Controller, Govt. of India and a decision is taken, which would not take place within a few months, in the interregnum, in the absence of the treatment, life of the petitioner would be in jeopardy and would rapidly lose their muscle strength and is facing growing fatigue on account of his condition.

5. Learned counsel for the petitioner submits that the only relief which he seeks is to seek a direction to the respondents to allow the Nutech Mediworld clinic from where the petitioner is receiving treatment to continue to provide the treatment to the petitioner till such time the formalities are completed and the Nutech Mediworld clinic or at least some other clinic obtains a licence.
6. Notice to show cause as to why the petition be not admitted. Counsels for the respondents accept notice.
7. 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 positively. 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.
8. Accordingly, as an interim measure and till such time Nutech Mediworld clinic or at least some other clinic applies for a licence and the licence is processed, the Nutech Mediworld clinic would continue to provide treatment to the petitioner.
9. In view of the agreed directions, the writ petition is disposed of, as prayed by the counsel for the petitioners. This arrangement is without prejudice to the rights and contentions of both the parties.

CM Appl. 26423/2019 (stay)

10. In view of the order passed in the writ petition, the application stands disposed of.

G.S.SISTANI, J

JYOTI SINGH, J

MAY 28, 2019/ck /

