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

% *Date of Order : 31st May, 2019*

+ W.P.(C) 6599/2019

RITA DEVI

..... Petitioner

Through Mr. Ajay Kohli, Advocate.

versus

UNION OF INDIA & ANR

..... Respondents

Through

Mr. Yashish Chandra, Mr. Piyush Gaur & Mr. Yashaswi SK Chocksey, Advocates for R-1.

Mr. Anuj Aggarwal, ASC with Mr. Atul Goyal, Advocate for R-2.

CORAM:

HON'BLE MR. JUSTICE G.S.SISTANI

HON'BLE MS. JUSTICE JYOTI SINGH

G.S. SISTANI, J. (ORAL)

CM.APPL 27895-96/2019 (Exemption)

1. Exemptions allowed, subject to all just exceptions.
2. The applications stand disposed of.

W.P.(C) 6599/2019 & C.M.27894/2019 (stay)

3. With the consent of the parties, the writ petition is set down for final hearing and disposal.
4. Some necessary facts which are required to be noticed for the disposal of the present writ petition are that the petitioner claims to be suffering from Dilated Cardiomyopathy which is condition wherein the heart becomes enlarged and cannot pump blood effectively. It is the case of the petitioner that he has been forced to approach this Court on account of Notification "New Drugs and Clinical Rule 2019" ("New Rule"),

which has been issued by respondent no.1, which includes “stem cell derived product” under the definition of “new drug” 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 would fall under the definition of “new drug” and would require approval from the concerned authority in terms of the said Rule. It is pointed out that the said Notification has resulted in stoppage of the petitioner’s Human 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 even for a few days, it would have a serious impact on the petitioner’s health as the clinic (Nutech Mediworld) which is administering the medicine cannot function under the New Rules until the licence is duly obtained. It is submitted that the New Rules would require the clinics engaged in such “new drug” to take a marketing licence and there is no provision for providing any interim arrangements during the intervening period i.e. between an application being made under the authority i.e. the Drug Controller, Government of India and a decision is taken. This process is likely to take a few months more and in the interregnum since the treatment has been discontinued by the clinic, the life of the petitioner would be in jeopardy and would have a debilitating impact on the petitioner’s health.

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. 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.
7. 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.
8. In view of the agreed directions, the writ petition and C.M.27894/2019 are disposed of, as prayed by the counsel for the petitioner. This arrangement is without prejudice to the rights and contentions of both the parties.
9. Dasti.

G.S. SISTANI, J

JYOTI SINGH, J

MAY 31, 2019/pst/