* IN THE HIGH COURT OF DELHI AT NEW DELHI

Date of decision: 4th September, 2019

- + W.P.(C) 5147/2019 with CM No. 22814/2019
- + W.P.(C) 5148/2019 with CM No. 22816/2019
- + W.P.(C) 5149/2019 with CM No. 22818/2019
- + W.P.(C) 6753/2019 and CM No. 28342/2019
- + W.P.(C) 6759/2019 and CM No. 28354/2019
- + W.P.(C) 6760/2019 and CM No. 28357/2019
- + W.P.(C) 6761/2019 and CM No. 28359/2019
- + W.P.(C) 6762/2019 and CM No. 28361/2019
- + W.P.(C) 6763/2019 and CM No. 28363/2019
- + W.P.(C) 6764/2019 and CM No. 28365/2019
- + W.P.(C) 6765/2019 and CM No. 28367/2019

ABHISHEK AGARWAL AND ANR.
ABHISHEK GUPTA
KIRAN VERMA
AYUSHI AMBASTHA
C. MANUSH SEKARAN
VAGGISH ANAND
MAASTER DHAIRYA S THACKER
HINA KHULBE
UJJWAL KUMAR

ARGHADEEP DEBNATH Petitioners
Through: Ms. Priyanka, Adv. for the
petitioners in W.P.(C) 5147, 5148,
5149/2019

versus

UNION OF INDIA & ANR

.... Respondents

Through: Mr. Ashok Kumar Sharma and Mr. R.M. Tripathi, Adv. for R-UOI in W.P.(C) 5147/2019

the licence is to be obtained by the clinic to continue the treatment which is already going on.

- 3. Counsel appearing for the respondents submitted that, if the clinic is injecting stem cells, the respondents have no objection because, for injecting stem cells, the clinic is not required to take any licence. Stem cells, *per se*, are not covered by the Rules, 2019. As per the Rules, 2019, "Stem Cells Derived Products" are included in the Rules, 2019 for which the concerned clinic/hospital has to take a licence. It is clarified by counsel for the respondents that these petitioners can continue the treatment which they are taking regularly from the clinic, including the treatment given by the clinic by injecting stem cells.
- 4. The position, as it emerges from the Status Note dated 14th June, 2019 filed by the Central Drugs Standard Control Organization (CDSCO), is that, while treatment using "stem cells" is permissible, treatment using "stem cells derived products" requires a licence under the Rules, 2019. The clinic would contend that it provides therapy using "stem cells", and not "stem cells derived products". This, however, is an aspect between the clinic and the CDSCO. It is a matter of record that the clinic has written, to the CDSCO, asserting that it provides therapy using "stem cells", and not "stem cells derived products". Though a tentative opinion, of a Committee constituted to examine the said representation, which is not favourable to the clinic was shown to this Court, no final decision has been communicated to the clinic till date. As and when any such response is communicated, the clinic would have its remedies available in law thereagainst.

- 5. The petitioners, in these cases, are, however, presently undergoing treatment using "stem cell therapy" from the clinic. It is an admitted position that discontinuance of the said treatment, even for a day, will have severely deleterious effects on their health. Till such time a final decision is, therefore, taken, by the CDSCO, regarding the issue of whether the clinic is providing therapy using "stem cells", or "stem cells derived products", we are of the opinion that the treatment presently being administered to these petitioners cannot be allowed to be discontinued, as such discontinuance is likely to have life-threatening consequences.
- 6. We, therefore, allow the petitioners to continue such treatment, from the clinic, till a final decision is taken, by the CDSCO, regarding the aspect of coverage, or otherwise, of the clinic, under the Rules, 2019.
- 7. We also clarify that no decision, adverse to the clinic regarding the aspect of its coverage under the Rules, 2019, would be taken, save and except in accordance with due law and due procedure and after giving the clinic an adequate opportunity of being heard.
- **8.** With these observations, these writ petitions are hereby disposed of.

CM No. 22814/2019 in W.P.(C) 5147/2019 CM No. 22816/2019 in W.P.(C) 5148/2019 CM No. 22818/2019 in W.P.(C) 5149/2019 CM No. 28342/2019 in W.P.(C) 6753/2019 CM No. 28354/2019 in W.P.(C) 6759/2019 CM No. 28357/2019 in W.P.(C) 6760/2019 CM No. 28359/2019 in W.P.(C) 6761/2019 CM No. 28361/2019 in W.P.(C) 6762/2019