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* IN THE HIGH COURT OF DELHI AT NEW DELHI

+ **W.P.(C) 2688/2019**

M/S FOCUS BRANDS TRADING (INDIA)
PRIVATE LIMITED AND ANR.

..... Petitioners

Through Mr Sandeep Sethi, Senior Advocate, Mr Raj Shekhar Rao, Mr Vivek Raja, Mr Ankur Kashyap, Advocates.

Mr Rajiv Nayyar, Senior Advocate with Mr Aashish Gupta, Mr Sandip Chillana, Mr Kamaljeet Singh, Aditya Mukherjee, Mr Rakshit Akshay Jha, Mr Saurabh Seth, Advocates.

versus

DIRECTORATE GENERAL OF HEALTH

SERVICES AND ORS.

..... Respondents

Through Mr Harpreet Singh, Sr. Standing Counsel for R2 with Ms Subhani Mathur, Advocate for R2. Mr Vinod Diwakar, CGSC with Ms Radhika Roy, Advocate for R1 and R3.

45.

+ **W.P.(C) 2351/2019**

LITEJOY INTERNATIONAL PVT LTD

..... Petitioner

Through Mr Sandeep Sethi, Senior Advocate, Mr Raj Shekhar Rao, Mr Vivek Raja, Mr Ankur Kashyap, Advocates.

versus

UNION OF INDIA & ORS.

..... Respondents

Through Ms Maninder Acharya, ASG with Mr Kirtiman Singh, Mr Vikas Mahajan, Mr Rakesh Kumar, Mr Parth Semwal, Mr Viplav Acharya, Mr Ranjit Singh, Mr Akash Varma, Advocates.

+ **W.P.(C)** 2735/2019

PIUSH AHLUWALIA

..... Petitioner

Through Mr Rajeev Nayyar, Senior Advocate with Mr Sandeep Sethi, Senior Advocate, Mr Raj Shekhar Rao, Mr Vivek Raja, Mr Ankur Kashyap, Mr Tanmay Mehta, Mr Adarsh Ramanujan, Mr Sanjay Subhudi, Mr Prabhat, Advocates.

versus

UNION OF INDIA & ANR

..... Respondents

Through Ms Maninder Acharya, ASG with Mr Kirtiman Singh, Mr Vikas Mahajan, Mr Rakesh Kumar, Mr Parth Semwal, Mr Viplav Acharya, Mr Ranjit Singh, Mr Akash Varma, Advocates.

CORAM:

HON'BLE MR. JUSTICE VIBHU BAKHRU

ORDER

% 18.03.2019

1. The petitioners have filed the present petitions impugning a communication dated 22.02.2019, and a circular dated 27.11.2018. The respondent no.1 has issued the impugned communication dated 22.02.2019 requesting the State licensing authorities to ensure that Electronic Nicotine Delivery systems (ENDS) including e-Cigarettes, Heat-Not Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and the like devices that enable nicotine delivery are not sold (including online sale), manufactured distributed, traded, imported and advertised in their jurisdictions, except for the purpose and in the manner and to the extent, as may be approved under the Drugs and Cosmetics Act, 1940.

- 2. Similarly, by the impugned circular dated 27.11.2018, all Customs Authorities have been requested to ensure that the advisory issued by the respondent is implemented, and all authorities are directed to ensure import consignments of ENDS including e-Cigarettes, Heat-Not-Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and the like devices/products are referred to drug control authorities. It further directs that the Assistant/Deputy Drugs Controller may thereafter check the compliance of such goods, in terms of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.
- 3. The petitioners claim that ENDS, including e-Cigarettes, are substitutes to smoking combustible cigarettes. It is also claimed that the same are healthier than combustible cigarettes, inasmuch as the use of such devices does not entail inhaling any tar, which is the product of inhaling smoke of burnt paper along with tobacco.
- 4. Mr Nayyar, learned counsel appearing for the petitioners also states that the impugned circulars seriously affect the rights of choice of the consumers. He states that the petitioner in W.P. (C) 2735/2019 is a person who has filed the present petition claiming his right to choose his ecigarettes in place of a paper roll cigarettes, as being less harmful.
- 5. Ms Acharya, learned ASG appearing for the respondents disputes the same. She states that the contention whether e-cigarettes are safer is yet to be determined, and the said statement cannot be accepted at its face value. She submits that the petitioners are professing that ENDS and such devices would assist smokers for giving up their addiction to tobacco. It is also

contended that it is a safer alternative and is used as a replacement therapy, and is akin to 'nicotine gum'. She submits that in view of the aforesaid assertion the ENDS and other devices would fall within the definition of a drug, as defined under Section 3(b) of the Drugs and Cosmetics Act, 1940. She also referred to Schedule K Rule 23 read with Schedule K of the said Act, and drew the attention of this Court to Entry 33 of the said schedule which includes "Nicotine gum and Lozenges containing upto 2 mg of nicotine". She submitted that since the products in question are stated to be a kin to nicotine gum, the same would be covered under the Cosmetics and Drugs Act, 1940. She further states that the petitions have been filed in various courts against the notifications but no interim orders have been passed.

- 6. Clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 defines the term "drug" and is set out below:-
 - "3. Definitions.—In this Act, unless there is anything repugnant in the subject or context.—

- (b) "drug" includes—
- (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be

specified from time to time by the Central Government by notification in the Official Gazette;

- (iii) all substances intended for use as components of a drug including empty gelatin capsules; and
- (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;"
- 7. According to Ms Acharya, the products in question are covered under Clause (b) of Section 3 of the said Act.
- 8. A plain reading of Clause (b) of Section 3 of the said Act indicates that it covers all medicines for internal or external use, and all substances intended to be used for or in the diagnosis, treatment mitigation or prevention of disease or disorder. It does not appear that the devices in question are sold as therapeutic devices, or as having any medicines for internal or external use of human beings, or animals intended to be used for in the diagnosis treatment of any disease. The said products do not have any medicinal value.
- 9. In view of the above, this Court is, *prima facie*, of the view that the products do not fall within the definition of a 'drug', as defined under section 3(b) of the Drugs and Cosmetics Act 1940.
- 10. The learned counsel for the petitioners had also drawn the attention of this court to the report of the 48th meeting of Drugs Consultative Committee constituted under Section 7 of the Drugs and Cosmetics Act, 1940, held on 24.07.2015. In the said meeting, the Consultative Committee considered the

question whether E-Cigarettes, containing Nicotine could be considered as a

'new drug' and recommended as under:

"E-cigarettes are not covered under the definition of the term 'drug' and therefore do not come under the purview of Drugs and Cosmetics Act. 1940. E-cigarettes therefore cannot be regulated

under the provisions of the said Act."

11. If the product in question is not a drug, respondent no.1 would not

have the jurisdiction to issue the impugned circular. In this view, the

impugned communication and the impugned circular are stayed, till the next

date of hearing.

12. The respondents may file their counter affidavit, within a period of

two weeks. Rejoinder, if any, be filed within a period of two weeks,

thereafter.

13. List on 17.05.2019.

14. Order *dasti* under the signature of Court Master.

VIBHU BAKHRU, J

MARCH 18, 2019 pkv