

F. No- P-16012/19/2017-TC
Government of India
Ministry of Health & Family Welfare

Dated, the 28th August, 2018

Advisory on Electronic Nicotine Delivery Systems (ENDS) including e-Cigarettes, Heat-Not-burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and the like products

Whereas, Electronic Nicotine Delivery Systems (ENDS) are devices that heat a solution to create an aerosol, which frequently also contains flavours, usually dissolved into Propylene Glycol or/and Glycerin. Electronic cigarettes, the most common prototype, are devices that do not burn or use tobacco leaves but instead vaporise a solution, which the user then inhales. The main constituents of the solution, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents. ENDS solutions and emissions contain other chemicals, some of them considered to be toxicants. Although ENDS is generally considered a single product class, these products constitute a diverse group with potentially significant differences in the production of toxicants and mechanisms for delivery of nicotine;

And whereas, Electronic Nicotine Delivery System (ENDS) aerosol contains nicotine, the addictive component of tobacco products. In addition to creating dependence, nicotine can have adverse effects on the development of the foetus during pregnancy. It may contribute to cardiovascular disease to the people who use ENDS. Also, nicotine may function as a "tumour promoter" and seems to be involved in the biology of malignant diseases. Foetal and adolescent nicotine exposure may have long-term consequences for brain development, potentially leading to learning and anxiety disorders. A number of metals - including lead, chromium, and nickel, and chemicals like formaldehyde have been found in aerosols of some ENDS, with concentrations equal to or greater than traditional cigarettes, under normal experimental conditions of use. As such, the evidence is sufficient to warn children and adolescents, pregnant women, and women of reproductive age against ENDS use and nicotine;

And whereas, nicotine is prohibited for use as an ingredient in any food item under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 of the Food Safety and Standards Act, 2006;

And whereas, both Nicotine and Nicotine Sulphate are listed as hazardous chemicals in the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989 made under the Environment (Protection) Act, 1986;

And whereas, nicotine is also listed as an insecticide in the Schedule of Insecticides under the Insecticide Act 1968, and subsequently its use as a pesticide is also highly restricted by Government of India;

And whereas, there are possibilities that children, adolescents & youth (and generally non-smokers) will initiate nicotine use through ENDS at a rate greater than expected if ENDS did not exist; and that, once addicted to nicotine through ENDS, such children, adolescents & youth are likely to switch to cigarette smoking;

And whereas, the scientific evidence regarding the effectiveness of ENDS as a smoking cessation aid is scant and of low certainty, making it difficult to draw credible inferences. The Drugs and Cosmetics Act, 1940 & Rules, 1945 permit the use of Nicotine up to 2 mg and 4 mg in gums, lozenges and strips, which may be used as aids for Nicotine Replacement Therapy (NRT). However, such a product should adhere to the provisions of Chapter IV of the Drugs and Cosmetics Act & Rules made thereunder, which require them to be manufactured under a valid drug manufacturing license and also a valid sales license for products containing more than 2mg of nicotine. ENDS are not yet approved as NRTs under the Drugs and Cosmetics Act;

And whereas, the Ministry of Health & Family Welfare, Government of India conducted a Roundtable discussion on Electronic Nicotine Delivery Systems (ENDS) in 2014, wherein eminent doctors, specialists, scientists and officers of Health and Drug departments concluded that available scientific evidences indicate that the ENDS and similar technologies that encourage tobacco use, are hazardous for an active as well as passive users and have an adverse impact on public health;

And whereas, the State Governments of Punjab [Vide Circular dated 5.9.13]; Karnataka [Vide Circular dated 15th June, 2016]; Mizoram [Vide Circular dated 8th

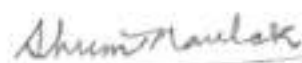
June, 2016]; Kerala [Vide Order dated 1st August, 2016]; Jammu & Kashmir [Vide Circular dated 24th July, 2017]; Uttar Pradesh [Vide Order dated 14th November, 2017]; Bihar [Vide Order dated 28th November, 2017] have prohibited the manufacture, distribution, import and sale of Electronic Nicotine Delivery Systems (ENDS);

And whereas, as per the World Health Organization Report on the Global Tobacco Epidemic 2017, the Governments of thirty (30) countries including Mauritius, Australia, Singapore, Korea (Democratic People's Republic), Sri Lanka, Thailand, Brazil, Mexico, Uruguay, Bahrain, Iran, Saudi Arabia, United Arab Emirates etc, have already banned Electronic Nicotine Delivery System (ENDS) in their countries;

Now therefore, it is evident that Electronic Nicotine Delivery Systems (ENDS) including e-Cigarettes, Heat-Not-Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and the like devices or products available by whatsoever name, that enable nicotine delivery or its use, are a great health risk to public at large, especially to children, adolescents, pregnant women and women of reproductive age. It is also evident that ENDS are not approved as NRTs under the Drugs and Cosmetics Act and Rules made thereunder.

As such, the States/Union Territories are advised, in larger public health interest and in order to prevent the initiation of ENDS by non-smokers and youth with special attention to vulnerable groups, to ensure that any 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 & in the manner and to the extent, as may be approved under the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

This issues with the approval of Competent Authority.


(T. Chinsum Naulak) 28/08/18
Under Secretary
Ministry of Health & Family Welfare
Government of India

Copy for information and necessary action to:

Principal Secretary (Health) of All States / UTs