Government of Punjab  
Food and Drugs Administration  
Department of Health and Family Welfare  

Office Circular

No. ..............................  Date 3-10-18

This is in continuation of this office letter No. Drugs(7) Pb. 2013/16988-89 dated 05.09.2013 in which it was mentioned that, that Nicotine preparations is coming in the form of E-Cigarettes which is unapproved drug and contravenes the provisions of Drugs and Cosmetics Act/Rules 1945 and the officers were asked to be vigilant about the spread of ENDS/E-Cigarettes and take necessary action.

The Inspector General Police, State Cyber Crime, Punjab vide letter no.496/R/IGP/CC Dated 24/08/2016 intimated to the Principal Secretary Health and Family Welfare Punjab that, E-Commerce sites, Advertising or selling Cigarettes products on their websites (E-Cigarettes) have been directed to block such advertisements from their websites.

Now vide letter no. F.No.P-16012/19/2017-TC dated 28th August 2018 an Advisory has been issued by Ministry of Health and Family Welfare, Government of India on Electronic Nicotine Delivery Systems (ENDS) including e-Cigarettes, Heat Not Burn devices, Vape e-sheesha, e-Nicotine, Flavoured Hookah and the like products as follows:

- "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 vapourise 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 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 and 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 5.9.131; Karnataka [Vide Circular dated 15th June, 20161; Mizoram I Vide Circular dated 8th June, 20161; Kerala [Vide Order dated 1st August, 2016]; Jammu & Kashmir vide Circular dated 24th July, 20171; 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 there under.

- 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 form under the 
Drugs and Cosmetics Act, 1940 and Rules made there under.”

In view of the afore mentioned facts, all the concerned 
enforcement officers are directed to enforce the provisions of Drugs and 
Cosmetics Act 1940/Rules 1945 and other applicable provisions of law as 
stated above, for sale (including online sale), manufacture, distribution, 
trade, import and advertisement of Electronic Nicotine Delivery Systems 
(ENDS) including e-Cigarettes, Heat-Not-Burn devices, vape, e-sheesha, e-
nicotine flavoured hookah, and the like devices (including kits and 
components that can be used to assemble ENDS and ENDS like products). The 
aforementioned un-approved products are hereby prohibited with 
immediate effect in the public interest.

Commissioner
Food and Drugs Administration Punjab

No. 9117 - 9122
Copy for information:
1. PS to Minister of Health and Family Welfare, Government of Punjab
2. PS to Addl Chief Secretary to Government of Punjab, Deptt of Health 
and Family Welfare
3. Director General of Police
4. Chairperson, State Pollution Control Board
5. Director, National Tobacco Control Programme, Ministry of Health and 
Family Welfare, Government of India

No. 9123 - 9180
Copy for Action:
1. Commissioner, (Central Excise)
2. Commissioner, (Customs)
3. Jt. Commissioner, Food Safety
4. Jt. Commissioner Drugs
5. All SSPs/Police Commissioners
6. ALL Deputy Commissioners
7. State Nodal Officer/ State Programme Officer (National Tobacco 
   Control Programme)
8. District Nodal Officers (National Tobacco Control Programme), All Districts

Commissioner
Food and Drugs Administration Punjab