E-Cigarettes(ENDS) and its regulation

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Manifest Pedagogy

The issue of Tobacco and health has been in news for the past few years. In this topic a clear segregation needs to be made between Prelims and Mains! Science related aspects like ENDS should be studied from the point of Prelims and Governance related aspects about tobacco and nicotine control should be more stressed on in Mains.

In news

Ministry of Commerce – Law to ban making the sale of e-cigarettes

Placing it in the syllabus

Indian society- Social Sectors lije health (not explicitly mentioned)

Indian Polity – Health

Static dimensions

- **What are e-cigarettes or ENDS?**
- Pros and Cons of e-cigarettes or ENDS
- Regulations under WHO

Current dimensions

The recent decision by Commerce Ministry

Content

Electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that do not burn or use tobacco leaves but instead vaporize a solution the user then inhales.

ENDS are devices that heat a solution to create an aerosol, which frequently also contains flavors, usually dissolved into Propylene Glycol or Glycerin

Pros of ENDS

- **Help to quit smoking: E-cigarettes help adults quit smoking and decrease deaths and disease caused by traditional cigarettes.**
- **Less toxic chemicals:** Although e-cigarettes contain nicotine substance, but e-cigarette vapor contains lower concentrations of potentially toxic chemicals than with cigarette smoke.
- **No ashes or smoke:** E-cigarettes don’t emit smoke or ashes thus, used in places where cigarette smoking is not allowed.
- **Alternative for smokers:** E-cigarette is used as an alternative for long-term cigarette smokers who are unable to quit smoking.

Cons of ENDS

- **Addictive:** ENDS aerosol contains nicotine, the addictive component of tobacco products.
- **Affect the development of fetus:** In addition to creating dependence, nicotine can have adverse effects on the development of the fetus during pregnancy.
- **Cardiovascular disease: Using ENDS would lead to cardiovascular disease. Also, nicotine may function as a “tumor promoter” and seems to be involved in the biology of malignant diseases.**
- Affect brain development: Foetal and adolescent

nicotine exposure may have long-term consequences for brain development, potentially leading to learning and anxiety disorders.

- Contain more metal: 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.

Hence, with this evidence, it is clear that the usage of ENDS is not good for children, adolescents, pregnant women, and women of reproductive age.

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.

Regulations under WHO (Conference of the Parties to the **WHO Framework Convention on Tobacco Control**)

Following are the **General regulatory objectives** to be followed by Governments while framing a regulatory strategy for ENDS:

- Impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;
- Minimize potential health risks to ENDS users and non-users;
- Prohibit unproven health claims from being made about ENDS; and
- Protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.

Specific Regulatory options

In order to achieve the general regulatory objectives mentioned above, Parties that have not banned the sale of ENDS could consider the following non-exhaustive list of regulatory options;

- **Health claims:** Prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval.
- **Use of ENDS in public places: Since the reasonable expectation of bystanders is not a diminished risk in comparison to exposure to second-hand smoke but no risk increase from any product in the air they breathe, ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapour is proven to be not harmful to bystanders and reasonable evidence exists that smoke-free policy enforcement is not undermined.**
- **Advertising, promotion, and sponsorship:** Given that the same promotional elements that make ENDS attractive to adult smokers could also make them attractive to children and non-smokers, Parties should contemplate putting in place an **effective restriction on ENDS advertising, promotion, and sponsorship.**

Some forms of ENDS promotion, however, may be considered acceptable by Parties if empirical evidence shows that ENDS might play a role in helping some smokers to quit without leading to increased ENDS use by minors and non-smokers who otherwise would not have used nicotine.

Any form of ENDS advertising, promotion and sponsorship must be regulated by an appropriate governmental body.

- **Protection from vested commercial interests:** Transparency should be required from ENDS and tobacco companies advocating for and against legislation and

regulation, both directly and through third parties.

- **Product design and information:** ENDS should be regulated to (a) minimize content and emissions of toxicants; (b) ensure use of nicotine of pharmacological quality, when nicotine use is intended; (c) standardize nicotine delivery at levels known to the consumers; (d) minimize acute nicotine toxicity; impede product alteration to use of other drugs; (f) ban ENDS solutions with fruit, candy-like and alcohol-drinks flavors until empirical evidence shows that they are not attractive to minors; (g) requires manufacturers and importers to disclose to governmental authorities information about the contents and emissions of ENDS; and (h) require registration of manufacturers and importers with governmental authorities.
- **Health warnings:** ENDS health warnings should be commensurate with proven health risks. In this regard, the following risk warnings could be considered: potential nicotine addiction; potential respiratory, eyes, nose and throat irritant effect; potential adverse effect on pregnancy (due to nicotine exposure).
- **Surveillance and monitoring:** Governments are recommended to use or strengthen their existing tobacco surveillance and monitoring systems to assess developments in ENDS and nicotine use by sex and age.
- **Sale to minors:** Retailers should be prohibited from selling ENDS products to minors, and vending machines should be eliminated in almost all locations.

In order to implement the suggested general regulatory objectives as well as the specific regulatory options, Parties will need to consider the available national regulatory frameworks that could best provide solid regulatory grounds.

The recent decision by Commerce Ministry

- In March The Ministry of Commerce has been asked by Ministry of Health to ban E-cigarettes but the recent

decision by the former stated that it cannot impose a ban on electronic cigarette imports as there is no legal basis for doing so. According to Commerce Ministry, halting imports of e-cigarettes into India will be against multilateral commitments with the World Trade Organization.

- It also stated that the country must first prohibit local sales through federal regulations that “can stand the scrutiny of law”. If it is done then The Directorate General of Foreign Trade (DGFT) can announce an “import ban”