INTRODUCTION

Pandemic spread of tobacco use is combated with armamentarium compromising of nicotine patches, lozenges, nasal sprays and prescription medications like bupropion and varenicline. However, efforts to curb tobacco menace have been hampered due to enormity of the situation. With the arrival of Electronic cigarettes (EC), when it was predicted that tobacco usage might just come down for the moment, its popularity was subjected to prejudice. The popularity of EC was culminated with incessant efforts put over a decade for its evolution, growth, improvement but well associated controversy. Although tobacco abstinence was the only motive associated with tobacco counselling, the use of EC as an adjunct have always faced flak and objection over its marketing and sale under pharmaceutical products. World Health Organisation (WHO) has not excluded the possibility of its use as an adjunct, but firmly stated its efficacy were not supported by sufficient clinical trials.

Infusion of Electronic cigarettes (EC) into the markets: The history of EC goes back five decades with its patency filed in 1963. However, it never made breakthrough in market till the late 2000s for the reasons best known to the regulatory bodies. Herbert A. Gilbert who predicted the dangers of smokeless and smoke tobacco, did not get market for his inventory product, probably because smoking was not deemed unhealthy then. The pharmacist Hon Lik from China introduced the idea of smokeless cigarette which allowed people to consume nicotine without inhaling the smoke. With China officially marketing EC, the former were officially introduced into international markets. Europe and United States of America were next to join the fray in 2006 and 2007 respectively.

Ban on Electronic cigarettes: The first ban on EC came in 2008 from health ministry of Turkey citing health concerns due to the presence of nicotine. Similar sanctions were imposed by Australia and Jordan for the possession, sale and import of EC. Australia stated any form of nicotine used except for replacement therapies were classified as poisons. Jordan voiced WHO’s proclamation that it did not consider EC as legitimate smoking cessation aid and should be removed immediately. USA and Canada banned them in 2009 with United States Food and Drug Association (USFDA) rejected its entry into its territory. Canada advised her citizens not to purchase or use them claiming propylene glycol (basic constituent) as an irritant. Likewise, Hong Kong, Panama, Israel, Brazil, Saudi Arabia, Singapore, Argentina, Venezuela and Holland discouraged its usage between 2009 to 2011 through law and enforcement. Penalties amounting to $10000 and two years of imprisonment and fine of $5000 on conviction were served in Hong Kong and Singapore respectively. On the other hand, Asian countries like China, India, Nepal and Pakistan, Nordic countries like Switzerland, Norway, Denmark and Finland, and European countries like Czech Republic, Estonia, Germany, Italy, Netherlands, Poland, Portugal and United Kingdom have legalised the sale.

The ambiguity surrounding use of Electronic cigarettes: The regulatory authorities and EC manufacturers always had a rocky relationship since...
the products were marketed. There has been a dearth of scientific data or studies substantiating the abuse, liability, efficacy and safety of the drug.4,5 As empirical research was not available to prove the efficacy and appropriateness of EC, regulatory bodies have been apprehensive to provide clean chit to the sale of EC under pharmaceutical products. The culprits were nicotine, propylene glycol and glycerol.1,8,11-16 Agency for Toxic Substances and Disease Registry (ATSDR) considered propylene glycol as Generally Recognized As Safe (GRAS) food additive which is widely used in food and tobacco products, pharmaceuticals, and cosmetics. In certain medicines, cosmetics, and food products, propylene glycol acted as an emulsifying agent, industrial drying agent, surfactant, and solvent. Propylene glycol is an FDA-approved additive for military dietary rations (Agency for Toxic Substances and Disease Registry 1997). In rare conditions, rapidly infused intravenous injections of propylene glycol-containing medications might be toxic but not life threatening.1 In a study conducted in 2009, it was stated that diethylene glycol is an anti-freeze ingredient and is toxic to humans which can cause dry mouth, sore throat and increased thirst on vaping.9

Glycerol, an organic liquid, is supposed to be hypoallergenic, non-carcinogenic, non-teratogenic and non-mutagenic. It has been approved by Health Canada, and is classified by the U.S. Food and Drug Administration (FDA) as "Generally Recognized As Safe" (GRAS) and complies with specifications for the Food Chemicals Codex (FCC), United States Pharmacopeia (USP), and European Pharmacopoeia (EP) E244. However, the implications of using this ingredient in products were much less severe as compared to the cigarette smoke. The side effects were dry mouth, excessive thirst and sore throat which are not considered as absolute contraindications for use.12

Nicotine, most potent carcinogen found in smoke and smokeless tobacco, is a major culprit in causing addiction and cancer. To camouflage the carcinogenicity of nicotine, manufacturers of EC have come up with nicotine free cigarettes.8 But irrefutable evidence from previous studies has proved toxic doses of nicotine in EC.1 Similar test conducted using Gas Chromatography and Mass Spectrometry Method in Department of Sophisticated Analytical Instrument Facility in Indian Institute of Technology, Powai, Mumbai, India, authenticated the findings (Table I). The laboratory analyses were performed on three different brands of electronic cigarettes. Although EC have proven to be less harmful and capable of emulating smoke, conclusive evidence regarding why EC should or should not be used have been corroborated only by few studies.1,16 Hence, EC have beguiled scientists till now. In future, unless, incontrovertible evidence determining the legitimacy of EC is proven, EC should not be dispensed to the consumers.

More research should be conducted to ensure the decisions taken by the regulators and consumers based on science. Safety profile of this product through public health and clinical trials should top the priority list with a halt to uncontrolled experimentation and marketing.

REFERENCES

13. Alliance Technologies LLC. Characterization of liquid “smoke

Table I: Name of the chemical and molecular weights detected in three brand of electronic cigarettes.

<table>
<thead>
<tr>
<th>Cigarette cartridges</th>
<th>Molecular weight detected</th>
<th>Name of the chemical</th>
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<tbody>
<tr>
<td>A. Local E-cigarette (Nicotine free)</td>
<td>162.0 84.01 132.98</td>
<td>Nicotine Glycerol Di-ethylene glycol</td>
</tr>
<tr>
<td>B. Branded E-cigarette (Nicotine free)</td>
<td>153.99 84.03 136.0</td>
<td>Nicotine Glycerol Di-ethylene glycol</td>
</tr>
<tr>
<td>C. Branded E-cigarette (Nicotine)</td>
<td>161.1 84.02 132.99</td>
<td>Nicotine Glycerol Di-ethylene glycol</td>
</tr>
</tbody>
</table>

