

正本

檔 號：
保存年限：

學

衛生福利部 函

機關地址：11558 台北市南港區忠孝東路六段488號

傳 真：(02)27877498

聯絡人及電話：黃筱琪 (02)27877461

電子郵件信箱：bexgenki@fda.gov.tw

100

台北市中山南路5號

受文者：教育部

發文日期：中華民國103年6月23日

發文字號：部授食字第1039903097號

速別：

密等及解密條件或保密期限：

附件：世界衛生組織（WHO）電子煙相關資料1份

主旨：有關 貴部函詢電子煙管理規定與宣導資訊一案，復如說明段，請查照。

說明：

一、復 貴部103年5月8日臺教授國字第1030050106號函。

二、有關目前我國電子煙管理規範，說明如下：

(一)含尼古丁成分之電子煙、電子霧化器產品屬藥品管理，目前衛生福利部尚未核准電子煙產品之藥品許可證。倘未依藥事法規定，向衛生福利部申請查驗登記取得藥品許可證而製造、輸入者，則應就其來源認屬藥事法第20條之偽藥，或同法第22條第1項第2款之禁藥，另依同法第82、83條規定，製造或輸入偽藥或禁藥者，最高可處10年以下有期徒刑，販賣者最高可處7年以下有期徒刑。

(二)電子煙如不含尼古丁或其他藥品成分，但宣稱具「幫助戒菸」、「減少菸癮」或「減輕戒斷症狀效果」等醫療效能詞句，即違反藥事法第69條，非藥物不得為醫療效能之標示或宣傳之規定，違者依同法處新臺幣60萬元以上2千5百萬元以下罰鍰，其違法物品沒入銷燬。

(三)依菸害防制法第2條第1款規定，菸品係指全部或部分



2

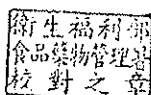
以菸草或其代用品為原料加工之製品，惟查電子煙之煙液成分，係以人工添加尼古丁或其他化學物品，非以菸草為原料加工之天然製品，故電子煙尚非屬菸害防制法規範之產品。

(四)若電子煙、電子霧化器等產品不含尼古丁或其他藥品成分也未宣稱具有戒菸療效，惟外型類似紙菸，則違反菸害防制法第14條，任何人不得製造、輸入或販賣菸品形狀之物品之規定，依同法第30條規定，製造或輸入業者處新臺幣1萬元以上5萬元以下罰鍰，販賣業者處新臺幣1千元以上3千元以下罰鍰。

三、國人易誤認電子煙非菸品、對人體無害或可幫助戒菸，惟電子煙產品所含成分對人體之安全性，及是否具輔助降低菸癮等醫療效能，於國際間尚無相關證據可證實，另世界衛生組織（WHO）因電子煙含有尼古丁及毒性化學物質，故不建議使用（如附件）。本部基於保障人民健康，將含尼古丁之電子煙以最嚴格之藥品進行前端管理，並納入不法藥物查緝，以進行源頭管制，惠請貴部協助轉知各級學校加強宣導，共同維護學生健康。

正本：教育部

副本：衛生福利部國民健康署



部長邱文達

本案依分層負責規定
授權組室主管決行

Tobacco Free Initiative (TFI)

Questions and answers on electronic cigarettes (e-cigarettes) or electronic nicotine delivery systems (ENDS)

Statement

9 July 2013

What are electronic cigarettes (e-cigarettes)?

E-cigarettes or ENDS (electronic nicotine delivery systems) are devices whose function is to vaporize and deliver to the lungs of the user a chemical mixture typically composed of nicotine, propylene glycol and other chemicals, although some products claim to contain no nicotine. A number of ENDS are offered in flavours that can be particularly attractive to adolescents. Electronic cigarettes (e-cigs) are the most common prototype of ENDS.

Each device contains an electronic vaporization system, rechargeable batteries, electronic controls and cartridges of the liquid that is vaporized. The manufacturers report that the cartridges typically contain between 6 and 24 mg of nicotine, but sometimes can contain more than 100 mg. In the form of tobacco products, nicotine is an addictive chemical that in excessive amounts can be lethal (0.5-1.0 mg per kg of weight of the person).

Most ENDS are shaped to look like their conventional (tobacco) counterparts (e.g. cigarettes, cigars, cigarillos, pipes, hookahs or shishas). They are also sometimes made to look like everyday items such as pens and USB memory sticks, for people who wish to use the product without other people noticing.

Are electronic cigarettes (ENDS) safe?

The safety of ENDS has *not* been scientifically demonstrated.

The potential risks they pose for the health of users remain undetermined. Furthermore, scientific testing indicates that the products vary widely in the amount of nicotine and other chemicals they deliver and there is no way for consumers to find out what is actually delivered by the product they have purchased.

Most ENDS contain large concentrations of propylene glycol, which is a known irritant when inhaled. The testing of some of these products also suggests the presence of other toxic chemicals, aside from nicotine. In addition, use of these products -when they contain nicotine- can pose a risk for nicotine poisoning (i.e. if a child of 30 Kilos of weight swallows the contents of a nicotine cartridge of 24 mg this could cause acute nicotine poisoning that most likely would cause its death) and a risk for addiction to nonsmokers of tobacco products. Nicotine, either inhaled, ingested or in direct contact with the skin, can be particularly hazardous to the health

and safety of certain segments of the population, such as children, young people, pregnant women, nursing mothers, people with heart conditions and the elderly. ENDS and their nicotine cartridges and refill accessories must be kept out of the reach of young children at all times in view of the risk of choking or nicotine poisoning.

As ENDS do not generate the smoke that is associated with the combustion of tobacco, their use is commonly believed by consumers to be safer than smoking tobacco. This illusive 'safety' of ENDS can be enticing to consumers; however, the chemicals used in electronic cigarettes have not been fully disclosed, and there are no adequate data on their emissions.

Is use of electronic cigarettes (ENDS) an effective method for quitting tobacco smoking?

The efficacy of ENDS for helping people to quit smoking has not been scientifically demonstrated.

ENDS are often touted as tobacco replacements, smoking alternatives or smoking cessation aids. But we know that for smoking cessation products to be most effectively and safely used, they need to be used according to instructions developed for each product through scientific testing. There are no scientifically proven instructions for using ENDS as replacements or to quit smoking. The implied health benefits associated with these claims are unsubstantiated or may be based on inaccurate or misleading information. When ENDS are used as cessations aids, they are intended to deliver nicotine directly to the lungs. None of the approved, regulated cessation aids, such as nicotine patches and chewing-gum, delivers nicotine to the lungs. Therefore, the biological mechanism by which smoking cessation might be achieved by delivery of nicotine to the lungs and its effects are unknown. Delivery to the lung might be dangerous. Therefore, independently of the effects of nicotine, it is of global importance to study lung delivery scientifically.

The dose of delivered nicotine is also unknown. It is suspected that the delivered dose varies notably by product, which contain nicotine in various quantities and concentrations.

Conclusion:

Until such time as a given ENDS is deemed safe and effective and of acceptable quality by a competent national regulatory body, consumers should be strongly advised not to use any of these products, including electronic cigarettes.

Related links

Marketers of electronic cigarettes should halt unproved therapy claims

Report on the Scientific Basis of Tobacco Product Regulation: third report of a WHO Study Group
WHO technical report series 955

More on tobacco product
regulation