

## E-CIGARETTES

### POLICY RECOMMENDATIONS

The Royal Pharmaceutical Society believes that despite the safety concerns outlined below, and current lack of robust evidence on their efficacy there is a potential role for quality-assured e-cigarettes as a short term support to encourage tobacco smokers to reduce or quit their smoking habit, either as a stepping stone to licensed nicotine replacement therapy (NRT), or instead of, where other methods have failed. It recommends that policy-makers must do everything they can to avoid a new generation of people becoming addicted to nicotine. This is particularly important in light of the current lack of evidence in relation to long-term health effects of using e-cigarettes, and their secondhand emissions.

As such, the Royal Pharmaceutical Society would recommend the following policy actions as a matter of priority to minimise potential undermining of existing public health tobacco control measures:

**The UK Government should ensure a speedy implementation of the European Tobacco Directive (TPD). In particular they should ensure that any e-cigarettes not licensed as medicinal products have advertising and sales restricted in line with the advertising and sales restrictions of tobacco products.**

**The UK and Scottish Governments should follow the Welsh Government policy and include e-cigarettes in the public spaces smoking ban to avoid the normalisation of e-cigarettes and their potential negative influences on lifestyle choices, particularly for young people.**

### BACKGROUND FACTS AND FIGURES

- E-cigarettes were invented in their current form by Chinese pharmacist Hon Lik in early 2000s.
- E-cigarettes are products that deliver a nicotine containing aerosol to users by heating a solution typically made up of propylene glycol or glycerol (glycerine), nicotine and flavouring agents.
- ASH estimates there are 2.1 million current e-cigarette users in the UK, of which they estimate 700,000 are ex-smokers and 1.3 million to be using them alongside normal cigarettes or tobacco<sup>1</sup>.
- Despite many unanswered questions regarding their safety, efficacy in harm reduction and smoking cessation and their total impact on public health, there has been a rapid market penetration. In the interim period, while awaiting the EU Commission and MHRA decisions on licensing and regulation, advertising spend on e-cigarettes and other materials and accessories in the UK increased almost eight-fold from £1.7 million in 2010 to £13.1 million in 2012<sup>2</sup>.
- According to a 2013 ASH survey of 11-18-year olds, of those who had never smoked a cigarette, 1% reported having tried e-cigarettes "once or twice". However, data from the US showed that e-cigarette use among middle and high school students doubled between 2011 and 2012, from 3.1% to 6.5% and led author Lauren Dutra, a postdoctoral fellow at the UCSF Center for Tobacco Control Research and Education to conclude that "Despite claims that e-cigarettes are helping people quit smoking, we found that e-cigarettes were associated with more, not less, cigarette smoking among adolescents" and went on to say that "E-cigarettes are likely to be gateway devices for nicotine addiction among youth, opening up a whole new market for tobacco."<sup>3</sup>

- E-cigarette use among adolescents is a unique concern as the extent of any adverse health effects is not yet fully evidenced. Besides effects from the toxic impurities in cartridges, nicotine may affect adolescent brain development<sup>4</sup> and increase likelihood of addiction.
- The most recent research from the UK showed that e-cigarette use was 60% more effective in helping people to quit smoking compared to nicotine patches and gum. However, according to the same research, the strongest evidence remains for using NHS Stop Smoking Services, which incorporates personal support. This approach tripled the odds (200%) of a smoker quitting when compared to buying nicotine replacement treatments without specialist help.<sup>5</sup>
- Despite claims by manufacturers that they are not targeting new smokers, e-cigarettes are sold in flavours that are likely to be more appealing to younger people: coca cola, bubble gum, strawberry, cherry etc. and they present their products using cosmetic appeals, such as innovative packaging and colours, making them seem attractive and 'cool'.<sup>6</sup>
- Manufacturers offer loyalty incentives to e-cigarette smokers, which contradicts claims that e-cigarettes should be used as an aid to quit smoking rather than an ongoing activity.<sup>13</sup>
- As part of an NHS smoking cessation programme pharmacists are only able to prescribe and dispense those smoking cessation products that are licensed for such use.

## SAFETY

- Although current data available suggest that e-cigarettes are less harmful than traditional cigarettes, it is insufficient to conclude that e-cigarettes are safe in absolute terms. Further studies are needed to comprehensively assess their safety, particularly in the long term<sup>7</sup>.
- Potentially harmful constituents have been documented in some e-cigarette cartridges, including irritants, genotoxins, animal carcinogens<sup>8</sup>, cytotoxic heavy metals and silicate particles<sup>9</sup>.
- While studies so far have demonstrated that toxins in the e-cigarette aerosol are at much lower levels when compared to conventional cigarette emissions<sup>10</sup>, little is known as yet about the long term exposure to second-hand e-cigarette aerosols.
- Deep inhalation via the lungs is a very effective way to administer medicines and much smaller doses are required than via the oral route. As with tobacco cigarettes, e-cigarettes particles are small enough to reach deep into the lungs and are absorbed into systemic circulation to reach all parts of the body.
- Fine particles can be variable and chemically complex, and the specific components responsible for toxicity and the relative importance of particle size and particle composition are generally not known. The thresholds for human toxicity from any ingredients in the e-cigarette aerosol are not yet known and the possibility of long term health risks to both the users of e-cigarettes and the passive effects in public places must be considered<sup>11</sup>.
- The quality of e-cigarette cartridges vary widely. The total amount of nicotine contained in nicotine cartridges is sufficient to cause harm or even death to children, and there have been reports of fire hazards with e-cigarettes exploding either during use or during charging.
- While nicotine alone has less potential to cause harm than tobacco smoke, it is not a neutral substance. It is highly addictive and has both physiological and psychological effects. There is a concern that the addictive nature of nicotine could lead to further use of tobacco cigarettes. It is both a stimulant and relaxant depending on dose. It constricts blood vessels, causing temporary increases in blood pressure, increases heart rate, respiration rate and blood glucose. Tolerance develops to nicotine requiring increasing doses for the same effect. In addition, nicotine indirectly causes a release of dopamine in the brain regions which control pleasure and motivation. This reaction is similar to that seen with other abused drugs—such as cocaine and heroin<sup>12</sup>.

**The RPS welcomes stronger regulation of e-cigarettes to ensure quality control and standardisation of products including carrying health warnings. However, we are concerned about the lack of longer-term studies into the health impact of e-cigarette use and would urge further research, including into the health impact of exposure to secondhand emissions.**

## REGULATION

- E-cigarettes are currently marketed in the UK under general product safety regulations which do not impose any standards of quality, or efficacy, and which control advertising only through voluntary codes of practice (currently under review). Breaches are presently dealt with reactively, in response to complaints, rather than proactively, through pre-screening<sup>12</sup>.
- In March 2014 the European Parliament and Council moved to restrict marketing and advertising under the terms of the new Tobacco Product Directive (TPD) which requires that more stringent controls for safety and quality will be imposed including;
  - advertising of nicotine-containing devices that are not licensed as medicines will be prohibited;
  - the product will be required to carry health warnings;
  - the product will be required to meet purity and emissions standards that are yet to be defined;
  - data on nicotine uptake must be provided;
  - there will be restrictions on total nicotine content
  - suppliers will be required to bear the full responsibility for quality and safety when used 'under normal or reasonably foreseeable conditions'.
- Transposition into national legislation is expected to be required by Member States by 2016 and full compliance by 2017. This means that from 2017, suppliers will have to choose to either have their products licensed as medicines to support smoking cessation or to comply with the TPD regulations for general sale<sup>13</sup>.
- MHRA originally had announced that all nicotine-containing products were to be regulated as medicines however the EU decision means that there will be a dual route to market and that MHRA regulation will no longer be obligatory in the UK from 2016, although the option of applying for a medicines licence remains open<sup>14</sup>.

**While the strengthened regulation of e-cigarettes is welcomed, the RPS is concerned that the two or more years until 2017 will allow e-cigarette companies to market aggressively and to recruit particularly young people into e-cigarette use. RPS urges the UK, Scottish and Welsh governments to take swift action to avoid this happening.**

## EFFICACY OF E-CIGARETTES

- The efficacy of e-cigarettes has been evaluated in studies in which people report great success in being able to cut back or stop tobacco cigarette consumption. However many of these studies include an element of bias and there is a scarcity of robust clinical trials with accredited data to provide accurate information. A recent survey of nearly 6,000 smokers found that 20% had quit with the aid of e-cigarettes, a 60% higher quit-rate than for those who had not used e-cigarettes, although notably the more effective option was the NHS Smoking Cessation Services which were approximately three times (200%) more likely to help people quit<sup>15</sup>.
- However, while quality-assured e-cigarettes could have a role to play in smoking cessation RPS would not necessarily advocate them as a first choice as this method continues the "smoking habit". One randomised trial showed that 29% of e-cigarette users continued to use e-cigarettes at 6 months compared to only 8% still using NRT patches, suggesting e-cigarette use might persist after other quit methods.<sup>16</sup>

**The RPS believes that while e-cigarettes could have a role in harm reduction and to support smoking cessation in the short term, more high-quality peer-reviewed studies on safety and efficacy should be completed in order provide health professionals with evidence-based assurance, particularly if they are to be included in the publicly funded smoking cessation programmes, once licensed by the MHRA.**

## THE ADVERTISING OF E-CIGARETTES AS A LIFESTYLE CHOICE

- Cigarette and other tobacco companies have been unable to market their products on television and radio since the 1970s. E-cigarette advertising on television and radio is mass marketing of an addictive nicotine product for use in a recreational manner which could appeal to new generations who have never experienced such marketing. Many of the themes used are similar to tobacco advertising prior to the 1970s when restrictions were imposed.
- According to recent US research<sup>17</sup>, health claims and smoking cessation messages that are unsupported by current scientific evidence are frequently used to sell e-cigarettes .e.g.
  - 95% of the websites made explicit or implicit health-related claims
  - 64% had a smoking cessation claim
  - 22% featured doctors
  - 76% claimed the product does not produce second-hand smoke
  - Comparisons to cigarettes included claims that e-cigarettes were cleaner (95%) and cheaper (93%).
  - 88% stated that the product could be smoked anywhere and 71% mentioned using the product to circumvent clean air policies.
  - Sweet, fruit and coffee flavours were offered on most sites.
  - Youthful appeals included images or claims of modernity (73%), increased social status (44%), enhanced social activity (32%), romance (31%) and use by celebrities (22%).
- An audit of all forms of e-cigarette marketing, as well as related public relations and editorial comment in tobacco industry and retail press in the UK from May 2012 to June 2013 identified five themes in terms of how e-cigarettes are presented:
  - A healthier and safer source of nicotine than traditional cigarettes.
  - Good for cutting down, quitting or switching from traditional cigarettes.
  - Suitable for use in situations where the smoke-free legislation applies; and without releasing harmful second-hand smoke.
  - Tasting similar to tobacco, but cleaner and more fragrant.
  - Cheaper than traditional cigarettes, backed by promotional pricing for starter kits to incentivise trials by committed smokers and pricing offers aimed at retailers to keep stock outlays to a minimum.

**The RPS supports the planned restrictions on e-cigarette advertising and sales as outlined in the TPD but calls for swift action from the UK, Scottish and Welsh Governments to address potential public health issues due to “normalisation” of smoking in public places and to avoid recruitment of non-smokers, particularly young people, in the intervening years until 2017.**

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