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ash briefing
action on smoking and health

Electronic cigarettes
(also known as vapourisers)

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Summary

- Electronic cigarettes are not cigarettes. They do not contain tobacco and using them is not smoking.
- ASH, in line with the NICE guidance on Tobacco Harm Reduction, always recommends that quitting all forms of nicotine use is the best option for smokers.
- However, for those who remain addicted to nicotine NICE guidance recommends the use of medicinally licensed nicotine containing products as an alternative to smoking or to cut down or for temporary abstinence to help reduce the harms of smoking.
- NICE guidance cannot recommend the use of unlicensed nicotine containing products but many smokers are finding unlicensed electronic cigarettes helpful. Research by ASH shows that their use has grown threefold in the last two years from 700,000 to 2.1 million users.[1]
- Electronic cigarettes are proving more attractive to smokers than NRT[1,2] while providing them with a safer alternative to cigarettes.[3] There is evidence that they can be effective in helping smokers' quit[2,4] and little evidence that they are being used by never smokers.
- The number of children and young people regularly using electronic cigarettes remains very low and their use is almost entirely amongst those who are current or ex-smokers.[1] This is a similar pattern to that found in jurisdictions such as the USA.[5]
- ASH supports enhanced regulation to ensure the safety and reliability of electronic cigarettes and to prevent their promotion to non-smokers and children.
- However, in the absence of evidence of significant harm to bystanders, ASH does not support the inclusion of electronic cigarettes in smokefree laws which would completely prohibit their use in enclosed public places.

Curently electronic cigarettes are regulated as general consumer products. Once the EU Tobacco Products Directive (TPD) comes into effect in Member States in May 2016, electronic cigarettes containing up to 20mg/ml of nicotine will come under the TPD (levels of 18mg/ml have been reported on user websites as suitable for typical smokers).[6] Above that level, or if manufacturers and importers decide to opt into medicines regulation, such products will require authorisation by the Medicines and Healthcare Products Regulatory Agency (MHRA) as over the counter medicines in the same way as nicotine replacement therapy (NRT).[7]

Nicotine Substitution

Smoking is the largest preventable cause of premature mortality in the UK.[8] The goal of tobacco control is to diminish the harm caused by tobacco products. While the ideal remains that people should stop using tobacco completely and permanently, consensus currently supports a properly regulated harm reduction approach for those unable to do so.[9,10,11] This is a framework by which the harmful effects of smoking are reduced without requiring the elimination of a behaviour that is not necessarily condoned. Such strategies have proved successful in the past, for example within the contexts of needle exchange programmes for illicit drug use and the promotion of safer sex to prevent HIV infection.[12,13]

In 1976 Professor Michael Russell wrote: "People smoke for nicotine but they die from the tar."[14] Indeed, the harm from smoking is caused primarily through the toxins produced by the burning of tobacco. By contrast, non-tobacco, non-smoked nicotine products, although addictive, are considerably less harmful.

Electronic cigarettes consequently represent a safer alternative to cigarettes for smokers who are unable or unwilling to stop using nicotine.

The National Institute for Health and Care Excellence (NICE) has developed guidance on a harm reduction approach to smoking.[15] NICE's recommendations aim to inform on how best to reduce illness and deaths attributable to smoking through a harm reduction approach. As part of this guidance, NICE supports the use of licensed nicotine containing products (NCPs) to help smokers cut down, for temporary abstinence and as a substitute for smoking, possibly indefinitely. NICE guidance cannot recommend the use of unlicensed nicotine containing products. However, the guidance is clear that using an electronic cigarette is safer than smoking.[13]

What are electronic cigarettes?

Electronic cigarettes, also known as vapourisers or electronic nicotine delivery systems (ENDS),[16] are often, although not always, designed to look and feel like cigarettes. They have been marketed as less harmful alternatives to cigarettes and for use in places where smoking is not permitted since they do not produce smoke.

There are three main types of electronic cigarettes or vapourisers:

- Disposable products (non-rechargeable)
- An electronic cigarette kit that is rechargeable with replaceable pre-filled cartridges
- An electronic cigarette that is rechargeable and has a tank or reservoir which has to be filled with liquid nicotine

The first two types of electronic cigarette are often known as 'cigalike' products as they resemble cigarettes and often have a light at the end that glows when the user draws on the device to resemble a lit cigarette. The liquid in the devices usually contains nicotine suspended in propylene glycol and glycerine. The level of nicotine in the cartridges may vary and most also contain flavourings.[17] When a user sucks on the device, a sensor detects air flow and heats the liquid in the cartridge so that it evaporates. The vapour delivers the nicotine to the user. There is no side-stream smoke but some nicotine vapour is released into the air as the smoker exhales.

Are electronic cigarettes safe to use?

Compared with smoking using an electronic cigarette is safer. However, in the absence of a thorough clinical evaluation and long term population level surveillance, absolute safety of such products cannot be guaranteed. By comparison, the harm from tobacco smoking – the leading cause of preventable death in the UK – is well established.

Most, but not all electronic cigarettes contain nicotine. As noted above, the harm from smoking comes mainly from inhaling tobacco smoke rather than the nicotine. However, nicotine is an addictive drug which stimulates the nervous system, increasing the heart rate and blood pressure.[18]

Toxins have been found in a number of studies of electronic cigarettes[19,20,21,22] although these are at levels much lower than those found in cigarettes and not at levels which would generally cause concern.[23,24,25]

One small study showed that after switching from tobacco to electronic cigarettes nicotine exposure was unchanged while exposure to selected toxicants was substantially reduced.[26]

Most of the safety concerns regarding electronic cigarettes relate to the absence of appropriate product regulation and inconsistencies in quality control. The current lack of regulatory oversight means that there is significant variability in device effectiveness, nicotine delivery and cartridge nicotine content both between and sometimes within product brands.[15]

Research has identified possible concerns about specific products. A recent study by the US Food and Drug Administration (FDA) has raised some safety concerns over the presence of toxins, released in low concentrations, from the vaporisation process of certain cartridges.[27]

There is little evidence of harmful effects in the short to medium term from repeated exposure to propylene glycol, the chemical in which nicotine is suspended.[28,29] One study concludes that electronic cigarettes have a low toxicity profile, are well tolerated, and are associated with only mild adverse effects.[30] More research is needed on long-term impact, particularly on the lungs.

Is there a risk to non-users from electronic cigarette vapour?

Although electronic cigarettes do not produce smoke, users exhale a smoke-like vapour which consists largely of propylene glycol and glycerine. The level of nicotine present in electronic cigarette vapour is about one tenth of that generated by a cigarette.[31] Any health risks of secondhand exposure to propylene glycol vapour are likely to be limited to irritation of the throat. One study exposed animals to propylene glycol for 12 to 18 months at doses 50 to 700 times the level the animal could absorb through inhalation. Compared to animals living in normal room atmosphere, no localised or generalised irritation was found and kidney, liver, spleen and bone marrow were all found to be normal.[25] A recent review of the impact of electronic cigarettes noted that passive exposure to the aerosol can expose non-users to nicotine but at concentrations that are unlikely to have any pharmacological significance.[32]

The fact that many electronic cigarettes look similar to conventional cigarettes has been said to risk confusion as to their use in enclosed public places, such as on public transport.[33,34] However, given that the most distinctive feature of cigarette smoking is the smell of the smoke, which travels rapidly, and that this is absent from electronic cigarette use, it is not clear how any such confusion would be sustained.

Furthermore, the absence of risk from “secondhand” inhalation of vapour from electronic cigarettes has been described as an “often unconsidered advantage” of electronic cigarettes.[35] As an alternative to smoking, electronic cigarettes are preferable in situations where secondhand smoke poses serious health risks to others, such as in vehicles or in the home.

Are electronic cigarettes effective in helping smokers quit?

The degree of effectiveness depends on what effect is being measured. ASH research shows that the most commonly reported reason for using electronic cigarettes (among all who report using or having tried them) was “to help me stop smoking tobacco entirely”.[36] Current smokers also report that they use the devices to “help me reduce the amount I smoke but not stop completely”. Effectiveness also varies between products and between users according to their experience in use.[37]

Currently in the UK, any nicotine-containing product which claims or implies that it can treat nicotine addiction is considered to be a medicinal product and is therefore subject to regulation by the MHRA. Consequently, electronic cigarette manufacturers have avoided making such explicit claims. Furthermore, the WHO has stated that “the electronic cigarette is not a proven nicotine replacement therapy”.[38]

Nevertheless, survey data suggests that, whatever the reason e-cigarette use may have been initiated, about 4 in 10 users in England currently use them in an attempt to quit smoking.[31] Recently published population level data shows they have taken over from over the counter NRT as the most popular support people use when quitting smoking[2] and are 60% more effective than NRT bought over the counter in helping smokers quit.[4] The effectiveness in that study was broadly similar to using a prescription medicine (including NRT) with limited professional support and less than using a prescription medicine with specialist behavioural support. A randomised controlled trial conducted in New Zealand found that electronic cigarettes, with or without nicotine, were modestly effective at helping smokers to quit, with broadly similar achievement of abstinence as with nicotine patches.[39] There is also some evidence to suggest that electronic cigarette use leads to abstinence among some smokers who had not intended to quit.[40]

Empirical data on the effectiveness of electronic cigarettes as nicotine delivery devices are still being collected.[41] Some reports from the published literature suggest that electronic cigarettes are inefficient nicotine delivery devices and result in only modest and unreliable increases in plasma nicotine levels.[42] Such findings appear to apply particularly to new users whereas studies using participants experienced in electronic cigarette use have been found to derive more reliable nicotine intake levels.[27] Whether experienced users are able to use these devices in a way in which their nicotine intake is maximised, or the variability is due to such users preferring certain devices which might significantly differ from those used by inexperienced users, is yet to be determined.[43,44]

Nevertheless, growing evidence suggests that electronic cigarettes are becoming more reliable in their nicotine delivery and that they have a beneficial impact in reducing subjective cravings and, in turn, number of cigarettes smoked.[27] Moreover, some studies have demonstrated an ability for certain brands of electronic cigarettes to reduce nicotine cravings despite delivering low plasma nicotine levels.[45] A recent review on the use, safety and effects of electronic cigarettes concluded that the devices do enable some smokers to reduce or quit smoking and that they offer a route to complete cessation of nicotine use.[33]

Another feature of electronic cigarettes that apparently lends to their effectiveness is an ability to provide an approximation to the superficial aspects of the experience of smoking. This has been demonstrated by users exhibiting reduced cravings, withdrawal symptoms and number of cigarettes smoked per day even when given a placebo electronic cigarette.[27]

The potential value, and perceived effectiveness, of electronic cigarettes in aiding smoking cessation has been assessed in user surveys. Caution must be exercised with these data as the samples have been recruited from electronic cigarette users' websites. However, one such survey conducted internationally reported that 72% of users believed that electronic cigarettes were beneficial in reducing cravings and withdrawal symptoms while 92% declared that the devices had reduced the number of conventional cigarettes they smoked. Indeed, in the same survey, 96% of former smokers claimed that electronic cigarettes had helped them quit, and 79% reported a fear that if they stopped using them they would start smoking again.[46]

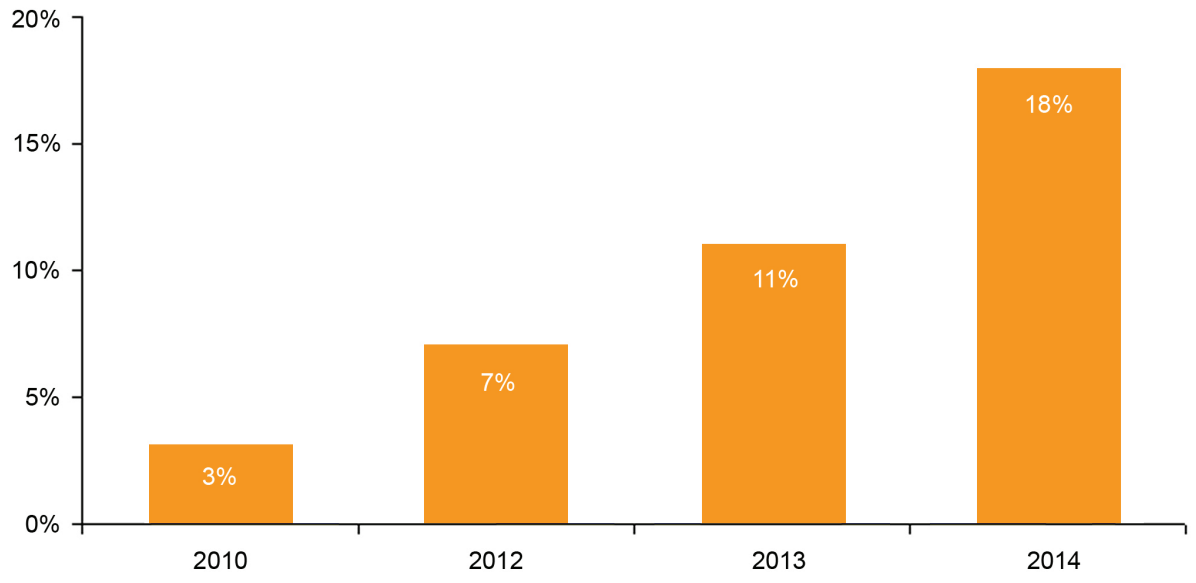
Who uses electronic cigarettes in the UK?

Public awareness of electronic cigarettes has grown substantially in recent years with online media playing an integral role in the growing popularity of the product.

Between the years 2009 and 2011 searches via the search engine Google using the terms 'electronic cigarette' increased fifty fold,[47] a fact the industry has attempted to capitalise on by funding various online adverts, web-pages and social networking site groups.[48] In addition to the influence of online media, there is also evidence to suggest that tighter tobacco control measures are also positively driving electronic cigarette behaviour.[49]

According to surveys commissioned by ASH, 3% of smokers in Great Britain reported using electronic cigarettes regularly in 2010, a figure that has increased to 18% in 2014 (see figure 1). Similarly, the number of smokers reporting having tried electronic cigarettes has increased significantly, from 9% in 2010 to 22% in 2012, 35% in 2013 and 52% in 2014.

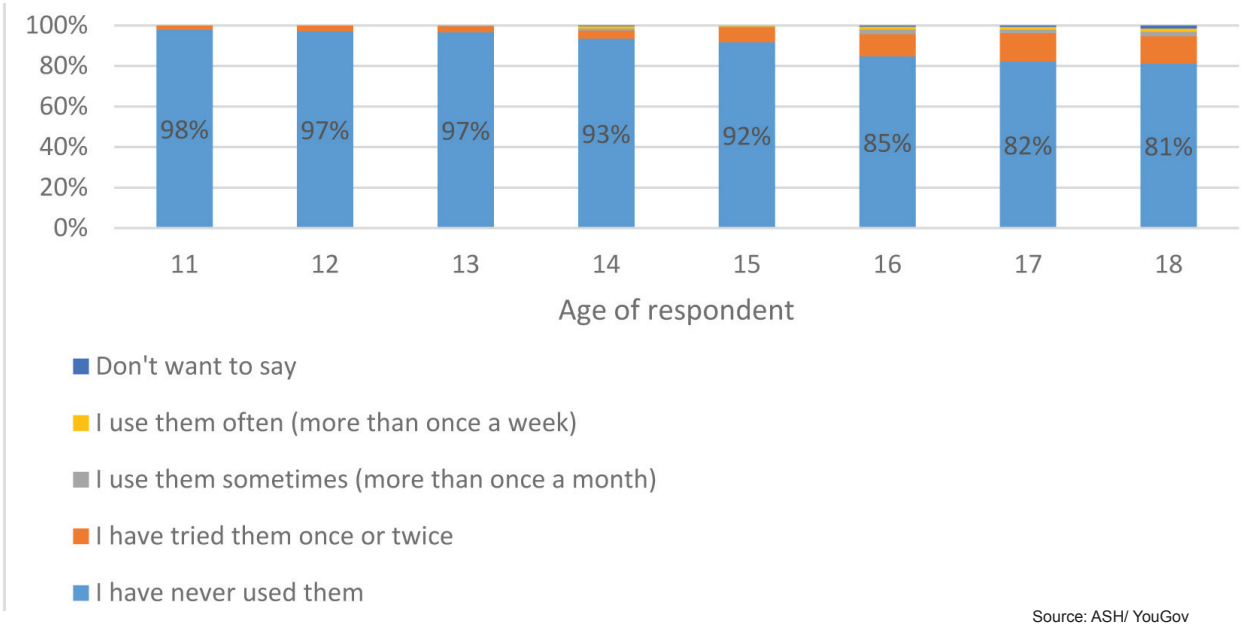
Figure 1: Usage of e-cigarettes amongst adult smokers in Britain



Source: ASH/ YouGov

One of the risks highlighted by professionals is that electronic cigarettes could act as a 'gateway' to smoking tobacco among children. Current evidence suggests this phenomenon is not occurring. Among children, current electronic cigarette use is confined almost entirely to those who have already tried smoking.[50,51] Figure 2 further shows that even having tried electronic cigarettes is rare among children, particularly those under the age of 15.

Figure 2: Usage of electronic cigarettes among children in Britain, 2014



Source: ASH/ YouGov

ASH estimates that there are 2.1 million current users of electronic cigarettes in the UK.[52] This number consists almost entirely of current and ex-smokers; of these approximately one third are ex-smokers while two thirds continue to use tobacco alongside electronic cigarettes. There is little evidence to suggest that anything more than a negligible number of never-smokers regularly use the product.[45]

For further information see:
ASH Factsheet: Use of electronic cigarettes in Great Britain
The National Centre for Smoking Cessation and Training (NCSCT) has produced an e-cigarette briefing summarising the evidence to date, especially in relation to the role of the stop smoking services and how stop smoking practitioners should respond to enquiries about e-cigarettes from smokers.

Regulation

Concerns have been raised about the rapid growth of the electronic cigarette market and the increasing involvement of tobacco companies in the industry. The World Health Organization treaty on tobacco (WHO Framework Convention on Tobacco Control) obliges signatories to protect health policy with respect to tobacco control from the 'commercial and vested interests' of the tobacco industry. Tobacco company involvement in tobacco harm reduction is a cause for concern.

Regulation has been seen as an important part of limiting the risk of tobacco industry involvement and to ensure the market evolves in a way that supports public health objectives.

In February 2014 the EU Tobacco Products Directive (TPD) was passed by the European Parliament and became law on 29 April. Member States now have until 20 May 2016 to transpose the new rules into national law.

Electronic cigarettes containing up to 20mg/ml come under the TPD.[53] Above that level electronic cigarettes will require marketing authorisation as medicines if they are to remain on the market.[5]

The detailed requirements of regulation under the TPD are as follows:

- A limit on nicotine strength of 20mg/ml (vaper websites say 18 ml/mg is the strength usually found suitable by average smokers[54])
- A size limit for e-liquids of 10ml for dedicated refill containers and 2ml for electronic cigarette cartridges and tanks.
- Safety mechanisms (such as childproof fastening and opening) for e-liquid containers, cartridges and tanks.
- Warnings on the two largest surfaces of the packs and any outside packaging covering 30% of the external area. These must state either '*This product contains nicotine which is a highly addictive substance*' or the above plus '*It is not recommended for use by non-smokers*'.
- Consumer information must also include instructions on use, information on addictiveness and toxicity, a list of all ingredients and information on nicotine content along with a prohibition on promotional materials on packs.
- Manufacturers and importers bear full responsibility for the quality and safety of their product and must notify detailed information about their products to competent authorities in each Member State.
- Prohibition on cross-border advertising promotion and sponsorship in line with that for tobacco products.
- Member States will be able to introduce extra safeguards for example on age-limits and flavourings in electronic cigarettes.

Until regulations implementing the EU Directive take effect electronic cigarettes not licenced as medicines will continue to be subject to general consumer protection law and it is the responsibility of trading standards officers to enforce the law.

In addition, the Children & Families Act 2014 gave the Government powers to ban the sale of electronic cigarettes to persons under the age of 18. A consultation on draft regulations is expected soon.

On 12 September 2014, Kind Consumer, a healthcare research and development company, announced that it had been granted marketing authorisation from the MHRA for a novel nicotine inhaler designed to help smokers cut down or quit smoking. The product called Voke is being developed with the company's partner, Nicoventures, a wholly-owned subsidiary of BAT.[55]

The MHRA has said that it "*continues to encourage companies to voluntarily submit medicines licence applications for electronic cigarettes and other NCPs as medicines*".[56] Public Health England supports the regulation by the MHRA of nicotine-containing products – including e-cigarettes – as medicines, to give people access to safe products that are also effective.[57] In the UK medicines regulation has some advantages for electronic cigarette manufacturers and importers over regulation under the TPD.

The following table shows the main elements of regulation under the TPD versus medicines regulation:

Characteristics of regulation under Tobacco Products Directive and MHRA	
Tobacco Products Directive regulation of electronic cigarettes	**MHRA licenced Nicotine Containing Products (NCPs) including e-cigs**
Products not available on prescription	Products available on prescription
20% VAT	5% VAT
Cross border advertising banned by 2016; up to Member States to decide on domestic advertising (billboards, Point of Sale, buses etc.)	Advertising allowed – under OTC rules so no celebrity endorsement, free samples and must be targeted at adult smokers etc.
Products widely available	Products available on general sale (GSL)
Can't make health claims	Can make health claims
Upper limits for nicotine content will be set and likely to be in force by 2017.	MHRA regulation is flexible; there are no upper limits.
30% health warning on packs about nicotine on front and back of packs	No health warnings on packs. Pack contains detailed Patient Information Leaflet.
Member States retain powers e.g. on flavours, domestic advertising.	Flavours require a marketing authorisation
Children and Families Bill allows for age of sale of 18 for nicotine products.	Age of sale 12 but can be varied by product so could be higher for e-cigarettes.

Following a referral from the Department of Health, NICE published guidance on tobacco harm reduction on 5th June 2013 as mentioned above.[7] This guidance recommended the use of licensed NCPs, which are nicotine replacement therapy products licensed by the MHRA (and do not at the current time include electronic cigarettes) for harm reduction purposes. Such purposes include using licensed NCPs as a substitute for tobacco, possibly indefinitely, to cut down prior to quitting, to smoke less, or to temporarily abstain from smoking.

Regulation of Advertising of electronic cigarettes

Some advertising for electronic cigarettes has been criticised as possibly attractive to young people and never-smokers.[58] There is a risk that inappropriate advertising could glamorise smoking and undermine public health goals. The involvement of the tobacco industry in the electronic cigarette market also raises questions about the opportunity of this industry to reach young people with pro-smoking messages.

Following a public consultation, CAP, the Committee on Advertising Practice, published new rules on the advertising of electronic cigarettes to cover the interim period between now and when the TPD comes into effect.

Key measures include:

- Ads must not be likely to appeal to people under 18
- People shown using e-cigarettes must neither be, nor seem to be under 25
- Ads must not be directed at people under 18 through the selection of media or the context in which they appear
- Ads must not encourage non-smokers or non-nicotine users to use electronic cigarettes
- Ads must make clear that the product is an e-cigarette and not a tobacco product.

CAP will monitor the effect of the rules and conduct a review after 12 months.

ASH's response to the public consultation can be viewed here.

Regulation of where electronic cigarettes can be used

Currently, electronic cigarettes are not regulated under smokefree laws in the UK, although this is under consideration in Wales.[59] In general, users are free to use them in most public places such as bars, restaurants and on public transport, although the managers of some premises have prohibited their use.

One stated advantage of smokefree legislation is that it de-normalises smoking, effectively distancing the behaviour from what is an accepted social norm. The ban on smoking in public places has reinforced in many people's minds that such behaviour has gone from a normal, widely accepted activity to one that is abnormal and unaccepted. There are concerns that electronic cigarettes will undermine this process, threatening the now established practice of smokefree public places, such as at work or on public transport. However to date there is little evidence to suggest this is the case.

ASH has worked with the Chartered Institute of Environmental Health and the Trading Standards Institute to produce guidance for organisations considering whether or not to ban the use of electronic cigarettes on their premises.[60] This provides a structure for thinking through the issues but leaves it to organisations to develop their own approach informed by the evidence.

Global Guidance

In August 2014 the World Health Organization published a report on ENDS (electronic nicotine delivery systems, more commonly known as electronic cigarettes) for discussion by the WHO Framework Convention on Tobacco Control Conference of the Parties meeting in October. Parties to the WHO FCTC were asked to note the report and '*provide further guidance*'.[61] The Framework Convention Alliance (FCA), which represents civil society organisations, developed a consensus position in advance of the COP on the principles which should underpin any regulatory system. See box below.[62]

The COP agreed with the FCA that global guidelines are not yet feasible but did invite "Parties to consider prohibiting or regulating ENDS including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health". Furthermore, the WHO was asked to prepare a report for the next COP with an update on the evidence of the health impacts, the potential role in quitting tobacco usage, methods to measure contents and emissions of these products, and impact on tobacco control efforts and policy options.

Principles to guide policy on tobacco harm reduction and electronic cigarettes:

- The global burden of death and disease from tobacco is primarily caused by smoking.
- While quitting tobacco use is paramount, quitting nicotine use altogether is the best option.
- For those unable to quit, switching to alternative sources of nicotine that are less harmful than tobacco can reduce, often very substantially, the harm smoking causes to the individual.
- The benefits of such an approach would be maximized if uptake were limited to existing smokers who are unable to quit.
- The risks of such an approach would be minimized by limiting uptake by never-smokers, in particular amongst young people, and by taking measures to protect non-users and discourage long-term dual use.
- There could be negative unintended consequences from over-regulation just as there could be from under-regulation.
- The involvement of tobacco companies in the production and marketing of electronic cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

Conclusion

ASH recognises that whilst efforts to help people stop smoking should remain a priority, many smokers either do not wish to stop quit or find it very hard to do so because of their addiction to nicotine. For this group, nicotine containing products which have been properly regulated to ensure product safety, quality and efficacy should be available as an alternative to tobacco.

Most of the diseases associated with smoking are caused by inhaling smoke which contains thousands of toxic chemicals. By contrast, nicotine is relatively safe. Electronic cigarettes, which deliver nicotine without the harmful toxins found in tobacco smoke, are a safer alternative to smoking. In addition, electronic cigarettes reduce secondhand smoke exposure in places where smoking is allowed since they do not produce smoke. Nonetheless, nicotine is an addictive substance, electronic cigarettes currently available are highly variable in terms of delivery of nicotine and product quality, and smokers are uncertain about the effectiveness of the product. There are concerns, as yet unsupported by evidence, that these products may provide a gateway into smoking for children and young people. The regulation of these products, in particular with respect to their advertising, promotion and sponsorship needs to be undertaken with these factors in mind.

In the UK smokefree legislation exists to protect the public from the demonstrable harms of secondhand smoke. ASH does not consider it appropriate for electronic cigarettes to be subject to this legislation, but that it should be for organisations to determine on a voluntary basis how these products should be used on their premises.[55]

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Adults:

March 2010: 2,297 adult smokers
March 2012: 12,436 adults
February 2013: 12,171 adults
March 2014: 12,269 adults

Children:

March 2013: 2,178 children aged 11-18
March 2014: 2,068 children aged 11-18

Surveys were conducted online and results weighted to reflect the British population, as appropriate.
52 Calculations were done by ASH applying the proportions of electronic cigarette use by smoking status in the 2014 YouGov survey to the most recent available ONS mid-year GB population estimates (2012).
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