
From: Deborah Arnott [<mailto:Deborah.Arnott@ash.org.uk>]
Sent: Tuesday, September 24, 2013 3:52 PM
To: SEYCHELL Martin (SANCO); SCHNICHELS Dominik (SANCO); [REDACTED]
[REDACTED] DUARTE GASPAR Paula (CAB-BORG); DARMANIN Joanna (CAB-BORG)
Cc: [REDACTED]
[REDACTED]
[REDACTED]
Subject: Medicines regulation for e-cigarettes

Dear DG SANCO

We write to you on behalf of the Royal College of Physicians (*the leading British professional body for doctors working in general medicine*), the Trading Standards Institute (*the UK professional body for Trading Standards Officers responsible for enforcing consumer legislation*) and Action on Smoking and Health (ASH, *which is the leading health charity in the UK working to reduce the harm caused by tobacco*) to emphasise our strong support for the Tobacco Products Directive to bring all e-cigarettes and other nicotine containing products into medicines regulation.

We are deeply concerned that the vote in plenary on the TPD has been put back to October 8th, and have written to all MEPs to urge them to vote on that date for a mandate for negotiations to start with the Council and the Commission and in support of the ENVI proposals including medicines regulation for nicotine containing products. (see attached brief for MEPs).

To summarise we believe that e-cigarettes have significant potential to help smokers who aren't otherwise ready or able to quit smoking by providing them with much safer alternatives to smoked tobacco, and indeed that e-cigarettes and similar products are a potential major benefit to public health. It is therefore important that regulation does not stifle the development and growth of this market. Currently e-cigarettes come under a range of consumer legislation, however, we believe that some additional safeguards are required to ensure that these products are effective, reliable, as safe as is reasonably possible, and that the advertising and promotion of these products to non-smokers, including children, can be prevented. We believe that the permissive medicines regulation proposed by the UK regulator (the Medicine and Healthcare Products Regulatory Agency - MHRA) will achieve this and provides a good model for other Member States.

We have also written to our Minister for Health to emphasise our strong support for the UK government's decision to bring e-cigarettes and other nicotine containing products into medicines regulation by the MHRA, as a rejoinder to evident heavy lobbying by opponents of such regulation. (see attached letter).

Do let me know if you have any questions?

Best wishes.
Deborah.

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Rt Hon Jeremy Hunt MP
Secretary of State for Health
Richmond House
79 Whitehall
London SW1A 2NS

24 September 2013

Dear Jeremy,

Regulation of e-cigarettes by the MHRA

We write to you on behalf of the Royal College of Physicians, the Trading Standards Institute and Action on Smoking and Health (ASH) to emphasise our strong support for the UK government's decision to bring e-cigarettes and other nicotine containing products into medicines regulation by the MHRA, as a rejoinder to evident heavy lobbying by opponents of such regulation.

To summarise we believe that e-cigarettes have significant potential to help smokers who aren't otherwise ready or able to quit smoking by providing them with much safer alternatives to smoked tobacco, and indeed that e-cigarettes and similar products are a potential major benefit to public health. While it is important that regulation does not stifle the development and growth of this market, safeguards not currently available under existing consumer regulation are required to ensure that these products are effective, reliable, as safe as is reasonably possible, and are not marketed to non-smokers, including children. We believe that the medicines regulation proposed by the MHRA will achieve this.

Our reasoning is set out in more detail below:

1. There are currently around 10 million smokers in the UK, with around 100,000 a year dying from smoking. To quote Professor Mike Russell, a pioneer in the treatment of nicotine addiction from the Institute of Psychiatry in the 1970s, these smokers "*smoke for the nicotine but they die from the tar.*" Most smokers want to quit smoking, and many do, particularly if they use the highly cost-effective NHS Stop Smoking Services; but most either try and fail, or perpetually step back from engaging with services and trying to quit.
2. Electronic cigarettes and similar devices in development which deliver nicotine in a form that mimics the act of smoking provide smokers with a socially acceptable and easily available alternative approach to quitting, or cutting down, on smoking without a formal commitment to or involvement of health professionals. Smokers like e-cigarettes because of their similarity to cigarettes, and because substituting one behaviour for a similar one is easier than stopping the behaviour altogether. Research by ASH and others shows that e-cigarettes are being used by smokers primarily for the same purposes as medicinal Nicotine Replacement Therapy (NRT) – to quit, to cut down, as an alternative to smoking and to use where they can't smoke – all purposes that NRT is licensed for in the UK and can be elsewhere. The e-cigarette industry says their products are used for recreational purposes, but smokers themselves freely admit they're using them to help them quit smoking.
3. Currently available electronic cigarettes are however highly variable in relation to the amount of nicotine they deliver (if any), and the purity of nicotine delivered. Nicotine delivery matters because many users may be put off an attempt to reduce or stop smoking if the device they buy is ineffective. Available evidence shows that e-cigarettes currently on the market are no more effective than medicinal nicotine patches, which probably explains why ASH surveys show that only one third of smokers who try e-cigarettes carry on using them, with most of the rest remaining dual users. These products will need to improve their nicotine delivery if they are to be the cure for smoking that some advocates claim. The purity of the nicotine delivered matters not because the risks of impurities in e-cigarette vapour are high, since in relation to smoking they are almost certainly negligible, but because it makes sense to avoid

inhalation of unnecessary or avoidable toxins in the nicotine vapour. The MHRA recently concluded that the products currently on the market do not meet appropriate standards of safety, quality and efficacy: *"Testing data confirm that nicotine levels can vary considerably from the labelled content and the amount of nicotine per product can differ from batch to batch. In terms of how well NCPs work, there can be widely differing amounts of nicotine from the same format with one form delivering what could be an effective therapeutic dose, another a 'placebo' dose. With regards to safety, toxic elements may be included at unexpectedly high doses which could produce adverse effects, particularly in vulnerable patient groups."*

4. We therefore believe that whilst electronic cigarettes and similar devices are undoubtedly a powerful force for the good in public health, they need regulation to ensure standards of purity and performance. Regulation is also needed to protect against irresponsible promotion and advertising aimed at recruiting new users, including young people. Of the various regulatory options available, medicines regulation appears to us to be the most appropriate since it will ensure suitable product standards, require pre-vetting of advertisements, and provide a means to act quickly against abuses of the market. That said, it is also crucially important that medicines regulation is applied appropriately, to ensure the above without stifling innovation and development in a product area with the potential to reduce dramatically the death and disability currently caused by addiction to tobacco smoking.

5. Some e-cigarette companies argue that medicines regulation would be too expensive and too difficult, but this is a potentially large and very profitable market. The costs of licensing, though substantial, are offset by taxation at the lowest level of VAT (5%), and the benefits of being eligible for provision on prescription through the NHS. A recent report by Wells Fargo, a US investment analyst, came to the conclusion that:

- *Within a decade e-cig sales in the US could overtake cigarettes.*
- *While the big 3 tobacco brands in the US are likely to be key players independents will continue to have significant market share.*
- *Margins are growing on e-cigarettes as the market grows and evolves: by 2017 margins could be higher than current conventional cigarette margins of around 40%*
- *The Wells Fargo model doesn't consider new entrants amongst non-smokers – all of the e-cig volume consumption in the model is driven by existing conventional cigarette users*
- *Regulation is not considered likely to undermine the long-term growth of the e-cigarette market. It is however considered likely to entrench existing e-cigarette players as it increases barriers to entry.*

6. E-cigarettes are a young and rapidly evolving product and consolidation is inevitable. Already the small companies are being swallowed up, largely by the tobacco industry, and this process will continue whether medicines regulation is imposed or not. We need a regulatory framework in place to help shape how the market develops, particularly because of the move into the market of the tobacco industry. We therefore support a permissive approach to regulation of this market, and believe that medicines regulation can provide that oversight in the UK, and provide a model for wider regulation in other EU Member States.

Do let us know if you have any questions.

Yours sincerely



John Britton
Chair
RCP Tobacco Advisory Group



Leon Livermore
Chief Executive
Trading Standards Institute



Deborah Arnott
Chief Executive
Action on Smoking and Health

Tobacco Products Directive (TPD)

E-cigarettes are potentially a powerful force for public health but they need to be better regulated if they are to deliver. Of all the legal options available, medicines regulation provides the best available framework.

As you know the European Parliament Committee responsible for the Tobacco Products Directive dossier (ENVI Committee) passed an amendment requiring medicines regulation for all e-cigarettes. We write to you on behalf of the Royal College of Physicians (*the leading British professional body for doctors working in general medicine*), the Trading Standards Institute (*the UK professional body for Trading Standards Officers responsible for enforcing consumer legislation*) and Action on Smoking and Health (*ASH, which is the leading health charity in the UK working to reduce the harm caused by tobacco*) to emphasise our strong support for the Tobacco Products Directive to bring all e-cigarettes and other nicotine containing products into medicines regulation.

We are deeply concerned that the vote in plenary on the TPD has been put back to October 8th, and urge you to vote on that date for a mandate for negotiations to start with the Council and the Commission and in support of the ENVI proposals including medicines regulation.

To summarise we believe that e-cigarettes have significant potential to help smokers who aren't otherwise ready or able to quit smoking by providing them with much safer alternatives to smoked tobacco, and indeed that e-cigarettes and similar products are a potential major benefit to public health. It is therefore important that regulation does not stifle the development and growth of this market. Currently e-cigarettes come under a range of consumer legislation, however, we believe that some additional safeguards are required to ensure that these products are effective, reliable, as safe as is reasonably possible, and that the advertising and promotion of these products to non-smokers, including children, can be prevented. We believe that the permissive medicines regulation proposed by the UK regulator (the Medicine and Healthcare Products Regulatory Agency - MHRA) will achieve this and provides a good model for other Member States.

It is not appropriate for e-cigarettes to be regulated under the Tobacco Products Directive, as amendments 110, 130 and 135 aim to do. The TPD lacks the regulatory framework that medicines regulation already has in place to set standards for nicotine delivery and update them regularly, to monitor adverse reactions and to pre-vet advertising, all backed by civil and criminal offences.

Our reasoning is set out in more detail below:

1. Smoking remains the major cause of preventable premature death in the EU. To quote Professor Mike Russell, a pioneer in the treatment of nicotine addiction from the Institute of Psychiatry in the 1970s, these smokers "*smoke for the nicotine but they die from the tar.*" Most smokers want to quit smoking, and many do, but most try and fail.
2. Electronic cigarettes and similar devices in development which deliver nicotine in a form that mimics the act of smoking provide smokers with a socially acceptable and easily available alternative approach to quitting, or cutting down, on smoking without a formal commitment to, or involvement of, health professionals. Smokers like e-cigarettes because

of their similarity to cigarettes, and because substituting one behaviour for another similar one is easier than stopping the behaviour altogether. Research by ASH and others shows that e-cigarettes are being used by smokers primarily for the same purposes as medicinal Nicotine Replacement Therapy (NRT) – to quit, to cut down, as an alternative to smoking and to use where they can't smoke – all purposes that NRT is already licensed for in parts of the EU and can be elsewhere. The e-cigarette industry says their products are used for recreational purposes, but smokers themselves freely admit they're using them to help them quit smoking.

3. Currently available electronic cigarettes are however highly variable in relation to the amount of nicotine they deliver (if any), and the purity of nicotine delivered. Nicotine delivery matters because many users may be put off an attempt to reduce or stop smoking if the device they buy is ineffective. Available evidence shows that e-cigarettes currently on the market are no more effective than medicinal nicotine patches, which probably explains why ASH surveys show that only one third of smokers who try e-cigarettes carry on using them, with most of the rest remaining dual users. These products will need to improve their nicotine delivery if they are to be the cure for smoking that some advocates claim. The purity of the nicotine delivered matters not because the risks of impurities in e-cigarette vapour are high, since in relation to smoking they are almost certainly negligible, but because it makes sense to avoid inhalation of unnecessary or avoidable toxins in the nicotine vapour. The UK regulator the MHRA recently concluded that the products currently on the market do not meet appropriate standards of safety, quality and efficacy: *“Testing data confirm that nicotine levels can vary considerably from the labelled content and the amount of nicotine per product can differ from batch to batch. In terms of how well Nicotine Containing Products work, there can be widely differing amounts of nicotine from the same format with one form delivering what could be an effective therapeutic dose, another a 'placebo' dose. With regards to safety, toxic elements may be included at unexpectedly high doses which could produce adverse effects, particularly in vulnerable patient groups.”*

4. We therefore believe that whilst electronic cigarettes and similar devices are a potential powerful force for the good in public health, they need regulation to ensure standards of purity and performance. Regulation is also needed to protect against irresponsible promotion and advertising aimed at recruiting new users, including young people. Of the various alternative regulatory options available, medicines regulation appears to us to be the most appropriate since it will ensure suitable product standards, require pre-vetting of advertisements, and provide a means to act quickly against abuses of the market. That said, it is also crucially important that medicines regulation is applied appropriately, to ensure the above without stifling innovation and development in a product area with the potential to reduce dramatically the death and disability currently caused by addiction to tobacco smoking.

5. Some e-cigarette companies argue that medicines regulation would be too expensive and too difficult, but this is a potentially large and very profitable market. A recent report by Wells Fargo, a US investment analyst, came to the conclusion that:

- *Within a decade e-cig sales in the US could overtake cigarettes.*
- *While the big 3 tobacco brands in the US are likely to be key players independents will continue to have significant market share.*
- *Margins are growing on e-cigarettes as the market grows and evolves: by 2017 margins could be higher than current conventional cigarette margins of around 40%*

- *The Wells Fargo model doesn't consider new entrants amongst non-smokers – all of the e-cig volume consumption in the model is driven by existing conventional cigarette users*
- *Regulation is not considered likely to undermine the long-term growth of the e-cigarette market. It is however considered likely to entrench existing e-cigarette players as it increases barriers to entry.*

6. E-cigarettes are a young and rapidly evolving product and consolidation is inevitable. Already the small companies are being swallowed up, largely by the tobacco industry, and this process will continue whether medicines regulation is imposed or not. We need a regulatory framework in place to help shape how the market develops, particularly because of the move into the market of the tobacco industry. We therefore support a permissive rather than a restrictive approach to regulation of this market, and believe that medicines regulation can provide that oversight in all EU Member States.

7. There is an understandable concern amongst users that medicinally regulated e-cigarettes will not continue to be available on general sale but only in pharmacies in some parts of Europe. However, most Member States (MS) already have forms of regulated Nicotine Replacement Therapy available as non-prescription medicines and most MS already have a category of medicines which can be sold outside pharmacies. And all MS can (and we think should) allow e-cigarettes to be on general sale in the transposing of the TPD to their domestic law.

24th September, 2013.