Regulating E-Cigarettes in the European Union

Presented by:
The Association of State and Territorial Health Officials (ASTHO)

April 8, 2014
11:00am-12:30pm ET
Webinar Agenda

Welcome & Introduction
- Elizabeth Walker–Romero & Diana Karczmarczyk, ASTHO
- Dr. Edward Ehlinger, MD, MSPH, Commissioner of Health, Minnesota Department of Health

Overview of E–Cigarettes in the European Union
- Dominik Schnichels, Head of Unit, DG SANCO, Substances of Human Origin and Tobacco Control, European Commission

Coalitions and Work at the Local and National Level
- Deborah Arnott, MBA, FRCP (Hon), Chief Executive, Action on Smoking & Health

E–Cigarettes: Facilitators and Challenges to Policy Change
- Linda McAvan, MEP, European Parliament

Q&A Session
- Facilitated by Elizabeth Walker–Romero & Diana Karczmarczyk, ASTHO
Regulating E-Cigarettes in the EU

ASTHO Webinar

Dominik Schnichels, Head of Unit
European Commission, DG SANCO, Unit D4, Substances of human origin and tobacco control
Brussels, 8 April 2014
Outline

1. E-cigarettes on the EU market
2. Regulation of E-cigarettes before TPD
3. Provisions on E-cigarettes in TPD
1. E-cigarettes on the EU market (I)

- Disposable, rechargeable and refillable electronic cigarettes
1. E-cigarettes on the EU market (II)
Market dynamics

- In 2010/2011 the market was estimated at 400 to 500 mEUR and growing rapidly (20-30% monthly according to one industry association)

- 340% increase in market in the UK and 500% retail sales increase in Ireland in 2013

- Some analysts predict that the market may overtake the tobacco market in Europe

- Increasing evidence that the tobacco industry is entering the electronic cigarette market in Europe (purchase of companies, launch of products)

- In a 2012 survey of European citizens, 7% had tried e-cigarettes and 1% were regular users (Eurobarometer 2012)
2. Regulation of E-cigarettes before TPD

In 2013, EU Member States regulated e-cigarettes differently:
- 11 Member States considered electronic cigarettes pharmaceuticals
- 8 considered them consumer products
- 6 had no specific regulation in place
- 1 applied the same provisions as tobacco products
- 1 banned these products

Provisions varied between Member States:
- Maximum threshold
- Prohibition of sales to minors
- Advertising restrictions
- Prohibition of brand stretching

→ Need for EU regulation of E-cigarettes
3. Provisions on E-cigarettes in TPD (I)

- The new Tobacco Products Directive (TPD) adopted in March 2014
- E-cigarettes – one of the key elements in the TPD
- Regulation of e-cigarettes with nicotine

Main elements of the TPD
- Ingredients
- Packaging and labelling
- Illicit trade
- **E-cigarettes**
- Cross border distance sales
- Novel tobacco products
- Herbal products for smoking

A. Regulates electronic cigarettes as consumer products (but allows EU Member States to classify electronic cigarettes as medicines)

B. Introduces safety and quality requirements at EU level

C. Sets packaging and labelling requirements

D. Requires notification, market surveillance and reporting to the EU Member States

E. Prohibits cross border advertising and regulates cross border distance sales
3. Provisions on E-cigarettes in TPD (III)

A. Regulatory framework: in the EU, products can be medicines 'by presentation' or 'by function'. Otherwise, the new TPD applies

B. Quality and safety requirements for all electronic cigarettes not requiring pharmaceutical authorisation:
   - Max concentration: 20 mg/ml
   - Max volumes: 2ml for cartridges/tanks and 10ml for refill bottles
   - Consistent dosing
   - Child- and tamper-proof design

C. Packaging / Leaflet
   - Ingredients list
   - No misleading elements
   - Health warning
   - Instructions for use
   - Contra-indications and other information on risks
   - Contact details of the manufacturer/importer
3. Provisions on E-cigarettes in TPD (IV)

D. Notification
E-cigarettes must be notified before placing on the EU market, manufacturers/ importers must report to MS on marketing success (profile of consumers), manufacturers/importers bear the responsibility for the safety of their products and must record and report adverse events.

E. Cross-border advertising of consumer electronic cigarettes is forbidden and cross-border distance sales are regulated in the same manner as for tobacco. Sales arrangement are left to MS.

*National competence: regulation of flavours in e-cigarettes, age limits, smokefree environments and sales points*

*Reports on the public health risks of "refillables" and and public health risks/benefits of e-cigarettes in general*
Thank you

Any questions?

Further Information

Policy work on e-cigarettes
the role of civil society

ASTHO presentation 8 April 2014
Deborah Arnott
Chief Executive
Action on Smoking & Health
ASH and alliance working

- ASH was set up by Royal College of Physicians in 1971 to reduce harm caused by smoking
- Core funding Cancer and heart charities
- Project funding from Ministry of Health to support implementation of Govt strategy
- No commercial funding
- Coordinates SFAC alliance now 250+ organisations
- Work on policy at UK and EU level
A story of success….BUT

Four leaders, the rest need to do better!

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**Tobacco Control Scale 2013**

**How does your country rate on tobacco control?**

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**ash.**

action on smoking and health
Each year smoking causes the greatest number of preventable deaths

- Smoking: 81,400
- Obesity: 34,100
- Alcohol: 6,541
- Suicide: 5,377
- Traffic: 2,502
- Drug misuse: 1,738
- HIV: 529

Plus 12% of disability adjusted life years attributable to tobacco from the UK analysis of the Global Burden of Disease study.
Smoking is the greatest cause of health inequalities beginning in childhood

The poorest are twice as likely to smoke as the richest

Children start smoking not adults: 90% of smokers start before age 19

References:
1. Smoking Attitudes & Behaviours, ONS 2011
Smoking cessation policy

• Britain in advance on smoking cessation and e-cigarette policy
• All smokers have access to smoking cessation services free at point of delivery
• Provide counselling and medicines on prescription (NRT, varenicline etc.)
• BUT uptake low – products not attractive
• Most disadvantaged continue to have high smoking rates
• So Royal College of Physicians, ASH and Smokefree Action Coalition develop harm reduction strategy
SFAC policy position 2008 before e-cigs take-off

100 organisations endorsed:

- Nicotine products must be attractive as direct replacements for cigarettes
- Consumers must understand the benefits of using pure nicotine products as an alternative to smoking
- Products should be widely available and highly visible on the high street
- Price should provide an incentive to switch from tobacco
- Regulation should be proportionate to risk
Current Government policy on nicotine and harm reduction

• E-cigarettes regulated as consumer products
• English government approach
  – Stopping smoking immediately best option
  – For those unwilling or unable to harm reduction approaches appropriate using licenced products
• Medicines regulator licences NRT for long-term use, to cut down, for temporary abstinence
• NICE guidance to healthcare professionals supports harm reduction approach
Use among British smokers has grown rapidly

E-cigarette use among British smokers, 2010-14

Currently use e-cigarettes
- 2010: 3%
- 2012: 7%
- 2013: 11%
- 2014: 18%

Have ever tried e-cigarettes
- 2010: 9%
- 2012: 22%
- 2013: 35%
- 2014: 52%
Current use in Britain

• Context - regulation as consumer products
• E-cigarette use is growing rapidly: from 700k in 2012 to 1.3 million in 2013 to 2.1 million in 2014
• In 2014, 1.5 million current smokers and 600k ex-smokers were e-cig users
• Health professionals have concerns about ‘renormalisation’ of smoking
• BUT so far little use by non-smokers either adults or young people
• Adult and youth smoking still going down
Sustained use among adults is still confined to smokers & ex-smokers in 2014

E-cigarette use in Britain, 2014
(All adults)
Children who have never smoked rarely use e-cigarettes

E-cigarette use among children in Britain, 2013
(Children who have heard of e-cigarettes, by smoking status)

- Never smoked: N=1042
  - I have never used them: 99%
  - I have tried them once or twice: 8%
  - I use them sometimes (more than once a month): 7%
  - I use them often (more than once a week): 4%
  - Don't know/Wouldn't say: 5%

- Tried smoking once: N=177
  - I have never used them: 92%
  - I have tried them once or twice: 4%
  - I use them sometimes (more than once a month): 7%
  - I use them often (more than once a week): 18%
  - Don't know/Wouldn't say: 6%

- Used to smoke: N=64
  - I have never used them: 82%
  - I have tried them once or twice: 4%
  - I use them sometimes (more than once a month): 18%
  - I use them often (more than once a week): 37%
  - Don't know/Wouldn't say: 5%

- Smoke <1 a week: N=65
  - I have never used them: 74%
  - I have tried them once or twice: 6%
  - I use them sometimes (more than once a month): 37%
  - I use them often (more than once a week): 59%
  - Don't know/Wouldn't say: 4%

- Smoke 1-6 a week: N=22
  - I have never used them: 59%
  - I have tried them once or twice: 4%
  - I use them sometimes (more than once a month): 48%
  - I use them often (more than once a week): 39%
  - Don't know/Wouldn't say: 5%

- Smoke 6+ a week: N=53
  - I have never used them: 39%
  - I have tried them once or twice: 4%
  - I use them sometimes (more than once a month): 48%
  - I use them often (more than once a week): 39%
  - Don't know/Wouldn't say: 5%
Weekly use is confined to older children

E-cigarette use in Britain, 2013
(Children who have heard of e-cigarettes, by age)

- I use them often (more than once a week)
- I use them sometimes (more than once a month)
- I have tried them once or twice
- I have never used them

11 to 15 (N=804)
- 1% I use them often
- 4% I use them sometimes
- 1% I have tried them once or twice
- 95% I have never used them

16 to 18 (N=624)
- 1% I use them often
- 8% I use them sometimes
- 1% I have tried them once or twice
- 90% I have never used them
Smoking Toolkit Study
Aids used in most recent quit attempt

Increase in use of e-cigarettes for quitting has been accompanied by a smaller reduction in use of other aids except behavioural support

N=4,810 adults who smoke and tried to stop or stopped in last year
Quitting smoking in England

Percent who have smoked in the past year who do not smoke now


N=14,027 adults who smoked in the past year; increase p<0.001
Adult and youth smoking in England

E-cigarette sales start to take off

Sources: GLS and Smoking Drinking and Drug use amongst young people in England 2013
Prevalence of nicotine/cigarette use
most recent data

Smoking Toolkit Study N=64,222 adults, decrease p<0.001 for both lines
Adult smoking prevalence estimate = 17.8%
Nicotine regulation in future

• In UK twin track approach – e-cigs currently regulated as consumer products, regulated as tobacco products from 2016 or can opt in to medicines regulation
• Medicines regulator ‘continues to encourage companies to voluntarily submit medicines licence applications for electronic cigarettes and other NCPs as medicines’
• 2 products publicly going through licencing process – other manufacturers/importers saying will do so
• Age of sale for e-cigs of 18 from Spring 2015
• Advertising rules being updated in light of rapid growth
Advertising of nicotine products

- Tobacco advertising, promotion and sponsorship completely prohibited
- Brand sharing completely prohibited
- E-cigarette advertising regulated in this light
- Consultation underway on advertising code
- E-cigarette advertising needs to evolve in light of emerging evidence
# TPD vs MHRA regulation

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<td>• 20% sales tax</td>
<td>• 5% sales tax</td>
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<tr>
<td>• Cross border advertising banned</td>
<td>• Advertising allowed to adults</td>
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<tr>
<td>• Can’t make health claims</td>
<td>• Can make health claims</td>
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<tr>
<td>• Limits on strength 20 ml/mg</td>
<td>• Flexibility on strength</td>
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<td>• 30% health warning on packs about nicotine</td>
<td>• Safety and quality ensured</td>
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<tr>
<td>• Member States retain powers e.g. banning flavours</td>
<td>• No health warning on packs</td>
</tr>
<tr>
<td>• Products not on prescription</td>
<td>• Flavours allowed</td>
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<tr>
<td>• Products widely available</td>
<td>• Products on prescription free to poor smokers</td>
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<td>• Products widely available including in pharmacies</td>
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Conclusions

- E-cigarettes still new and evolving
- May be electronic but not cigarettes nor smoked
- So far in Britain helping smokers quit while not undermining denormalisation
- Regulation needs to evolve in the light of the evidence –to be flexible, ensure safety and quality of product and require market surveillance and monitoring
- Over-regulation could undermine quitting
- Britain will be going down a dual route from 2016 (TPD or opt in to medicines regulation)
- US needs to ensure e-cig regulation maximises benefits while minimising risks
Background information

ASH information on electronic cigarettes
• Briefing: www.ash.org.uk/information/facts-and-stats/ash-briefings
• Factsheet on e-cig use in Britain: www.ash.org.uk/files/documents/ASH_891.pdf
• Contact details: deborah.arnott@ash.org.uk 07976 935 987

Royal College of Physicians reports:
• Harm reduction in nicotine addiction http://tinyurl.com/na3dbs4
• Smoking and Mental Health http://tinyurl.com/no8ybwp

• Smoking Toolkit Study data on e-cigarette use: http://tinyurl.com/oehv6t3
• MHRA information on licencing of nicotine products: http://tinyurl.com/mohqp2s
• NICE guidance on tobacco harm reduction www.nice.org.uk/PH45
• CAP consultation on advertising of electronic cigarettes http://tinyurl.com/nuggt37
E–Cigarettes: Facilitators and Challenges to Policy Change

Linda McAvan, MEP
Member of the European Parliament
Yorkshire and the Humber
ASTHO E-Cigarette Resources

- Archived Webinar Recordings and Resources
  - [www.astho.org/Prevention/Tobacco/Tobacco–Webinars](http://www.astho.org/Prevention/Tobacco/Tobacco–Webinars)

- E–Cigarette Website & Resources Page
  - [www.astho.org/E–Cigarettes](http://www.astho.org/E–Cigarettes)

- E–Cigarette Workgroup
  - For more information, email: dkarczmarczyk@astho.org

- E–Cigarette Issue Brief & State Stories
  - *Coming soon!*
If you would like to ask a question, please type it into the chat box on your screen.
Thank you for joining us!

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  dkarczmarczyk@astho.org

ASTHO Tobacco Website:
www.astho.org/Programs/Prevention/Tobacco

ASTHO E–Cigarettes Website:
www.astho.org/E–Cigarettes