The English experience in a European regulatory context

E-cigarette summit Washington DC
1st May 2018
Deborah Arnott
Chief Executive
ASH (UK)
Declaration of Interest

• ASH (UK) is a public health charity set up by the Royal College of Physicians in 1971 to advocate for policy measures to reduce the harm caused by tobacco.
• Funded primarily by 2 leading UK health charities: British Heart Foundation and Cancer Research UK.
• Has received project funding from the Ministry of Health in England to support tobacco control.
• ASH does not accept commercial funding
• ASH does not have any direct or indirect links to, or receive funding from, the tobacco industry.
What this presentation covers

• The European regulatory context for tobacco control
• How England differs in its vision rather than its regulatory framework
• The European regulatory framework for e-cigarettes  
  – How it compares to WHO  
  – How it compares to the US
• Outcomes
European tobacco control regulation sets minimum standards for Member States

- **Tobacco Advertising Directive**
  - Bans cross border advertising, promotion and sponsorship (TV, radio, internet and print)

- **Tobacco Tax Directive**
  - Sets minimum excise taxes on all tobacco products

- **Tobacco Products Directive**
  - Large pictorial health warnings on cigarette packs
  - Minimum pack sizes
  - Tracking and tracing for tobacco products
  - Bans flavours in tobacco products (menthol from 2020)
  - Requires notification for any new tobacco product
  - Regulates e-cigarettes
From 2007 onwards UK led the way

<table>
<thead>
<tr>
<th>Country</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>81</td>
</tr>
<tr>
<td>Ireland</td>
<td>70</td>
</tr>
<tr>
<td>Poland</td>
<td>50</td>
</tr>
<tr>
<td>Germany</td>
<td>37</td>
</tr>
<tr>
<td>Austria</td>
<td>36</td>
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6 countries continue to lead... 3 continue to disappoint!
UK leadership translated into results
Eurobarometer smoking prevalence 2006-2017
UK e-cigarette regulation laid down by EU = in line with WHO

<table>
<thead>
<tr>
<th>WHO recommendation</th>
<th>Action in England</th>
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<tbody>
<tr>
<td>Prevent the initiation among non-smokers and youth</td>
<td>✓ Age of sale of 18.</td>
</tr>
<tr>
<td></td>
<td>✓ Packs must state the products not for use by non-smokers or children</td>
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<tr>
<td>Minimise health risks to EC users and protect non-users from exposure</td>
<td>✓ Prior notification of all new e-cigarette products;</td>
</tr>
<tr>
<td></td>
<td>✓ limits nicotine concentration and size of tamper proof/child resistant refill containers</td>
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<td>✓ requires information on safe use, contra-indications/adverse effects</td>
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<td>✓ Warnings on packs</td>
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<td>✓ protected from breakage and leakage</td>
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<td>✓ ingredients to be of high purity and not a risk to health</td>
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<td>✓ Removal of products that do not comply</td>
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<td>Prevent unproven health claims</td>
<td>✓ Banned from the outset.</td>
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<td>Protect tobacco control activities from vested interests related to EC</td>
<td>✓ The UK is a signatory to the WHO Framework Convention on Tobacco Control and has policies and procedures in place to protect health policy from the vested interests of the tobacco industry</td>
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<td>Consider prohibiting or regulating EC, including as tobacco products, medicinal products, consumer products</td>
<td>✓ The UK provides both medicinal and consumer product regulatory frameworks for e-cigarettes.</td>
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<td>Consider banning or restricting advertising, promotion and sponsorship</td>
<td>✓ From May 2016 advertising of unlicensed EC in print, broadcast, online and other electronic media and sponsorship of large events and broadcast programming are prohibited.</td>
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| Comprehensively monitor the use of EC, including the relevant questions in all appropriate surveys | ✓ EC use among adults and children is comprehensively monitored by several national Government surveys  
   ✓ Additional national and local surveys are undertaken by other organisations |
US vs EU regulation of e-cigarettes

EU - notification not authorisation
- Have to meet generic standards rather than be individually authorised
- Products have to be notified six months in advance – contents and emissions
- Advertising allowed but limited to local – no TV, radio, internet, print
- Health warnings on packs
- System up and running - review in five years

US – authorisation not notification
- Novel products have to be authorised before coming on market PMTA
- Only exemption if can prove substantial equivalence with products on market pre-8 Aug 2016
- July 2017 deadline for SE applications for e-cigs extended to 8 Aug 2022
- New guidance on what’s required promised ‘shortly’ still not published
## English national TC plan 2017
### First smokefree generation by 2022

### The first smokefree generation
People should be supported not to start smoking, so we aim, by the end of 2022 to reduce:

- adult smoking prevalence from **15.5%** to **12%**
- young people smoking prevalence from **8%** to **3%**
- Inequality gap in smoking prevalence between those in routine and manual occupations and the general population

### A smokefree pregnancy for all
Every child deserves the best start in life, so we aim, by the end of 2022 to:

- Reduce the prevalence of smoking in pregnancy from **10.7%** to **6%** or less

### Mental health: parity of esteem
People with mental ill health should be given equal priority to those with physical ill health, so we aim to:

- Make all mental health inpatient services sites smokefree by 2018
- Improve data collected on smoking and mental health to help us to support people with mental health conditions to quit smoking

### Innovations to support quitting
We are committed to evidence-based policy making, so we aim to:

- Help people to quit smoking by permitting innovative technologies that minimise the risk of harm
- Maximise the availability of safer alternatives to smoking

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**ash.**

action on smoking and health
# English national TC plan 2017

Harm reduction integral to achieving goal

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English national TC plan
unified approach to harm reduction

- **Ministry of Health**: provides overarching context
- **Medicines regulator** – supports consumer products and encourages applications for medicines licensing
- **Public Health England and NICE** - provide guidance to healthcare professionals and public
- **Civil society** – medical organisations, leading tobacco control academics, health charities and advocacy organisations support harm reduction
How TPD notification process is working

• Notifications cost £150 (= $210) has generated £5.34 million to date ($7.48 million)

• Up to January 2018 - 2,927 e-cigarettes and 30,831 e-liquids on published list

• Reporting system for side effects and safety concerns – so far 39 reports all minor

• Concerns raised about noncompliance – enforcement weak (under funded)
Outcomes:
TPD to date not had impact on e-cig use

Prevalence of e-cigarette use

Use of e-cigarettes has remained stable since late 2013

N=89539 adults from Nov 2013
Outcomes:
NRT and ecig use by never smokers very low

Nicotine use by never smokers and long-term ex-smokers

E-cigarette use by never smokers remains negligible but use among long-term ex-smokers has grown

N=71732 never and long-term ex-smokers from Nov 2013
Outcomes:
Dual use e-cigarettes similar to NRT

Proportion of e-cigarette and NRT users who are smokers

The majority of both e-cigarette and NRT users are ‘dual users’ (also smoke)

N=4665 e-cigarette users and N=2369 NRT users
Outcomes:
small improvement in harm misperceptions

<table>
<thead>
<tr>
<th>Year</th>
<th>More or equally harmful</th>
<th>Don’t know</th>
<th>Less/lot less harmful</th>
<th>Completely harmless</th>
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<td>2018</td>
<td>22%</td>
<td>22%</td>
<td>53%</td>
<td>2%</td>
</tr>
<tr>
<td>2017</td>
<td>22%</td>
<td>28%</td>
<td>47%</td>
<td>2%</td>
</tr>
<tr>
<td>2016</td>
<td>20%</td>
<td>28%</td>
<td>50%</td>
<td>2%</td>
</tr>
<tr>
<td>2015</td>
<td>16%</td>
<td>20%</td>
<td>59%</td>
<td>4%</td>
</tr>
<tr>
<td>2014</td>
<td>10%</td>
<td>25%</td>
<td>60%</td>
<td>4%</td>
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Outcomes:
Youth use of e-cigs still rare in never smokers
Outcomes: England on track to be smokefree

Current trend: smokefree by 2030 under 5% adult smoking

Smoking in adults:
• Adult smoking prevalence 15.5%
• Since 2010 declined most rapidly in 18-24 yr olds
• On track to be under 12% by 2022 and 5% or less by 2030

Smoking in children:
• 11-15 yr old current smoking 6%
• 15 yr old regular smoking 7%
• On track to be 3% or less by 2022
Key considerations for prudent e-cig regulation

Public Health and smokers/vapers
• Protect children while reducing the harm to adults
• Ensure products which are safer, reliable and attractive alternatives to smoking can be marketed
• Ensure products promoted in line with the evidence

Business
• Establish a level playing field
• Provide clarity about what’s needed to meet the standards required
• Foster innovation and encourage competition
THANK YOU

Contact: deborah.arnott@ash.org.uk
Resources:
ASH research: www.ash.org.uk
Ministry of Health Tobacco Control Plan for England 2017
Public Health England e-cigarette expert evidence review 2018
NICE guidance NG92 smoking cessation interventions and services 2018
MHRA regulation of e-cigarettes:
• Regulations for consumer products
• Medicines licensing process
British Medical Association e-cigarette position paper 2018