Tobacco harm reduction: UK policy environment and context

Deborah Arnott
Chief Executive
Action on Smoking & Health
Warsaw June 2014
What is ASH?

• ASH is a British NGO dedicated to reducing the harm caused by tobacco
• Set up by the Royal College of Physicians in 1971
• Our role is advocacy, networking and information provision - anti-smoking not anti-smoker
• ASH (UK) receives core funding from British Heart Foundation and Cancer Research UK
• ASH (UK) receives no commercial funding
This presentation

- I am at this meeting on behalf of the Framework Convention Alliance
- FCA = coalition of NGOs around the world – over 350 organisations in over 100 countries
- Dedicated to the development, ratification and implementation of the WHO Framework Convention on Tobacco Control (FCTC)
- FCA positions developed by consensus – position on e-cigarettes under discussion
- This presentation is on behalf of ASH (UK) not the FCA
- The views expressed are those of ASH (UK) not the FCA
History of Tobacco Harm Reduction in the UK

• ASH worked to get support for harm reduction for over 10 years in collaboration with RCP

• Engaged MHRA in discussion about regulation of NRT

• UK medicines regulator liberalises licensing of NRT starting in 2005:
  – on basis that “there are no circumstances in which it is safer to smoke than to use NRT”
  – licensed in combination;
  – for patients with heart disease;
  – for use in young people 12 upwards
  – for pregnant smokers
  – For cutting down
  – For temporary abstinence

• Encouraged Government support for harm reduction approach
Beyond Smoking Kills 2008: recommendations to Government

Endorsed by 100 public health organisations:

- To support the development and use of alternative pure nicotine products for smokers unable or unwilling to quit
- To implement a communications programme to counter public misunderstanding of health impacts of nicotine
- To encourage commercial development of products and tax at lowest rate of VAT (5%)
- To evaluate cost effectiveness of provision on prescription
- Increase investment in research into nicotine
- To regulate the market either by new authority or within existing structures
Regulatory options considered in BSK in 2008

Regulation options for pure nicotine products designed as long-term substitutes for smoking

<table>
<thead>
<tr>
<th>Approach</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines regulation</td>
<td>Existing regulatory structure already handles nicotine. Ensures coherent regulatory framework for all nicotine products. Enables VAT to be levied at a reduced rate of 5% (this may not be possible under other regulatory structures).</td>
<td>Potentially bureaucratic and inflexible. Costly to develop faster acting new products under current system so would lead to high prices to consumers. Time consuming to get products to market. Products likely to be limited to prescription only in the first instance, which would limit access.</td>
</tr>
<tr>
<td>Food regulation</td>
<td>Existing regulatory structure.</td>
<td>Unlikely food regulators would pass nicotine products as reaching food standards.</td>
</tr>
<tr>
<td>Light touch regulation (e.g. by DH)</td>
<td>Already regulates tobacco. Enables DH to take the strategic lead to encourage the development and promotion of such products.</td>
<td>Potential lack of capacity in DH to take on such a role.</td>
</tr>
<tr>
<td>Retain current situation (no regulation)</td>
<td>Change might be quicker. No regulatory costs to meet. Possible to promote such products.</td>
<td>Lack of clarity about regulatory position. Lack of control and monitoring. To date, this approach has not encouraged well funded new entrants to the market.</td>
</tr>
</tbody>
</table>
Much has changed since then

Growth in use of electronic cigarettes in Britain

• E-cigarettes first introduced in UK 2007 initially growth very slow
• Many thought just a fad – not mentioned in BSK or RCP 2007 report on tobacco harm reduction
• ASH started researching use in 2010, qual and quant
• Use increased from 700k in 2012 to 1.3 million in 2013 to 2.1 million in 2014
• Tobacco industry has moved in
• Pharmaceutical industry has not
Rapid growth of e-cigs

E-cigarette use among British smokers, 2010-14

<table>
<thead>
<tr>
<th>Year</th>
<th>Currently use e-cigarettes</th>
<th>Have ever tried e-cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>3%</td>
<td>9%</td>
</tr>
<tr>
<td>2012</td>
<td>7%</td>
<td>22%</td>
</tr>
<tr>
<td>2013</td>
<td>11%</td>
<td>35%</td>
</tr>
<tr>
<td>2014</td>
<td>18%</td>
<td>52%</td>
</tr>
</tbody>
</table>
Sustained use among adults is confined to smokers & ex-smokers

E-cigarette use in Britain, 2014
(All adults)

- Smoker: 44%
- Ex-smoker: 81%
- Never smoker: 87%

- I have tried e-cigarettes and still use them: 18%
- I have tried e-cigarettes but do not use them (anymore): 34%
- I have heard of e-cigarettes but have never tried them: 7%
- I have never heard of e-cigarettes and have never tried them: 1%
Most users motivated by quitting or preventing relapse.

**All adults who reported using an electronic cigarette 2014**

- To help me stop smoking tobacco entirely
- Because I had made an attempt to quit smoking already and I wanted an aid to help me keep off...
- To help me reduce the amount of tobacco I smoke, but not stop completely
- To save money compared with smoking tobacco
- Because I felt I was addicted to smoking tobacco and could not stop using it even though I wanted to
- Other
- Because I want to continue to smoke tobacco and I needed something to help deal with situations where...
- To avoid putting those around me at risk due to second-hand tobacco smoke
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)

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>Don’t know/ Wouldn’t say</th>
<th>I have never used them</th>
<th>I have tried them once or twice</th>
<th>I use them sometimes (more than once a month)</th>
<th>I use them often (more than once a week)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never smoked</td>
<td>0%</td>
<td>4%</td>
<td>8%</td>
<td>18%</td>
<td>37%</td>
</tr>
<tr>
<td>Tried smoking once</td>
<td>99%</td>
<td>8%</td>
<td>7%</td>
<td>18%</td>
<td>37%</td>
</tr>
<tr>
<td>Used to smoke</td>
<td>92%</td>
<td>7%</td>
<td>18%</td>
<td>37%</td>
<td>48%</td>
</tr>
<tr>
<td>Smoke &lt;1 week</td>
<td>82%</td>
<td>7%</td>
<td>18%</td>
<td>37%</td>
<td>48%</td>
</tr>
<tr>
<td>Smoke 1-6 week</td>
<td>74%</td>
<td>6%</td>
<td>37%</td>
<td>48%</td>
<td>6%</td>
</tr>
<tr>
<td>Smoke 6+ week</td>
<td>59%</td>
<td>5%</td>
<td>48%</td>
<td>6%</td>
<td>7%</td>
</tr>
</tbody>
</table>

N=1042
N=177
N=64
N=65
N=22
N=53
Adult and youth smoking in England

E-cig marketing starts taking off

![Graph showing the percentage of adult smokers in England and regular smokers in England aged 15 from 1998 to 2012. The percentage of adult smokers shows a downward trend, while the percentage of regular smokers in England aged 15 shows a significant decrease after 2007.](image-url)
Conclusions

• Massive increase in electronic cigarette use
• No evidence of regular use by never smokers or children so far

BUT:
• Around 1 in 3 of those who try them carry on using
• Around 1 in 3 users have quit smoking completely
• 2 out of 3 carry on smoking too

PLUS:
• Rapid growth of marketing causing concern
• Just because not yet a gateway doesn’t mean it won’t be

SO:
• Not a magic bullet
• Concerns about potential youth uptake
UK THR position 2010

- Government tobacco strategy supports harm reduction using licenced nicotine products
- Medicines regulator licensed NRT for long-term use as alternative to smoking
- Potentially brings e-cigs within regulatory remit
- So consulted on options
  - Regulate and take off market
  - Regulate and allow time to comply
  - Do nothing
- NICE commissioned to provide guidance
Evolving UK THR position

• 2011 MHRA announce needs more research, but will not take electronic cigarettes off the market
• 2013 MHRA announce will regulate but not take off market until TPD implemented
• 2014 after decision to bring within TPD MHRA still encouraging applications for medicines licensing
• 2 products known to be going through the process
• MHRA public position that wants to support the availability of safe, effective, good quality products for smokers.
Global policy responses

No level playing field

• US will regulate as tobacco product
• Europe twin track approach – from 2016 either consumer product or medicine
• Canada personal consumption legal – sales banned
• LMICs: banned – Brazil, HK, Malaysia, Turkey, UAE… legal – China, India….
• South Korea legal but heavily taxed……
• WHO examining regulatory options
## Future regulatory framework in Europe – twin track

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

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

• Policy should be evidence-based
• Regulatory framework should be consistent; and:
  – Support quitting completely as the best outcome
  – Ensure easy access for smokers
  – Restrict marketing to adult smokers only
  – Prohibit marketing that promotes smoking-like behaviour
  – Facilitate communication of accurate information on relative risks
  – Encourage improvements in quality, safety and efficacy
  – Support innovation
  – Monitor the market and be responsive as it evolves

• The UK should set the standard for effective regulation in Europe and worldwide
Will medicines regulation be beneficial or not?

**FOR**
- Regulation triggers innovation making production more efficient.
- Cost savings overcompensate for compliance/innovation costs of regulation.
- Reassurance of quality and safety to smokers.

**AGAINST**
- Users will be put off if medicines.
- Costs disproportionate.
- Slows down innovation.
- Will reduce diversity.
- Will destroy supply chain.
EUROPEAN STATE OF PLAY

- Twin track approach gives producers and consumers choice about which market they’re in
- UK has made commitment to make medicines regulation work
- UK licences expected soon
- Opt in model so proof will be whether manufacturers opt in or not
- And whether licenced products popular or not
What should regulation achieve?:

Maximum benefit
- Encourage switching
- Support quitting
- Discourage relapse

Minimum risk
- Discourage uptake amongst youth
- Discourage uptake amongst never smokers
Thank you
deborah.arnott@ash.org.uk

• Public Health England

• NICE guidance on tobacco harm reduction
  – Prioritises quitting but supports harm reduction approaches for smokers currently unable or unwilling to quit. http://www.nice.org.uk/PH45

• NCSCT briefing
  – Summarises evidence with helpful advice for stop smoking advisers http://tinyurl.com/ovwcnny

• MHRA regulatory approach http://tinyurl.com/l4h8xom

• ASH briefings and research www.ash.org.uk

• Smoking in England toolkit data http://www.smokinginengland.info/latest-statistics/