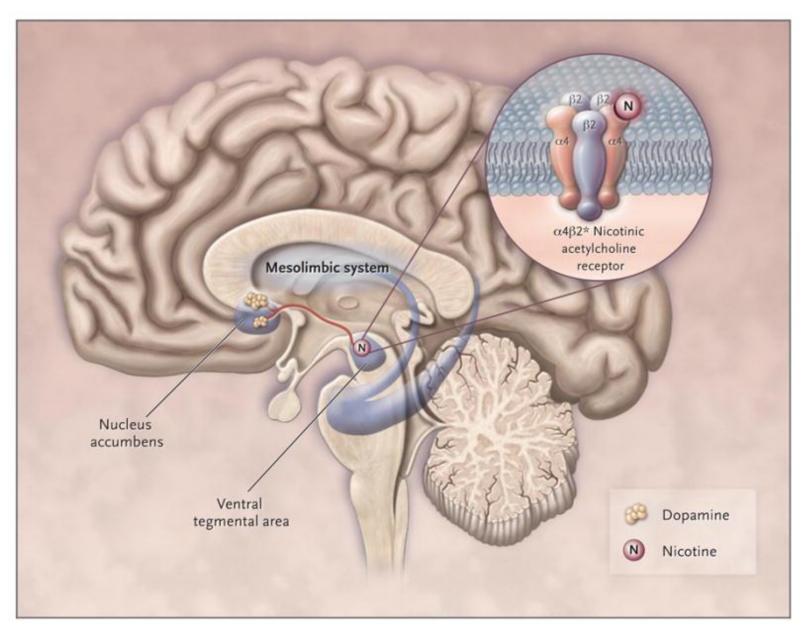
Insights: Nicotine & E-cigarettes Szczecin 13 December 2013

Dr Delon Human

- Context of nicotine use
- What are E-cigarettes?
- Benefits
- Concerns
- Opportunity for a tobacco-free Poland



Nicotine – How can SCIENCE reduce harm?



CULTURAL DRUGS

- ALCOHOL, BEER, WINE, HARD LIQUER
- CAFFEINE, SODA, TEA, COFFEE
- NICOTINE, CLEAN NIC. SMOKEFREE, CIGARETTES

Semi cultural

• THC, marijuana etc

Origins of knowledge on nicotine



Jean Nicot, 1550



Posselt and Reimann, 1828



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Nicotine sources

- •65-85% of nicotine users take it in combustible form (World Bank)
- •Other forms:

NRT (medicine)

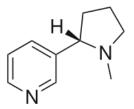
Bidi (India)

Kretek (Indonesia)

Oral tobacco (India, South Asia)

E-cigarettes / "ENDS"

Nicotine effect



- Addiction to tobacco products caused by the drug nicotine
- •Cigarette smokers crave the "HIT" within seconds from inhalation nicotine peak produces dopamine release in brain acute feeling of satisfaction, relief from craving

Nicotine relative to other addictions

- Drugs: 13-15 Million Intravenous Drug Users
- •Alcohol: 2,5 Million deaths per year, World's 3rd largest risk factor for disease burden
- Tobacco: 1,3 Billion Users, kills up to half of its users

Size of the Problem (Smoking): World Health Organisation statements

- Approximately 1,4 billion smokers on earth
- Up to half of current users will eventually die of a tobacco-related disease.

Tobacco caused 100 million deaths in the 20th century.
 If current trends continue, it may cause about one

billion deaths in the 21st century

Essence of Public Health Science

- Preventing disease
- Preventing premature death
- Promoting health

Through the organized efforts and informed choices of society, organizations in both public and private sectors

- Preventive rather than Curative
- Population-based rather than Individuals

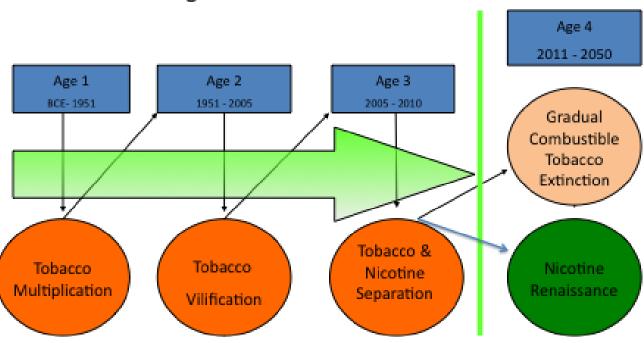
BUT

"All tobacco kills" "No safe form of tobacco"

- Are tobacco and nicotine the same?
- Scientifically accurate?
- Will risk-based differentiation of ingredients, products and harm be helpful for sound regulation?

Tobacco & Nicotine Evolution

The Ages of Tobacco and Nicotine



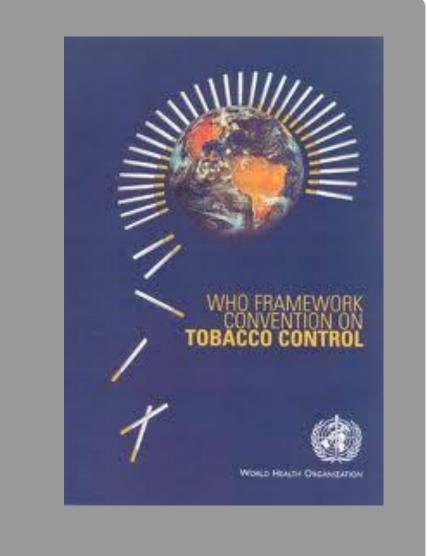
Evidence-based Risk Differentiation + Improved Health Communication

WHO

- 25% Reduction in Preventable Deaths of NCDs by 2025
- 30% Reduction in Smoking Prevalence

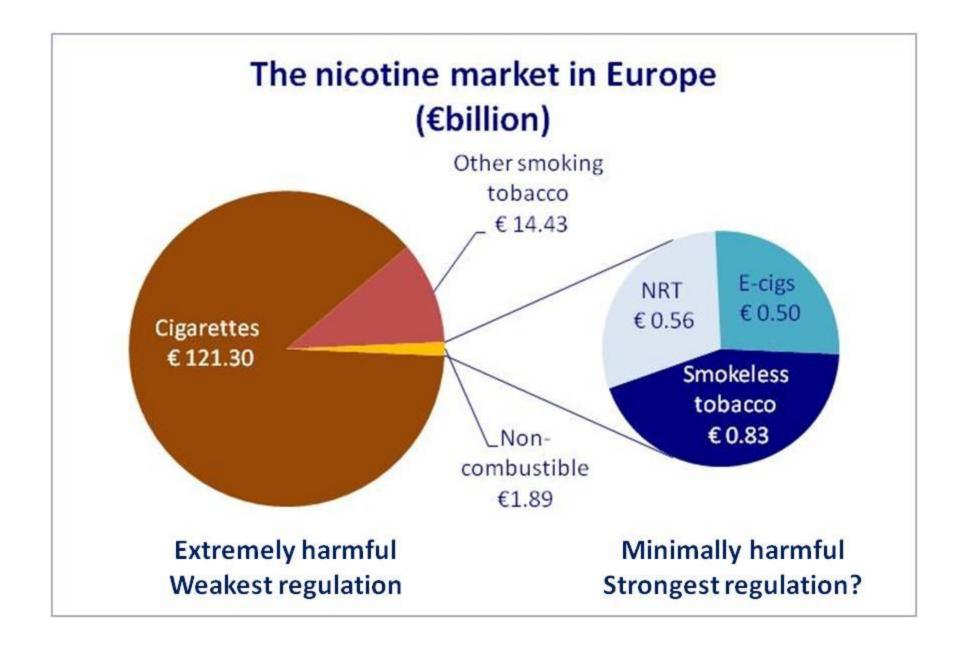
HOW?

- Monitor tobacco use & prevention policies
- Protect from tobacco smoke
- Offer help to quit
- Warn about dangers of tobacco
- Enforce bans on advertising, promotion, & sponsorship
- Raise taxes



Public Health End-Game for Cigarettes

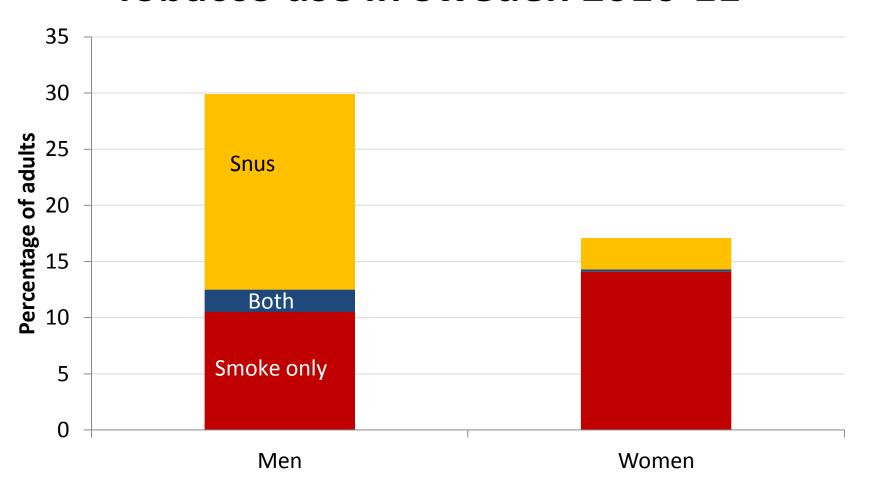
- 75+ % tax
- Ban on all advertising
- Smoke Free Public Spaces
- Commodotized, Plain Packaging
- No Retail Displays
- Mandatory Lowering of « Priority Toxicants »
- No Taste Differentiation
 - * Priority toxicants
 - * Flavoring



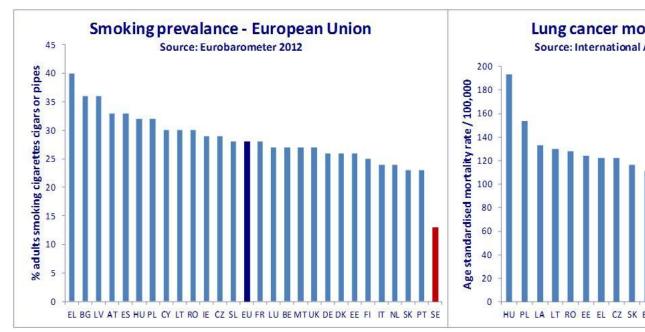
Source: Matrix for the European Commission

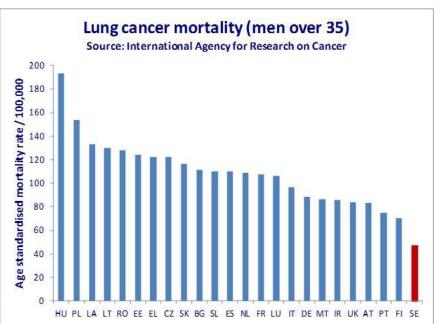
Snus – proof of concept

Tobacco use in Sweden 2010-11

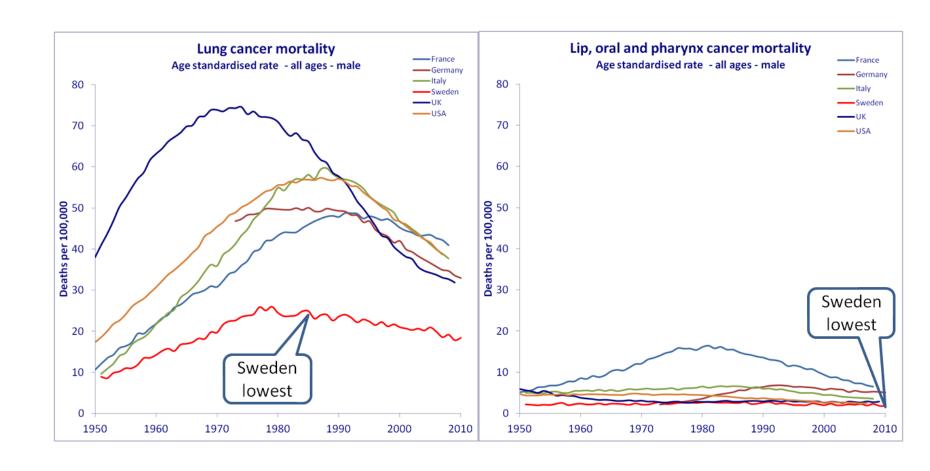


Swedish Exception

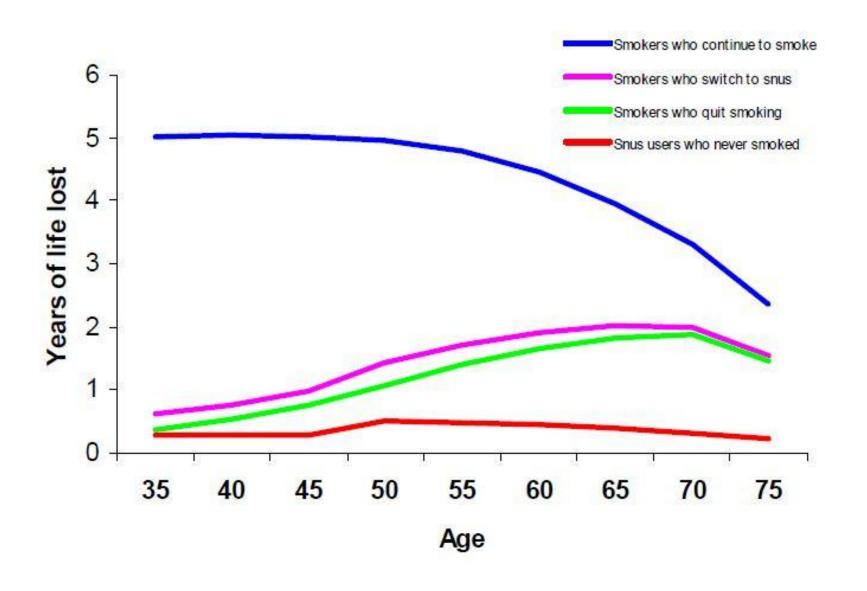




Cancer Mortality Rates in the EU



Smokeless tobacco almost the same as quitting



EU Policy Context (TPD)

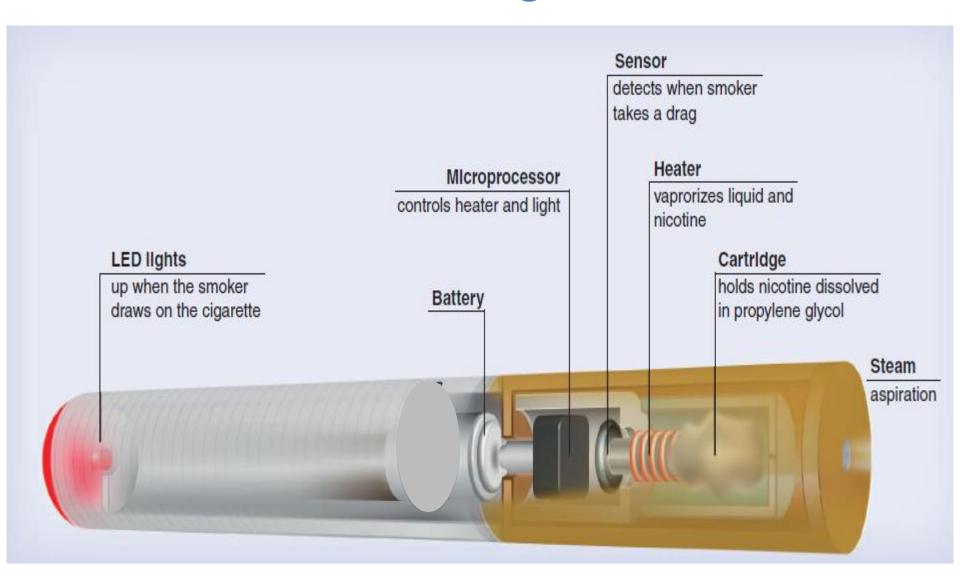
Snus - banned

E-cigs – to be classified as medicines & over-regulated?

Novel tobacco products – authorisation procedure

Combustibles – (FCTC) packaging, flavourings, additives

What is an e-cigarette?



Types of e-cigarettes

- E-cigarettes can come in various forms:
 - 1. Disposables (e.g. Vype disposable)
 - Rechargeable (e.g Vype Reload)
 - Modular (eGo products with tanks that can be filled/refilled with e-liquids from vials/bottles)
- The products are evolving rapidly with a range of flavours for e-liquids, varying battery power options, customisation of device for aesthetic and performance, accessorisation...

Forms of e-cigarettes







Common to all e-cigarettes

- An e-liquid formulation usually containing a mixture of nicotine, glycerol, propylene glycol, water and flavours
- Offer comfort to smokers due to the close proximity to the hand-to-mouth ritual
- Generate a 'vapour' on puffing, mimicking the sensation of smoking in the throat and often giving a nicotine hit

Why are e-cigarettes reduced risk?

- Do not contain tobacco
- Do not involve combustion of tobacco that leads to the formation of thousands of toxicants and carcinogens in cigarette smoke
- Nicotine is simply delivered in an aerosol of inert glycerol

How are smokers responding globally?

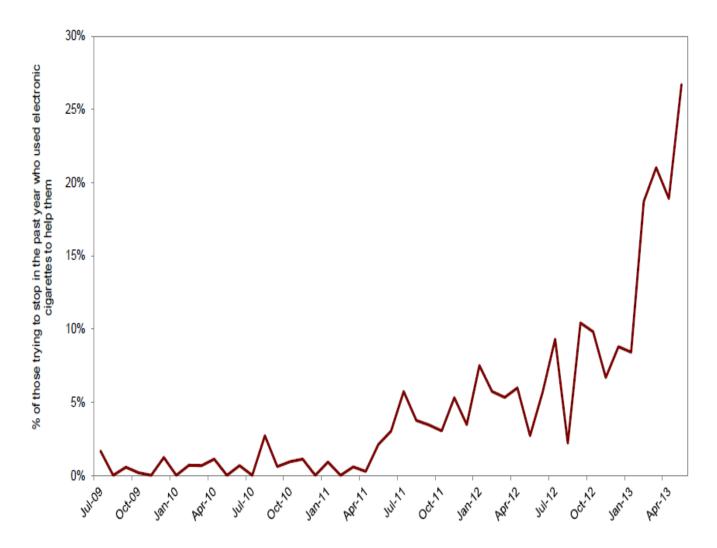
- Data from an ASH-UK survey shows that e-cigarettes' usage among smokers went up from 2.7% in 2010 to 11% in 2012.
 There are an estimated 700,000 e-cig users in the UK alone*.
- Data from the USA shows that e-cigarette usage prevalence in the population went up from 0.6% in 2009 to 6.2% in 2011 **.
- E-cigarette usage is primarily limited to smokers, as evidenced by numerous representative surveys in the UK, USA, Australia, New Zealand, Poland, Czech and Switzerland***

^{*} Dockrell, ASH UK, 2013

^{**} Regan Tobacco Control 2011, , McMillen Journal of Env and Pub Health 2012

^{***} Cho J Adol Health (2011), Choi Am J Public Health (2013), Corey MMWR (2013), Dockrell Nic Tob Res (2013), Douptcheva J Epidemio Comm H (2013), Goniewicz Pediatrics (2012), King Nicotine Tob Res (2013), McMillen J Environ Public H (2012), Pearson Am J Public health (2012), Regan Tob Control (2011), Sutfin Drug Alc Depend (2013)

% of those trying to quit who used e-cigs to help them quit

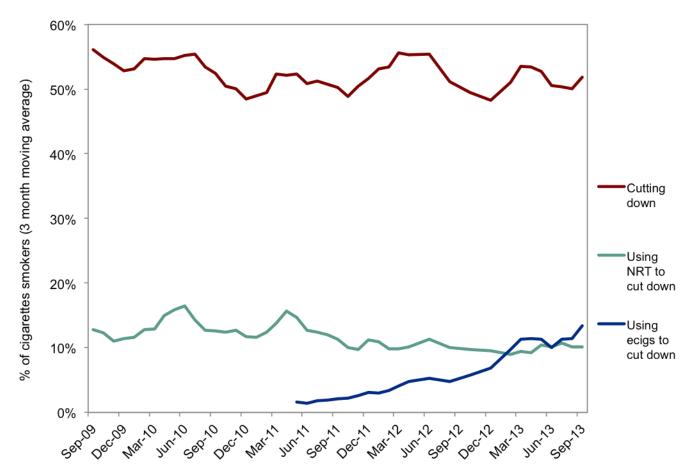


Source: Smoking Toolkit Study, R. West, University College London. Sept 2013 http://www.smokinginengland.info/latest-statistics/ NRT: medicinal Nicotine Replacement Therapy products such as nicotine gums, patches, inhalator

Population level e-cigarette usage may contribute to tobacco harm reduction because..

- Nicotine needs/cravings of smokers met, without the accompanying smoke
- Offer an acceptable alternative to smokers to reduce smoking or completely switch

E-cigarettes' use among smokers already replacing NRT in the UK as a means of achieving harm reduction



Source: Smoking Toolkit Study, R. West, University College London. Sept 2013 http://www.smokinginengland.info/latest-statistics/ NRT: medicinal Nicotine Replacement Therapy products such as nicotine gums, patches, inhalator

Win-win-win: Public Health

- Preventing disease
- Preventing premature death
- Promoting health

Public Health Support

- Tobacco Harm Reduction with e-cigarettes ideologically clashes with a 'denormalisation' and 'quit or die' approach of tobacco control
- But growing recognition among key thought leaders in countries with stagnating smoking prevalence for the need to liberalise nicotine regulation to incentivise consumer friendly 'clean nicotine' products

Professor John Britton, Chair of the Tobacco Advisory Group, Royal College of Physicians, UK, 2013: "If all the smokers in Britain stopped smoking cigarettes and started smoking e-cigarettes we would save 5 million deaths in people who are alive today. It's a massive potential public health prize."

Public Health Support.. continued

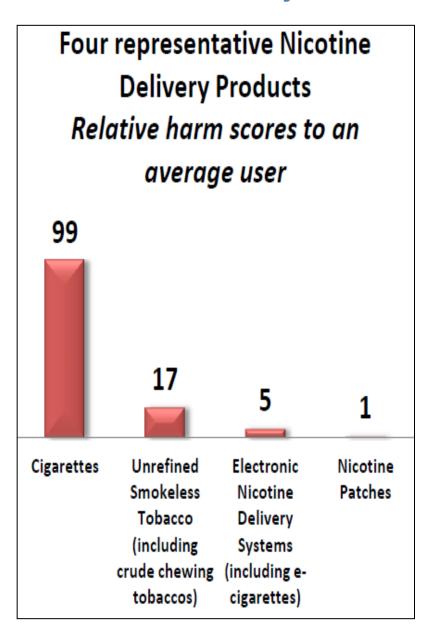
Professor Robert West, smoking cessation expert, University College London, UK: "If those young people are people who would have smoked but instead they're using e-cigarettes, then that's a huge public health gain. If they're people who would never have smoked but they've taken up e-cigarettes, frankly in public health terms it's not really an issue – it's like drinking coffee or something, there's no real risk associated with it. BBC, 6th July 2013. http://www.bbc.co.uk/news/magazine-23196369

Professor David Sweanor- Tobacco Control expert: "..disease risk can be massively reduced through use of a different delivery system. The very rapidly growing global demand for electronic cigarettes (e-cigarettes) reinforces this message with what appears to be a far more acceptable product for many smokers, and even the presence of long-term users of nicotine replacement therapy (who use the products for well over a decade), shows the viability of vastly less hazardous alternatives to obtaining nicotine via smoking cigarettes." South African Medical Journal, November 2013. http://www.samj.org.za/index.php/samj/article/view/7513/5471

Public Health Concerns

- Relative safety
- Gateway to smoking
- Dual Use
- Normalisation of smoking "cigalikes"
- Addiction
- Second-hand vapour exposure
- Quality
- Decrease in tobacco cessation

Relative Safety- multi-criteria decision analysis



- Prof David Nutt et al, used a multi-criteria decision analysis method with a panel of experts who considered 12 representative nicotine delivering products based on 14 sorts of harms- 7 types of harms to the user (product related – death) and 7 types of harms to others (economic cost).
- The graph shows the relative harmfulness of four products.
- Reference: http://nicotinepolicy.net/documents/inthe
 http://nicotinepolicy.net/documents/inthe
 news/2013-08/ISCD-Nicotine-MCDA-Briefing-August-2013.pdf

Gateway

Concern: Unregulated mass availability of e-cigarettes may act as a "gateway" to use of conventional combustible cigarettes, especially among adolescents and youth

Evidence against: A survey conducted and published by ASH-UK shows that-

"Among children regular use of e-cigarettes is extremely rare. Children who had heard of e-cigarettes were asked about their use and knowledge of them. What little use that is reported is confined almost entirely to children who currently smoke or used to smoke.

- 1 in 10 16-18 year olds who had heard of e-cigarettes (1 in 20 among 11-15 year olds) has "tried e-cigarettes once or twice".
- 1 in 100 16-18 year olds (0% 11-15 year olds) uses e-cigarettes more than once a week.
- Among young people who have never smoked 1% have "tried e-cigarettes once or twice", 0% report continued e-cigarette use and 0% expect to try an e-cigarette soon.

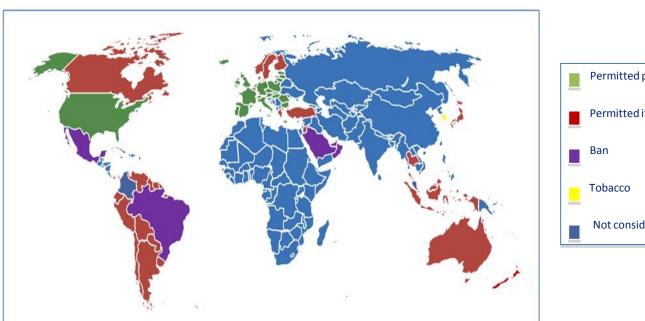
Among adults electronic cigarette current use has grown among smokers and ex-smokers and remains at 0% among those who have never smoked. Ex-smokers report having used e-cigarettes to help a quit attempt (48%) to prevent relapse to tobacco use (32%)." *

^{*} Action on Smoking and Health Fact Sheet, May 2013, based on a survey in the UK among 2178 children aged 11-18. http://ash.org.uk/files/documents/ASH 891.pdf

Global Regulatory landscape

Regulatory pathway unclear

- •Inconsistent regulatory treatment across EU and rest of the world
- •On-going uncertainty how it will evolve *period of unpredictability*
- •Consumer lead growth vs. lack of trust from regulators (safety, efficacy, gateway)
- •Divided opinions within public health community WHO
- •Emerging clarity from UK/US/ EU...
- •NRT clear regulatory pathway but too restrictive in some areas...





Preferred regulatory future

- Product standards: demonstrable safety, quality
- Distribution freedoms: No restrictions limiting it to e.g. Pharmacy/tobacconists
- Responsible Marketing, especially no to kids
- A regulatory process that does not impede innovation
- Appropriate tax
- Youth safeguards: child proofing, advertising to adult smokers only

Challenges to Science

- How best to <u>save lives</u> & PREVENT disease
- Expand <u>nicotine</u> research to support evidence-based policy
- <u>Differentiation</u> of product, risk, consumer and science
- Scientifically accurate, precise health & risk communication
- Harmonization of regulation across EU Member States



Szczecin, 13 December 2013

THANK YOU!!