



# Proposed changes to how e-cigarettes are regulated: UK and EU context

Linda Bauld



UKCTAS

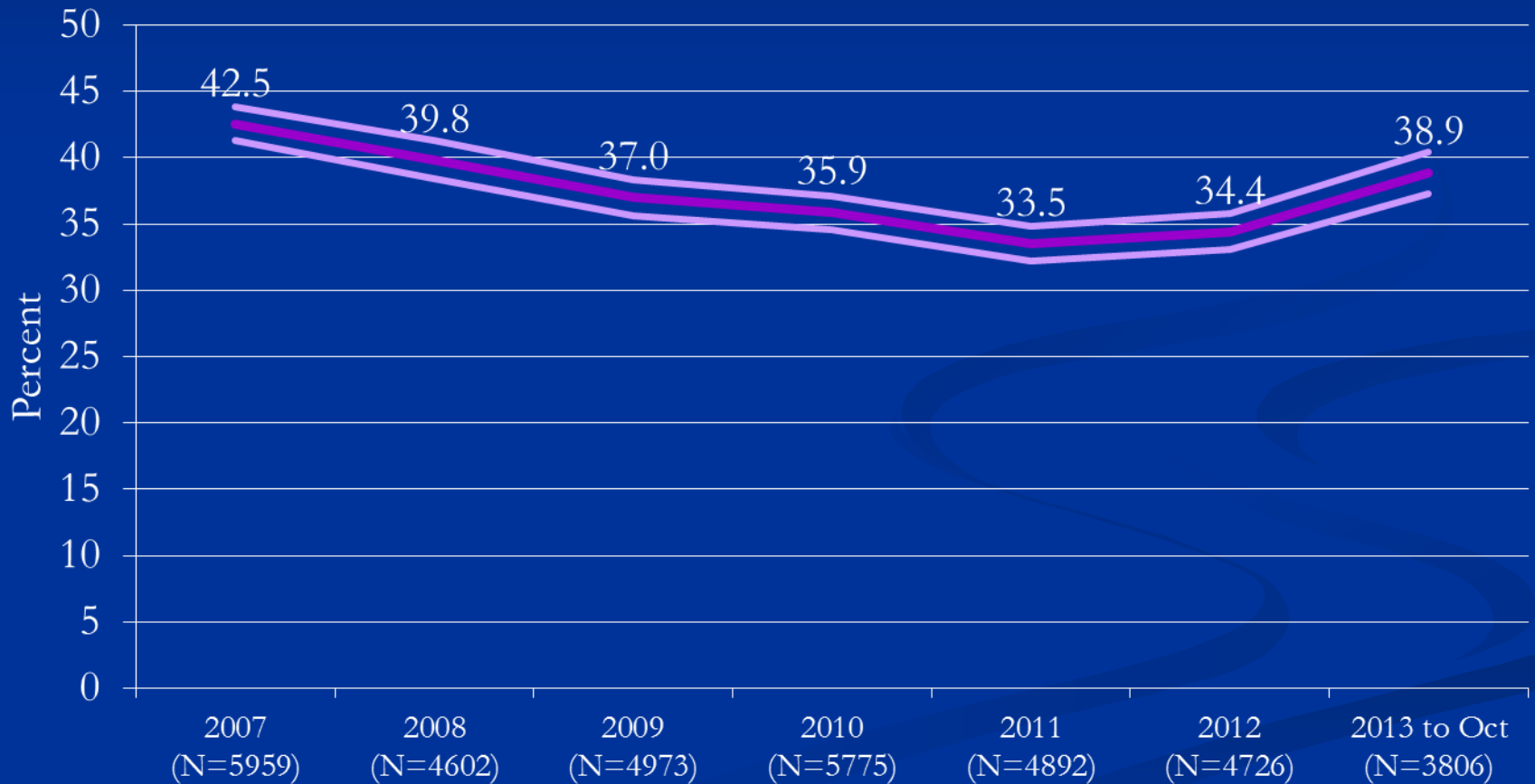
UK Centre for Tobacco & Alcohol Studies

# Outline

- Where do e-cigarettes fit within the wider context of smoking and tobacco policies?
  - Where we are now: cessation and harm reduction
  - Does reducing smoking work?
  - NICE guidance
  - EU Tobacco Product Directive
  - Next steps?

# Where we are now

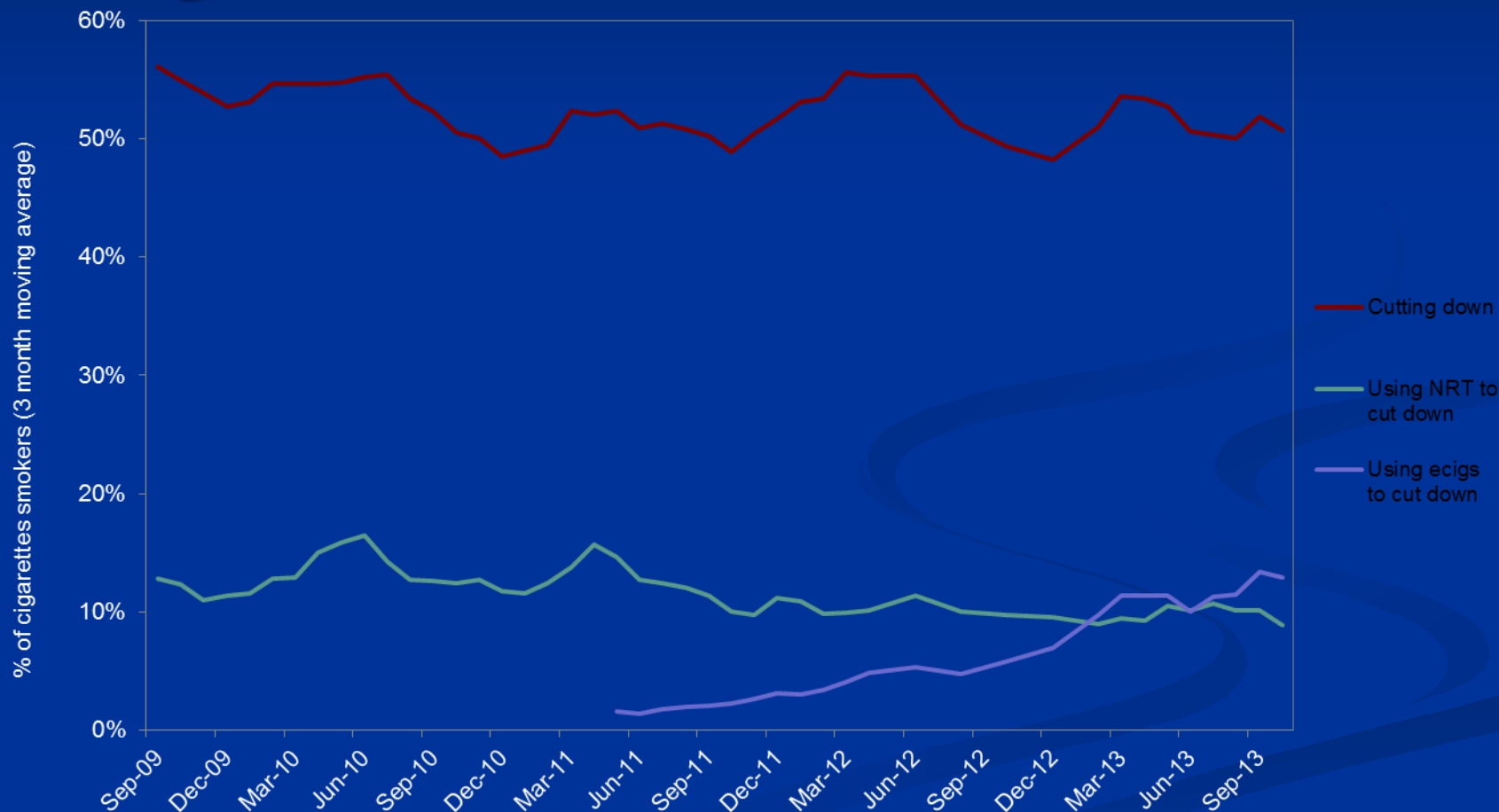
## Quitting behaviour



Source: West, 2013, [www.smokinginengland.info](http://www.smokinginengland.info)

# Where we are now

## Cutting down

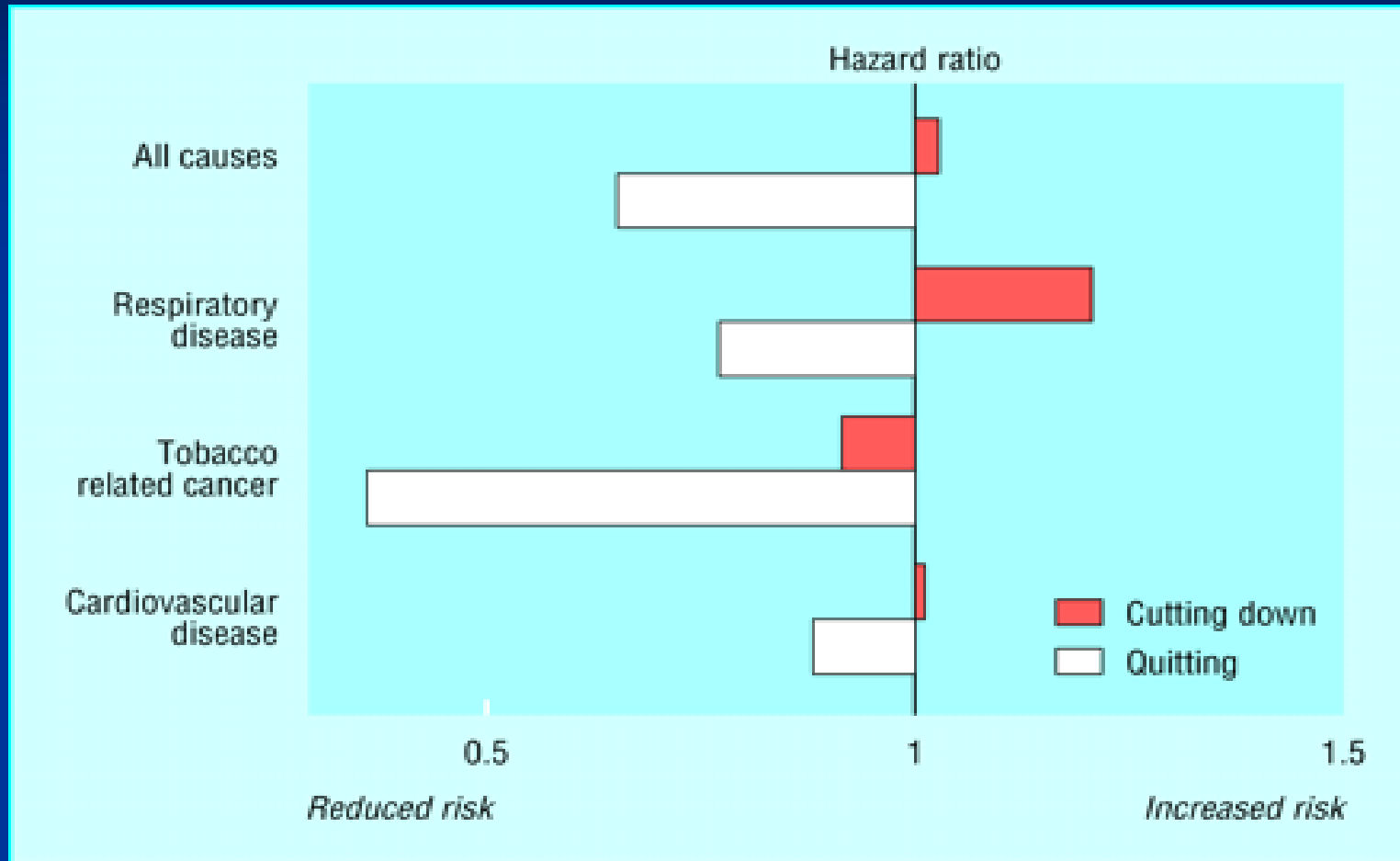


Source: West, 2013, [www.smokinginengland.info](http://www.smokinginengland.info)

# Harm reduction

- The benefits of smoking cessation are well-established
- The benefits of smoking reduction or temporary abstinence are unclear
- This is important for e-cigarette users, as research and surveys to date suggests that many continue to smoke and use e-cigarettes as a harm reduction tool.

# Cutting down alone



A number of studies have found little or no health benefits to cutting down

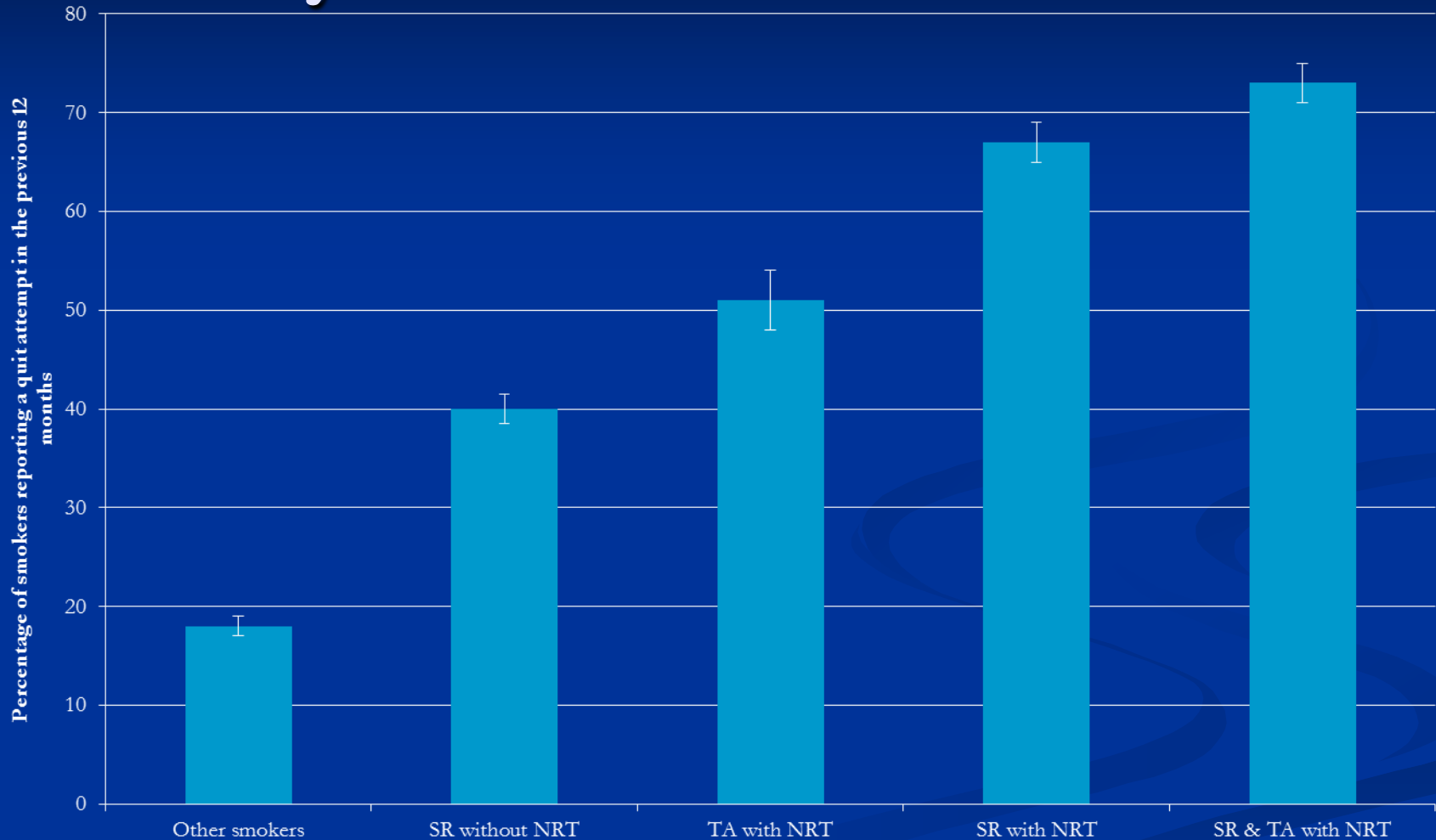
# Renfrew and Paisley study: Hazard ratios of all-cause mortality

	Collaborative	Renfrew & Paisley
Increased	1.15 (0.97 – 1.35)	1.17 (1.04 – 1.32)
Maintained	1	1
Reduced	0.91 (0.75 – 1.10)	1.08 (0.97 – 1.20)
Quit	0.66 (0.56 – 0.78)	0.75 (0.67 – 0.84)

Adjusted for age, sex, social class, cigarettes, cholesterol, systolic blood pressure, body mass index, diabetes, pre-existing CHD

Source: Hart, Bauld and Gruer, AJE, 2013.

# But... cutting down may have benefits with NRT



Source: Beard, E., & West, R. (2012) Use of nicotine replacement therapy for smoking reduction and temporary abstinence: an update to Beard et al. *Addiction*, 107, 1185-1187.



## Tobacco - harm reduction: draft guidance consultation

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NICE is developing public health guidance on Tobacco: harm reduction approaches to smoking.

All registered stakeholders for the above public health guidance are invited to comment on the provisional recommendations via this website during an 8 week consultation with stakeholders.

Organisations not registered as stakeholders **are not able to comment**. For further information about how your organisation can become a stakeholder, please see the [stakeholder registration page](#).

Please note - the provisional recommendations presented here do not constitute NICE formal guidance on this topic. The recommendations are provisional and may change after consultation.

**This consultation will take place between 24 October and 19 December 2012.**

The draft guidance sets out the provisional recommendations that have been developed.

### Consultation documents

- [Tobacco harm reduction: draft guidance](#)
- [Tobacco harm reduction: stakeholder comments form](#)

# NICE Guidance

- NICE guidance has played an important role in supporting the NHS and others to introduce and deliver evidence-based tobacco control interventions
- This has included guidance for smoking cessation interventions and services, but to date these have been aimed at supporting people to stop smoking in one step.
- Guidance on tobacco harm reduction was developed over two years and published in June 2013.

# Focus of Guidance

- The guidance aims to reduce the illnesses and deaths caused by smoking tobacco among people who smoke and those around them. People who smoke can do this by:
  - stopping smoking
  - cutting down prior to stopping smoking
  - smoking less
  - abstaining from smoking temporarily.

# Licensed Nicotine Products

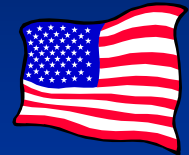
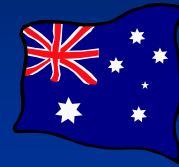
- The harm reduction approaches set out in the guidance can involve substituting the nicotine in tobacco with nicotine from less harmful, nicotine-containing products.
- These include NRT products that are licensed by the MHRA as pharmaceutical treatments for smoking.
- Electronic cigarettes are currently unregulated. *The guidance only recommends use of licensed products recognising that when electronic cigarettes become licensed, they can be recommended for use.*
- Nicotine-containing products might be used either temporarily or indefinitely and as a partial or complete substitute for tobacco

# Nicotine-containing products

The guidance states that:

- There is reason to believe that lifetime use of licensed nicotine-containing products will be considerably less harmful than smoking
- There is little direct evidence on the effectiveness, quality and safety of nicotine-containing products that are not regulated by the MHRA. However, they are expected to be *less harmful than tobacco*.

# Barriers to implementation: Beliefs about nicotine



	Canada	Aust.	U.K.	U.S.
<b>Nicotine causes most cancer</b> (% answering "true")	41%	45%	49%	44%
<b>Nicotine causes most cancer</b> (% answering "true") LOW INCOME	46%	52%	57%	51%
<b>NRT might harm health</b> (% agree strongly + somewhat)	37%	33%	25%	33%



Source: Siahpush et al, Tobacco Control 2006;(Suppl III):iii65-70.

# EU Tobacco Control Directive

- Original TPD was adopted in 2001
- The Directive aims to approximate national regulation on the manufacture, presentation and sale of tobacco products
- It covers content (tar, nicotine), labelling, ingredients and descriptors ('light', 'mild' etc)
- Member states can introduce more stringent provisions, it provides a minimum.



# TPD Development

- The current TPD is under review, a process that began in 2009
- A legislative proposal for revision of the TPD was produced earlier this year
- The European Parliament voted to approve a mandate for negotiations to proceed on a revised TPD on October 8<sup>th</sup> of this year
- These negotiations are now underway through a 'trialogue' (parliament, council, commission)



# TPD and electronic cigarettes

- The original legislative proposal relevant to e-cigarettes recommended that those containing nicotine (above a small amount) be regulated as medicines.
- This part of the proposal was **rejected** in the vote on October 8<sup>th</sup>.
- The new tabled amendment recommends general product safety regulation (with some additions), unless the products claim to treat or prevent disease.
- It also recommends age-restricted sales and advertising restrictions

# Next steps

- The European parliament needs to ratify an agreement on a revised TPD, including provisions on e-cigarettes, by its last plenary in **March 2014**.
- It is currently unclear what the outcome will be
- The key debate is between the need to ensure the **efficacy and safety** of products while providing **access**
- In the meantime, within the UK the MHRA's role is key – as Jeremy will explain.

Thank you

[Linda.Bauld@stir.ac.uk](mailto:Linda.Bauld@stir.ac.uk)

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