

# The regulation of Nicotine-Containing Products (NCPs)

12 November 2013

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# Outline



- Regulation of Nicotine Containing Products (NCPs)
- UK Government policy
- EU Tobacco Products Directive



# Regulation of NCPs in the UK



- NRT, licensed medicine since the 1970s,
- Expert Working Group in 2005
- Every strength/form available non-prescription
- Flexible framework rather than fixed criteria
- Objective to enable safe and effective products to meet public health aims





All of these products contain nicotine





**NCPs  
regulated by MHRA**

**These products are  
NOT regulated by MHRA**



**All of these products contain nicotine**



# Developing electronic cigarette market



# Challenge for regulation



- To enable safe and effective products
- Not to ban potentially useful ones
- To listen to stakeholders
- To protect and promote public health



- Growing concerns about safety and quality of products on the UK market
  - Harm reduction approach to smoking
- “..to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them”**





# Outcome of consultation



## Against MHRA regulation

Some importers

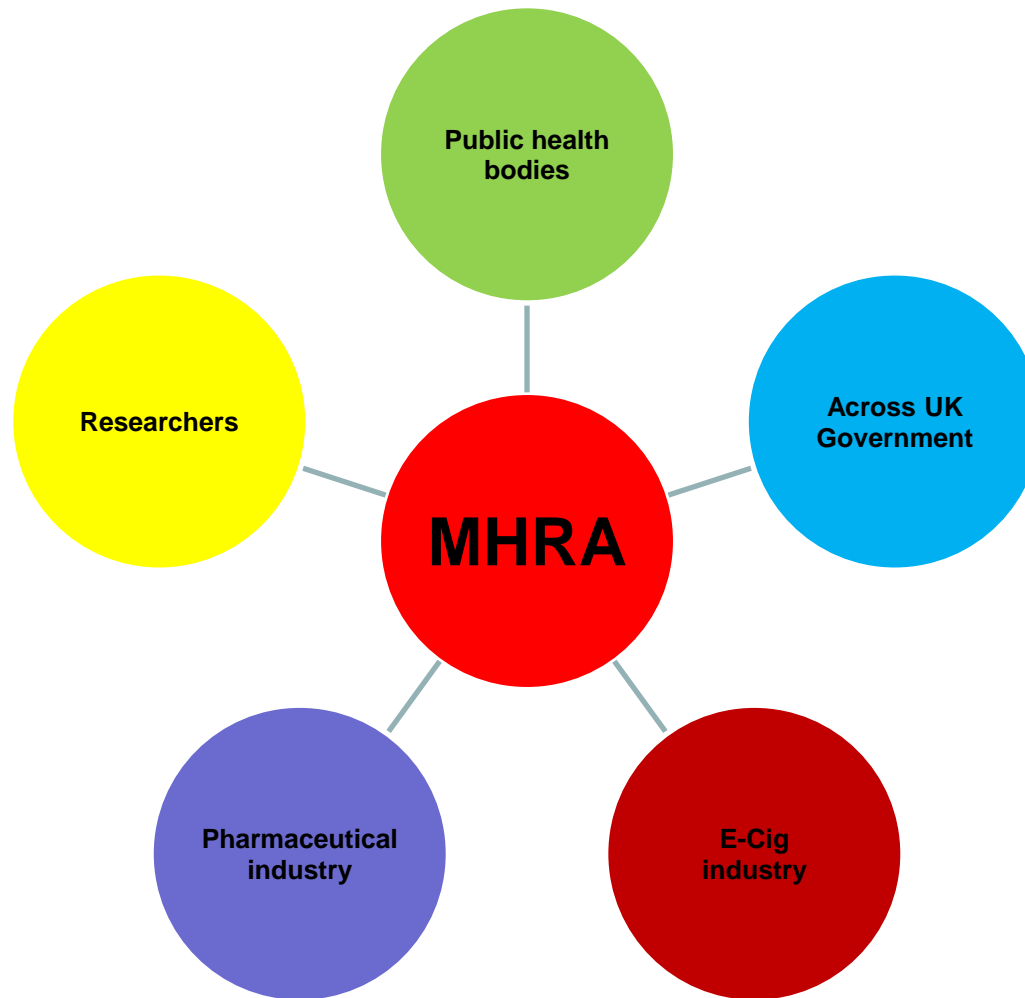
Users of NCPs

## For MHRA regulation

ASH, Medical professional bodies, NHS, Pharma, tobacco trading standards some importers



# Working with stakeholders



- Investigation of the levels of nicotine
- The nature, quality and safety of unlicensed NCPs
- The actual use of unlicensed NCPs in the marketplace
- The efficacy of unlicensed NCPs in smoking cessation
- The potential impact of bringing NCPs into medicines regulation on public health outcomes



# Summary of main findings

- Variable nicotine levels - labels and batches
- Variable nicotine delivery
- Unlicensed NCPs fail to meet standards of safety, quality and efficacy
- Most NCP used to support stop smoking or harm reduction
- Limited evidence of effectiveness
- GPSD regulation does not serve public health objective





# Medicines regulation

- Proportionate licensing regime
- Labelling and product information
- Sale and Supply
- Advertising controls
- Safety monitoring
- Risk management tools



# OTC medicines market – highly competitive, FMCG



**Canesten® AF**  
**Dual Action Cream**  
Clotrimazole  
Effective dual action treatment for ATHLETE'S FOOT.



**Boots**  
PHARMACEUTICALS  
**Athlete's foot**  
View some of our best products to tackle athlete's foot  
Contains Benzyl Alcohol, Eucalyptus Oil. Always read the label



# OTC branded and own brand products even in small markets





# OTC medicines market





# Safety issues

- Yellow card Vs media reports
- Relative risk:benefit
  - For smokers
  - For never smokers
- Gateway?
- Smoking maintenance?



# European proposals on NCPs

- Part of wider Tobacco Products Directive
- Nicotine threshold approach
- Medicines licence required for some products
- Warnings for others



# EP Position on NCPs

- NCPs medicines by presentation
- For others
  - Some controls like tobacco ones
  - Some controls like medicines ones
- Conflicting provisions
- Does not amount to a regime capable to protecting and promoting public health
- Inflexible and unresponsive requirements
- Fails to “future proof”



# UK Government position



- Medicines framework for NCPs serves public health objectives
- MHRA stands ready to license NCPs now (by presentation)
- Supporting true innovation, diversity, appeal
- Support Europe wide certainty on legal position on NCPs as medicines





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