THE E-CIGARETTE SUMMIT
Science, Regulation & Public Health
The Royal Society ▪ London ▪ November 17th 2017

How Might Medicinal Regulators Evolve in their Expectations for ENDS?

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Chief Impact Officer - NJOY


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4 Years Ago

THE *E*-CIGARETTE SUMMIT

Science, Regulation & Public Health

The Royal Society, London, November 12th 2013

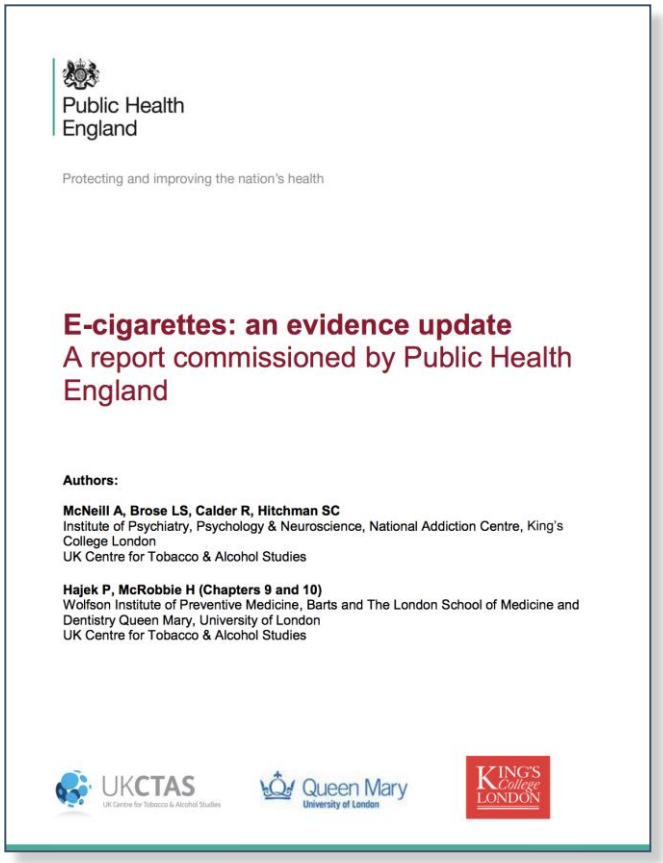
The Regulation of Nicotine-Containing Products
– Jeremy Mean

Medicines regulation

MHRA

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

2015


Public Health England

Protecting and improving the nation's health

E-cigarettes: an evidence update
A report commissioned by Public Health England

Authors:

McNeill A, Brose LS, Calder R, Hitchman SC
Institute of Psychiatry, Psychology & Neuroscience, National Addiction Centre, King's College London
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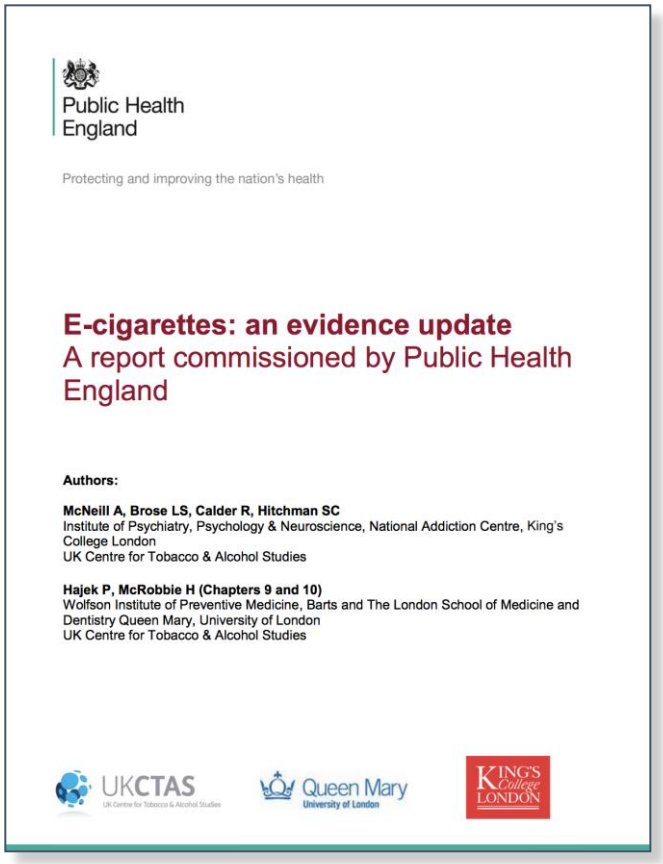
Hajek P, McRobbie H (Chapters 9 and 10)
Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry Queen Mary, University of London
UK Centre for Tobacco & Alcohol Studies

UKCTAS UK Centre for Tobacco & Alcohol Studies
Queen Mary University of London
King's College London

"The fact that no licensed EC are yet on the market suggests that the licensing route to market is not commercially attractive. The absence of non-tobacco industry products going through the MHRA licensing process suggests that the process is inadvertently favouring larger manufacturers including the tobacco industry, which is likely to inhibit innovation in the prescription market."


WALLED GARDEN

2015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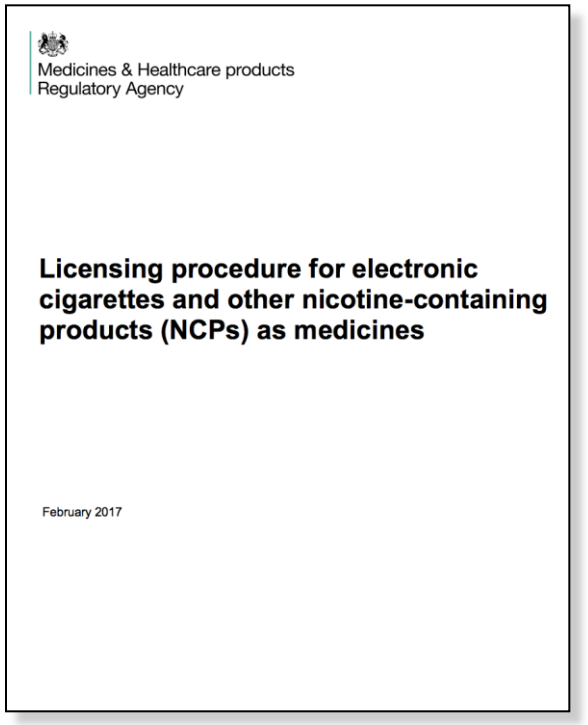
"Much of England's strategy of tobacco harm reduction is predicated on the availability of medicinally licensed products that smokers want to use. Licensed ECs are yet to appear. A review of the MHRA EC licensing process therefore seems appropriate, including manufacturers' costs, and potential impact. This could include a requirement for MHRA to adapt the processes and their costs to enable smaller manufacturers to apply, and to speed up the licensing process."

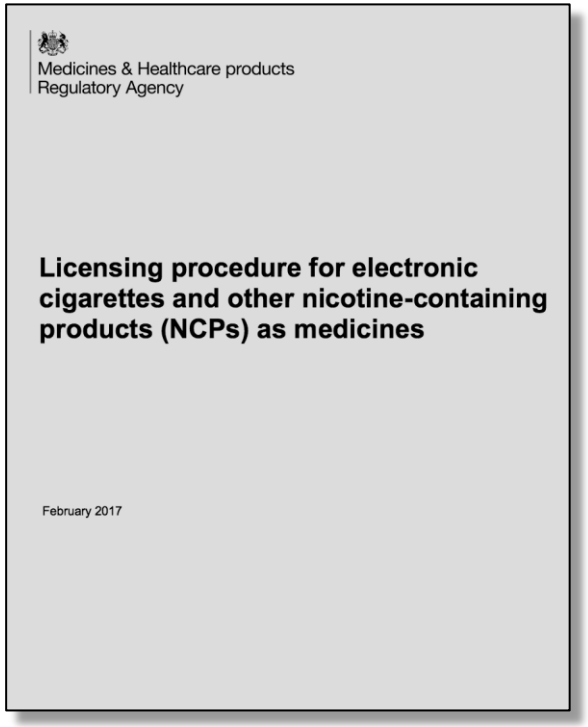
MHRA Guidance -Feb 2017

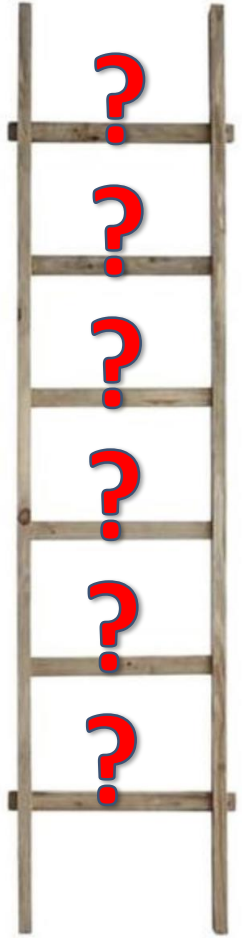


The findings of the ad-hoc expert working group on nicotine containing products, of the Commission on Human Medicines (CHM), recommended a ***proportionate*** *assessment of any future marketing authorisation applications (MAA) regarding electronic cigarettes and other nicotine containing products (NCPs).*

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/595533/Licensing_procedure_for_electronic_cigarettes_and_other_nicotine_contain_products_as_medicines.pdf

Procedure not Proportion…





Pharmacovigilance

- Monitoring of the safety of medicines once they have been authorised and placed on the market
  - also termed 'post-authorisation supervision' or 'post-marketing surveillance’
- Geared towards the prevention, detection and assessment of any adverse reactions to medicines

Guideline on good pharmacovigilance practices Module V – Risk management systems

- A medicinal product is authorised on the basis that in the specified indication(s), at the time of authorisation, **the risk-benefit balance is judged to be positive** for the target population.
- Generally, a medicinal product will be associated with adverse reactions and these will vary in terms of severity, likelihood of occurrence, effect on individual patients and public health impact.
- However, not all adverse reactions and risks will have been identified at the time when an initial marketing authorisation is granted and some will only be discovered and characterised in the post-authorisation phase.

(Rev 2) 28 March 2017 EMA/838713/2011 Rev 2 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129134.pdf

The aim of a risk management plan (RMP) is to document the risk management system considered necessary to identify, characterise and minimise a medicinal product's important risks.

To this end, the RMP contains:

1. the identification or characterisation of the safety profile of the medicinal product, with emphasis on important identified and important potential risks and missing information, and also on which safety concerns need to be managed proactively or further studied (the 'safety specification');
2. the planning of pharmacovigilance activities to characterise and quantify clinically relevant risks, and to identify new adverse reactions (the 'pharmacovigilance plan');
3. the planning and implementation of risk minimisation measures, including the evaluation of the effectiveness of these activities (the 'risk minimisation plan').

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/03/WC500224771.pdf

Breaking New Ground for Nicotine Product Regulation..?

Or has this been done before…?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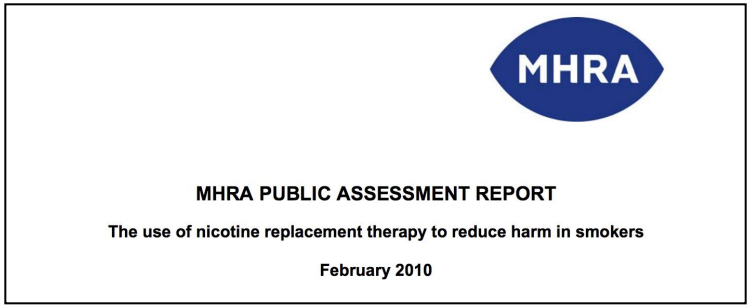
2010

MHRA PUBLIC ASSESSMENT REPORT

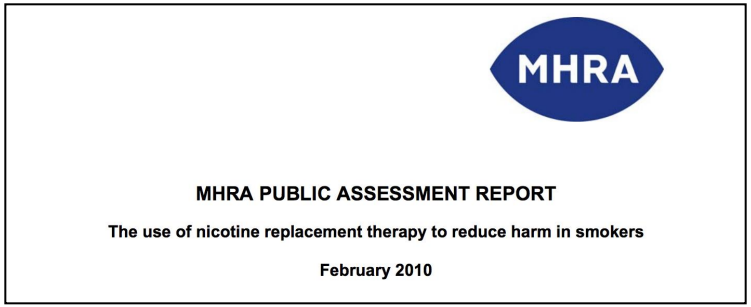
The use of nicotine replacement therapy to reduce harm in smokers

February 2010



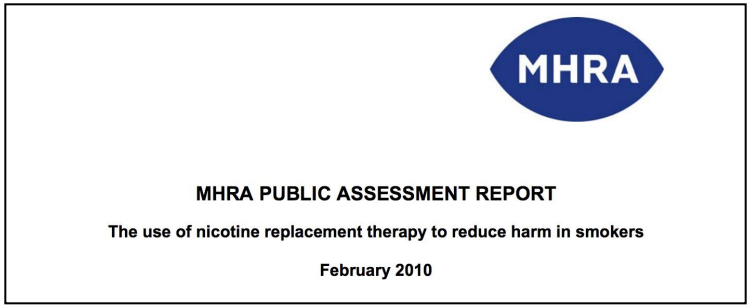
Over several years the MHRA has been in discussion with the Department of Health (DH) and other interested parties to determine and implement actions necessary for the effective regulation of NRT. This evolving approach has focussed on extending access to new patients and supporting wider access to new formulations of NRT.

http://webarchive.nationalarchives.gov.uk/20120511053931/http://www.mhra.gov.uk/PrintPreview/DefaultSP/CON068572



”The MHRA received an application to expand the use of Nicorette Inhalator, an NRT product, to include a ”harm reduction” element”

http://webarchive.nationalarchives.gov.uk/20120511053931/http://www.mhra.gov.uk/PrintPreview/DefaultSP/CON068572



In October 2009, this application was reviewed by a specific CHM Working Group on Harm Reduction & NRT. The working group considered the evidence on the safety and efficacy of a harm-reduction element as part of the indication for the Nicorette inhalator, and also advised whether indications including harm reduction are appropriate for other forms of NRT.

http://webarchive.nationalarchives.gov.uk/20120511053931/http://www.mhra.gov.uk/PrintPreview/DefaultSP/CON068572

Commission on Human Medicines (CHM)
Working Group on Harm Reduction & Nicotine Replacement Therapy
Extract from the minutes of the meeting held on 14th October 2009

5.12 The WG noted that in cases where there was a lack of long term safety data this would be addressed **in a risk management plan**.

5.13 The WG advised that the MA holder should be asked to provide a robust **risk management plan** that would satisfactorily address the outstanding issues including:

- Further investigation of the impact of the harm reduction indication on quit rate at a population level
- Re-assurance on the safety of long-term use – particularly cardiovascular safety in those with underlying cardiovascular disease
- Possible promotion of relapse among quitters by suggesting that low-rate smoking is relatively safe
- Possible increased initiation of smoking by suggesting that smoking can be done in a somewhat safe manner.

http://webarchive.nationalarchives.gov.uk/20120511053931/http://www.mhra.gov.uk/PrintPreview/DefaultSP/CON068572

Commission on Human Medicines (CHM)
Extract from minutes of the meeting held on 15th October 2009

2. It was noted that, since the advice of the Working Group in 2005, it had become widely accepted that **there were no circumstances in which it was safer to smoke than to use NRT**.

8. The Commission advised that there was a need for further research and data collection to assess long term safety and agreed that the MA holder should be asked to provide a **robust risk management plan** that would satisfactorily address the outstanding issues.

http://webarchive.nationalarchives.gov.uk/20120511053931/http://www.mhra.gov.uk/PrintPreview/DefaultSP/CON068572

Extract from MHRA Drug Safety Update Oct 2010

Since the advice of the Working Group in 2005, it has become widely accepted that there are no circumstances in which it is safer to smoke than to use NRT, and following advice from the Commission on Human Medicines (CHM) in October 2009, the MHRA has approved an extension to the indication to include a 'harm reduction' element for a particular product—the Nicorette Inhalator either as a complete or partial substitute for smoking. This now includes its use in those who choose or are forced into temporary abstinence (i.e. who do not wish to expose others to their second-hand smoke or cannot smoke because they are in a smoke-free area), and those who wish to reduce the number of cigarettes smoked without a specific intention to quit completely, without a limit to the duration of use.

http://webarchive.nationalarchives.gov.uk/20120511053931/http://www.mhra.gov.uk/PrintPreview/DefaultSP/CON068572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2016

“We all agree that e-cigarettes are significantly less harmful than smoking”

“There is no circumstance in which it is better for a smoker to continue smoking”

- Public Health England
- Action on Smoking and Health
- Association of Directors of Public Health
- British Lung Foundation
- Cancer Research UK
- Faculty of Public Health
- Fresh North East
- Healthier Futures Public Health Action
- Royal College of Physicians
- Royal Society for Public Health
- UK Centre for Tobacco and Alcohol Studies
- UK Health Forum

July 2016 E-cigarettes: a developing public health consensus Joint statement on e-cigarettes by Public Health England and other UK public health organisations

ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

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RESEARCH REPORT

Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study

Jamie Brown, Emma Beard, Daniel Kotz, Susan Michie, Robert West

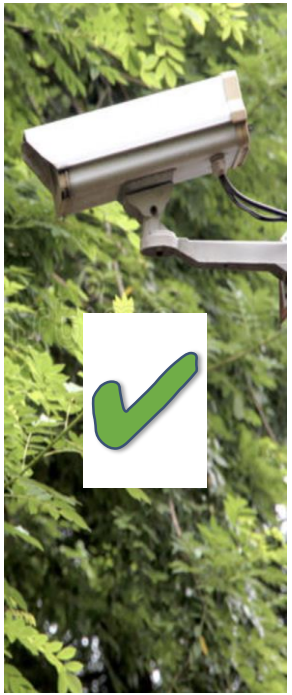
First published: 8 August 2014 Full publication history

DOI: 10.1111/add.12623 View/save citation

Among smokers who have attempted to stop without professional support, **those who use e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product** bought over-the-counter or no aid to cessation.

Enable Innovation

Clearly Proportionate - Accessible - Monitored



In Scope

Corporate Plan Refresh 2016

An update of the Medicines & Healthcare products Regulatory Agency's 2013-18 Corporate Plan

- Theme 1 - Vision, scope and partnerships
- Theme 2 - Enabling innovation
- Theme 3 - Vigilance
- Theme 4 - Secure global supply chains
- Theme 5 – Organisational excellence

Figure 1 The Agency's five strategic themes

Expand the support offered to innovative businesses, especially SMEs, and academia via the Innovation Office and increase awareness of our innovation support work

Enable safe access to innovative products with prospective risk/benefits monitoring

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/519539/Medicines_and_Healthcare_products_Regulatory_Agency_Corporate_Plan_Refresh_2016.pdf

U.S. Food and Drug Administration
Center for Tobacco Products

- ***"the agency plans to examine actions to increase access and use of FDA-approved medicinal nicotine products, and work with sponsors to consider what steps can be taken under the safety and efficacy standard for products intended to help smokers quit."***

Release July 28, 2017

"We also need to consider what we can do - in lieu of helping them quit completely – to encourage addicted smokers to switch to a potentially less harmful product.
Quitting cigarettes is still the preferred outcome.
That's why we're also looking at ways to encourage innovation for therapeutic nicotine products regulated as drugs."

Remarks by Dr. Gottlieb on the Regulation of Nicotine – October 19, 2017