Modified Risk Tobacco Product Applications – A Succinct ENDS Industry Perspective

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Content

- Brief overview of the MRTP regulatory framework for ENDS
- FDA MRTP activity to date
- Commissioner Gottlieb's July 28 continuum of risk statements referencing ENDS
- UK Government statements on ENDS comparative risks
- Conclusions/Questions

MRTP Regulatory Framework

2009 Family Smoking Prevention and Tobacco Control Act:

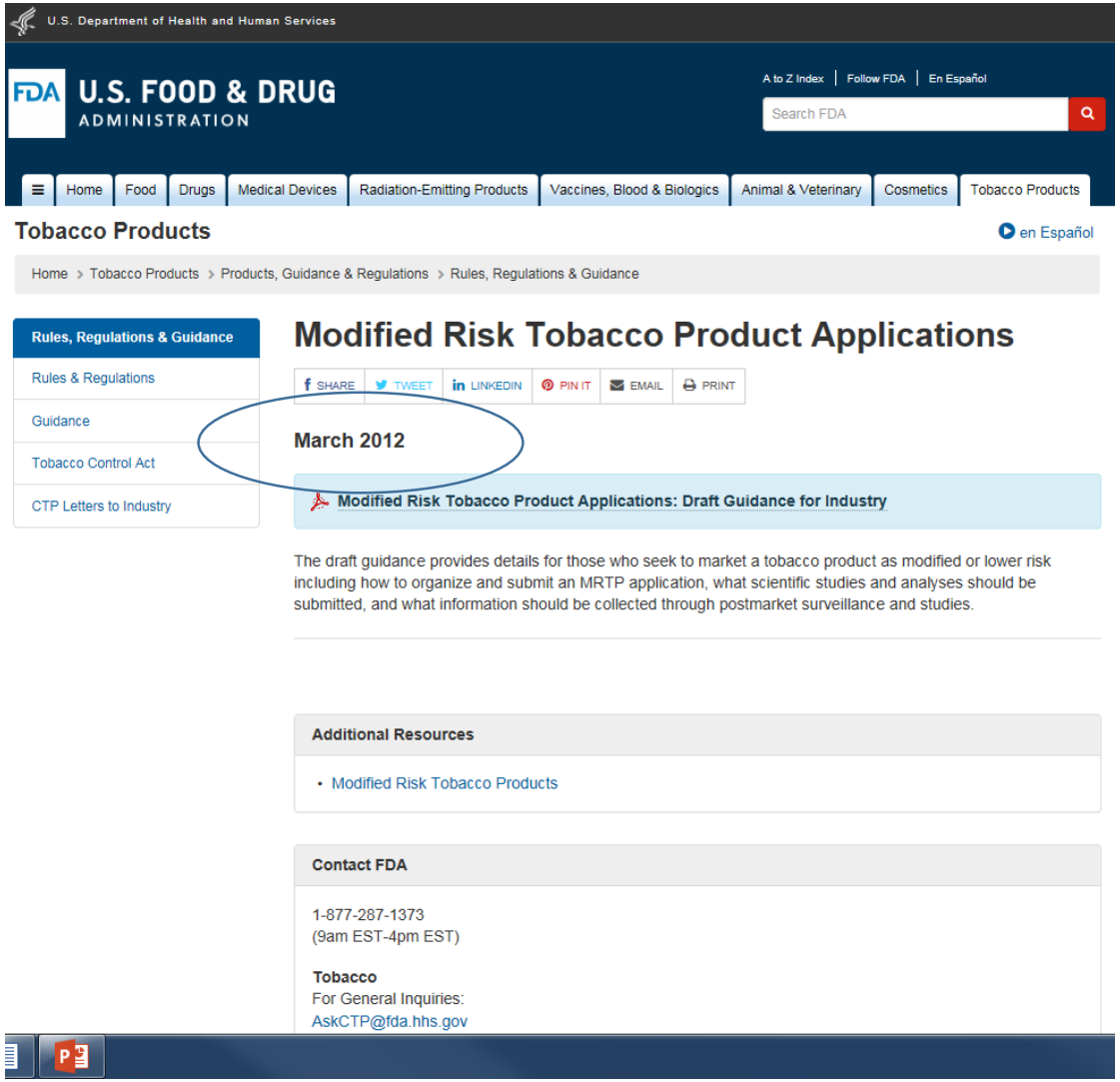
Section 3 – Purpose

- “(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products”

Section 911 – Modified Risk Tobacco Products

March 2012 FDA Draft Guidance

MRTP Regulatory Framework



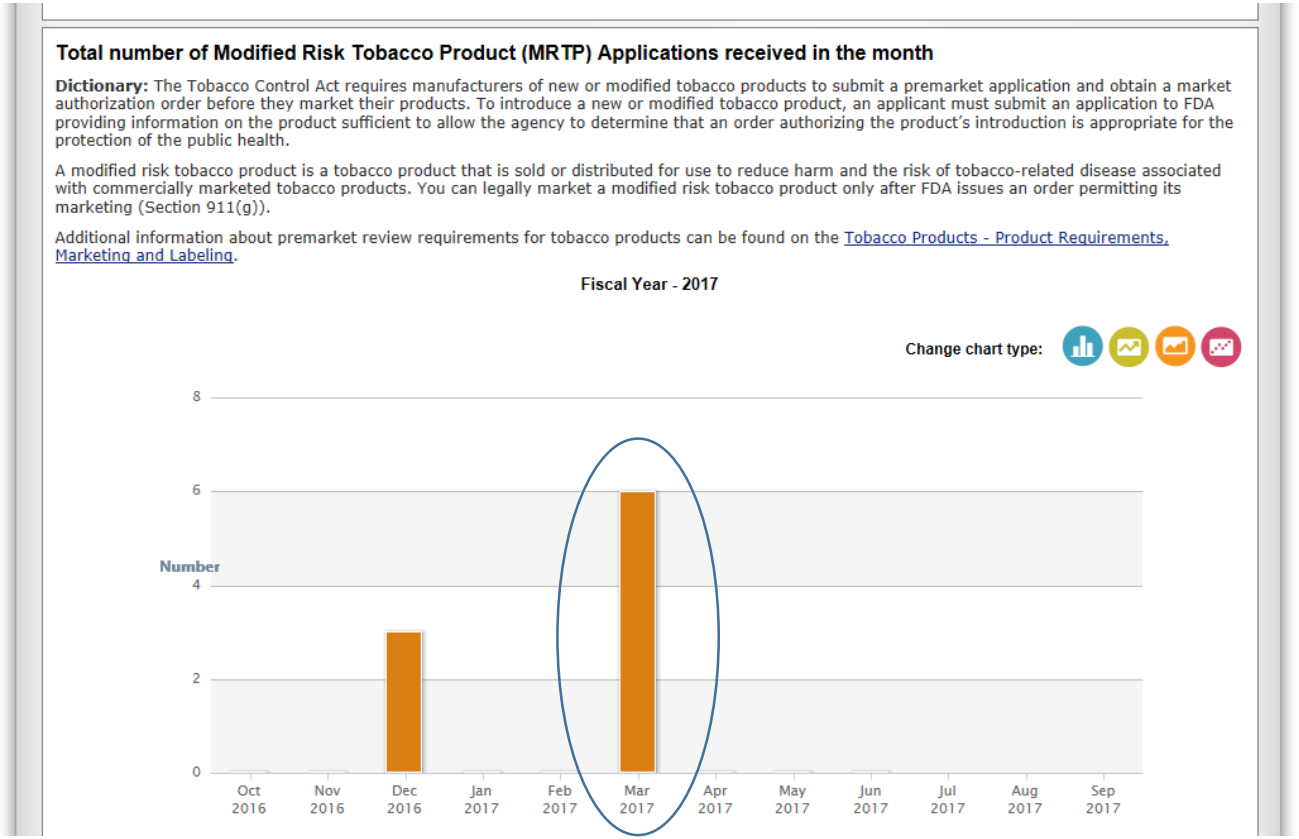
At the time (March 2012) the only regulated tobacco products were:

- Cigarettes
- Cigarette Tobacco
- Roll-your-own
- Smokeless tobacco

The March 2012 MRTP Draft Guidance does not account for certain inherent reduced risk/exposure characteristics of most ENDS products, recently acknowledged by Commissioner Gottlieb in his July 28 speech.

A review of the publicly available information from the comprehensive PMI MRTP application suggests that the elements of that application are relevant to cigarette products, however, not all elements may be relevant to an ENDS modified risk/modified exposure claim.

FDA MRTPA Dashboard



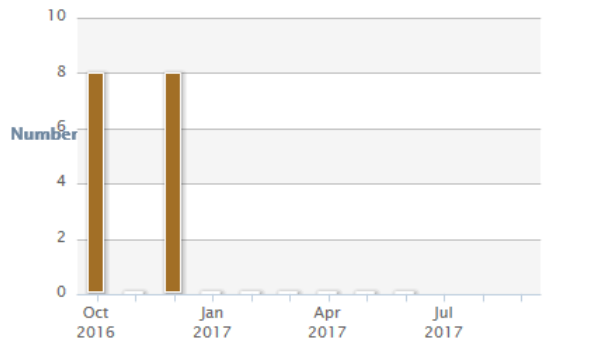
Presumably this number refers to the accept-to-file letter issued to PMI.

FDA MRTPA Dashboard

FDA issued an Order letter, issued a Refuse-to-Accept letter or the application was withdrawn by the applicant.

Fiscal Year - 2017

Change chart type:



Time	Target	Number
Oct 2016	N/A	8
Nov 2016	N/A	0
Dec 2016	N/A	8
Jan 2017	N/A	0
Feb 2017	N/A	0
Mar 2017	N/A	0
Apr 2017	N/A	0
May 2017	N/A	0
Jun 2017	N/A	0
Jul 2017	N/A	TBD
Aug 2017	N/A	TBD
Sep 2017	N/A	TBD

FY 2017 YTD: 16

Presumably these numbers refer to the Swedish Match MRTP.

Commisioner Gottlieb's July 28 Statement

"[…] we must acknowledge that there's a continuum of risk for nicotine delivery. That continuum ranges from **combustible cigarettes at one end**, to medicinal nicotine products at the other."

"And we must recognize the potential for innovation to lead to less harmful products, which, under FDA's oversight, could be part of a solution. While there's still much research to be done on these products and the risks that they may pose, they may also present benefits that **we must consider**. FDA's investment in regulatory science will eventually answer many of those benefit and risk questions. […]'

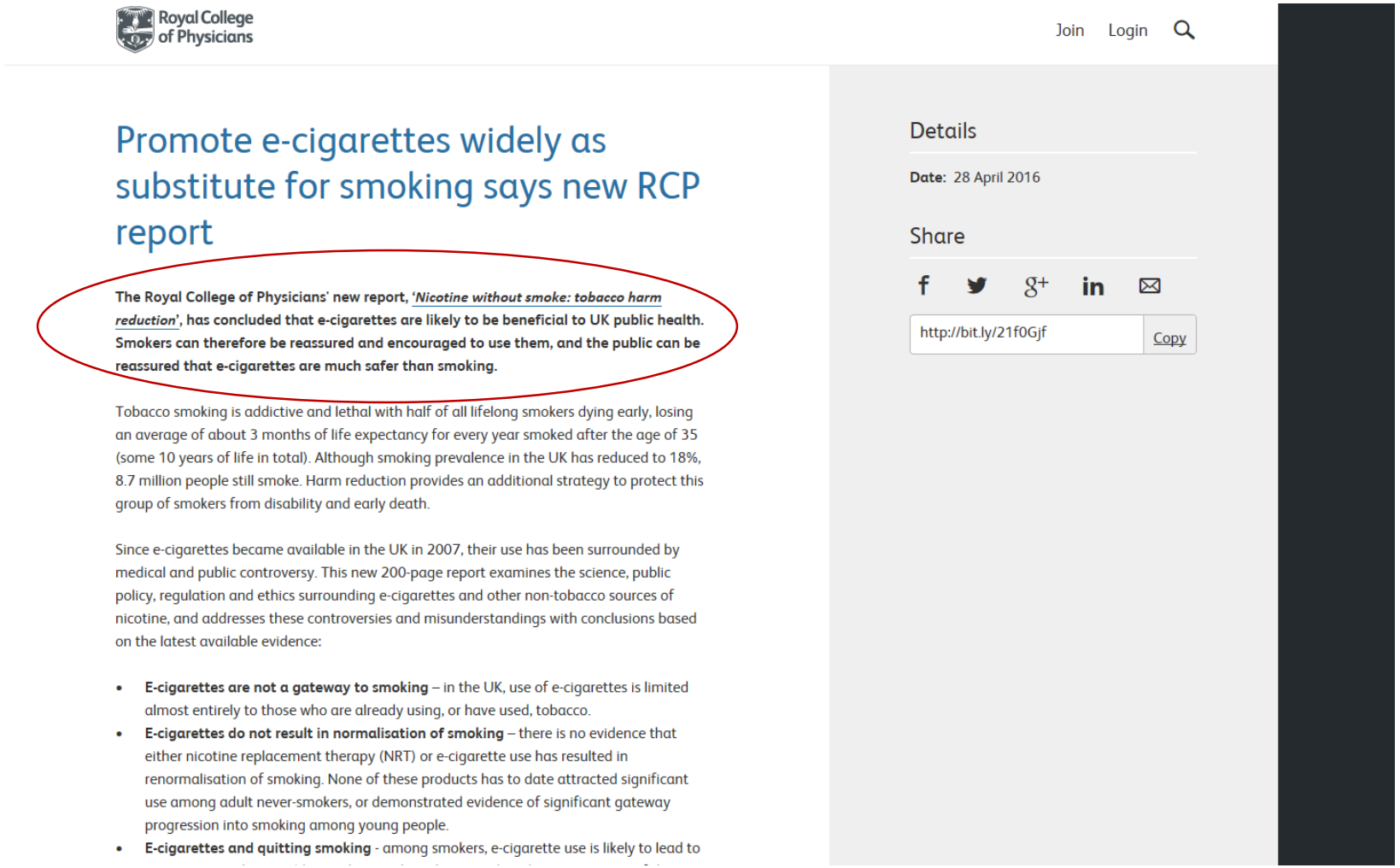
"Among other things, **we will advance rules that will lay out what needs to be in applications for** Substantial Equivalence, **Modified Risk Tobacco Product**, and Pre-Market Tobacco Product applications […]"

Commisioner Gottlieb's July 28 Statement (cont'd)

"As we move forward, **I also hope that we can all see the potential benefits** to addicted cigarette smokers, in a properly regulated marketplace, of **products capable of delivering nicotine without having to set tobacco on fire**. The prospective benefit may be even greater for the subset of current cigarette smokers who find themselves unable or unwilling to quit.

It's incumbent upon us as regulators to explore both the potential public health benefits and the risks of this new technology with an open mind. "

UK Government Statements on ENDS Comparative Risk



Royal College of Physicians

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Promote e-cigarettes widely as substitute for smoking says new RCP report

The Royal College of Physicians' new report, '*Nicotine without smoke: tobacco harm reduction*', has concluded that e-cigarettes are likely to be beneficial to UK public health. Smokers can therefore be reassured and encouraged to use them, and the public can be reassured that e-cigarettes are much safer than smoking.

Tobacco smoking is addictive and lethal with half of all lifelong smokers dying early, losing an average of about 3 months of life expectancy for every year smoked after the age of 35 (some 10 years of life in total). Although smoking prevalence in the UK has reduced to 18%, 8.7 million people still smoke. Harm reduction provides an additional strategy to protect this group of smokers from disability and early death.

Since e-cigarettes became available in the UK in 2007, their use has been surrounded by medical and public controversy. This new 200-page report examines the science, public policy, regulation and ethics surrounding e-cigarettes and other non-tobacco sources of nicotine, and addresses these controversies and misunderstandings with conclusions based on the latest available evidence:

- **E-cigarettes are not a gateway to smoking** – in the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.
- **E-cigarettes do not result in normalisation of smoking** – there is no evidence that either nicotine replacement therapy (NRT) or e-cigarette use has resulted in renormalisation of smoking. None of these products has to date attracted significant use among adult never-smokers, or demonstrated evidence of significant gateway progression into smoking among young people.
- **E-cigarettes and quitting smoking** - among smokers, e-cigarette use is likely to lead to

Details

Date: 28 April 2016

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UK Government Statements on ENDS Comparative Risks

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Research and analysis

E-cigarettes: an evidence update

From: Public Health England
Part of: Electronic cigarettes and Smoking
Published: 19 August 2015
Last updated: 28 August 2015, see all updates

An expert review of the latest evidence concludes that e-cigarettes are around 95% safer than smoked tobacco and they can help smokers to quit.

Documents

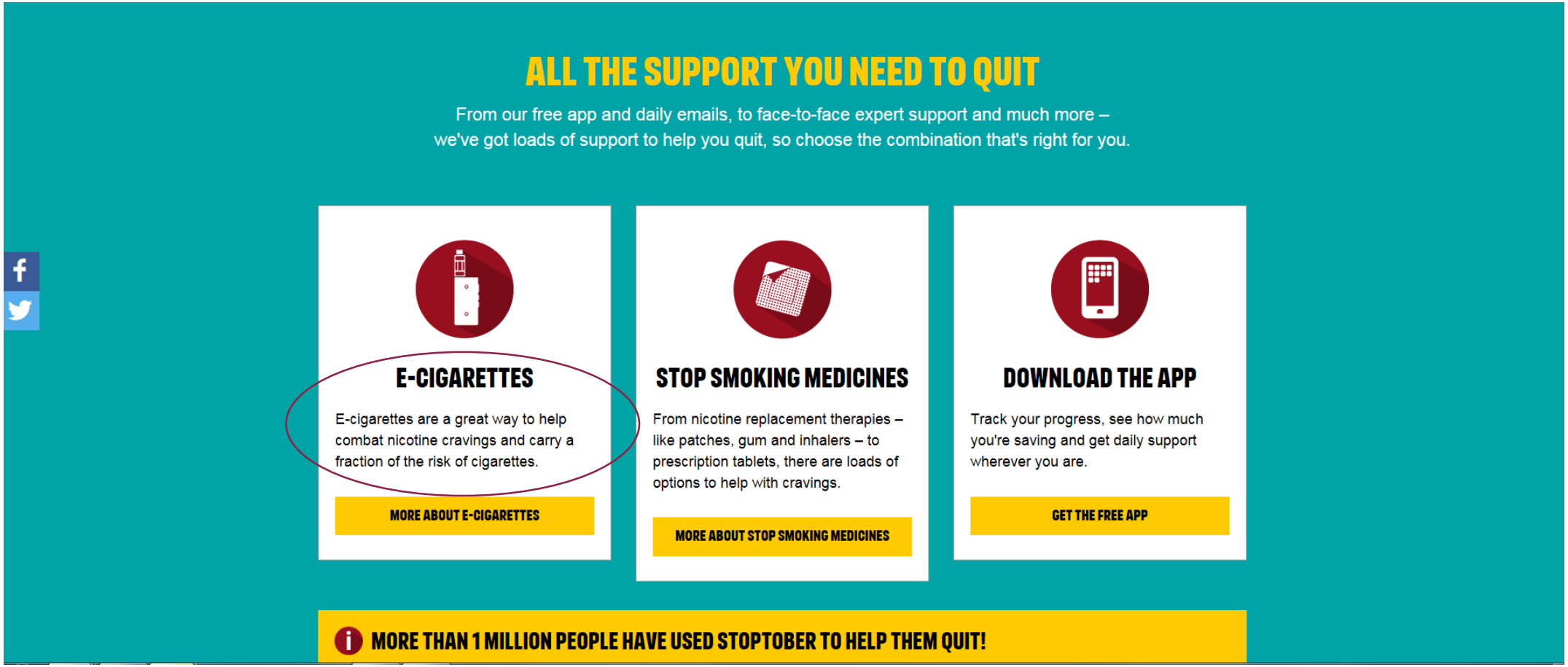
E-cigarettes: an evidence update

Ref: PHE publications gateway number: 2015260
PDF, 2.07MB, 113 pages

This file may not be suitable for users of assistive technology. Request an accessible format.

E-cigarettes: a new foundation for evidence-based policy and practice

“Stoptober” -UK Government Quit Smoking Campaign – October 2017



Conclusions/Questions

Do ENDS manufacturers have sufficient information from the FDA to develop an MRTP application?

Given recent, domestic and international, government statements, and what adult smokers empirically observe when switching to ENDS is it even worth engaging in an MRTPA?