Medicinal E-cigarettes in the UK: Market Authorization, Post-Market Surveillance and Prescriptions

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New Guidance

- The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) issued new guidance in October encouraging e-cigarette firms to apply for market authorization as medicines
- MHRA is competent authority for pre-market approval and post-market safety reviews, along with notified bodies
- This paves the way, but does not guarantee, availability of e-cigarettes via prescription, covered by the UK's National Health Services
- This is a step beyond Australia, where nicotine containing e-cigarettes are only available via prescription, but the Therapeutic Goods Administration has not approved any product and does not monitor safety

MHRA
Regulating Medicines and Medical Devices

Medicines &
Healthcare products
Regulatory Agency

Why is this a big deal?

- Change in access: UK's National Health Services procure in bulk. Prescription charges are capped for patients.
- Change in use: 1/3 of smokers in UK have not tried e-cigarettes due to health and safety concerns
- E-cigarettes approved as medicines not subject to same restrictions, e.g., can allow higher concentration of nicotine
- Proponents point to evidence that higher nicotine concentrations promote switching

Under the NHS, there is no co-pay or charge to see a physician, visit a clinic or go to a hospital

UK prescription charge = GBP 9.35 per item
About $12.50

Pack of 20 cigarettes = GBP 10.20
About $13.65

Juul starter kit with 4 pods = GBP 15.00
About $20.00

Why now? New Politics, Not New Laws

- Not caused by change in laws due to Brexit
- Regulation of E-cigarettes in the UK is still based on EU laws, transposed into UK law
- This may change over time, although regulatory divergence for commercial e-cigs may cost industry
- Key difference is that High Court is no longer within EU court system with CJEU. Last resort for legal redress now international arbitration

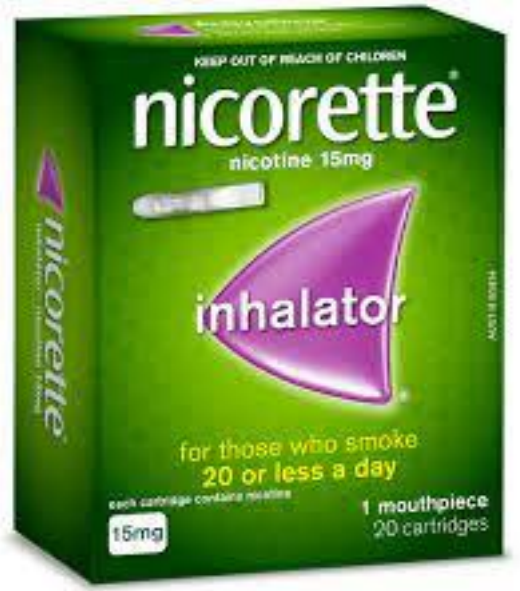
What did the e-cigarette industry want from Brexit?

- Allow snus
- Allow higher nicotine concentrations
- Eliminate restrictions on tank sizes
- Allow advertising
- Reduce or eliminate warnings

These all relate to restrictions placed on commercial e-cigarettes in EU and UK law

Points of interest in MHRA's guidance

- Refillable and reusable e-cigarettes with quit claims regulated as medicines AND medical devices. MHRA already regulates 'harm reduction' products, e.g., patches, gum, inhalers
- MHRA also regulates commercial e-cigs, which may not make health claims
- Truncated authorization process (either 'generic' or 'hybrid'), does not require clinical trial data
- Because 'nicotine is not a new chemical entity'. Based on existing reference product – MHRA recommends a reference product!
- Synthetic nicotine likely passes bioequivalence test?
- 'Hybrid' process would allow higher strength products
- Advising process pre-application assists firms
- Potential for products in the FDA's PMTA process to submit same data to MHRA –affect international market



Key questions

- How will NHS procurement of e-cigarettes affect e-cigarette markets?
- Guidance to physicians is matter of policy, not law. What will the guidance be?
- What will happen to dual use?
- How well will post-market surveillance work? Less good for medical devices than medicines
- How well will import controls work? What about Northern Ireland?
- Will MHRA authorize flavored products?
- Does this pave the way over time for more changes that the e-cigarette industry wants to see?

Thank you!

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