Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

E-cigarette notification scheme: current status

Beryl Keeley

UK notification scheme

- Producers of e-cigarettes and nicotine-containing refill containers must submit a notification to MHRA
- Producer makes declarations of conformity
- Over 32,000 notified products in UK
- 90% e-liquids, 10% devices
- Recent rise in ‘nicotine shots’

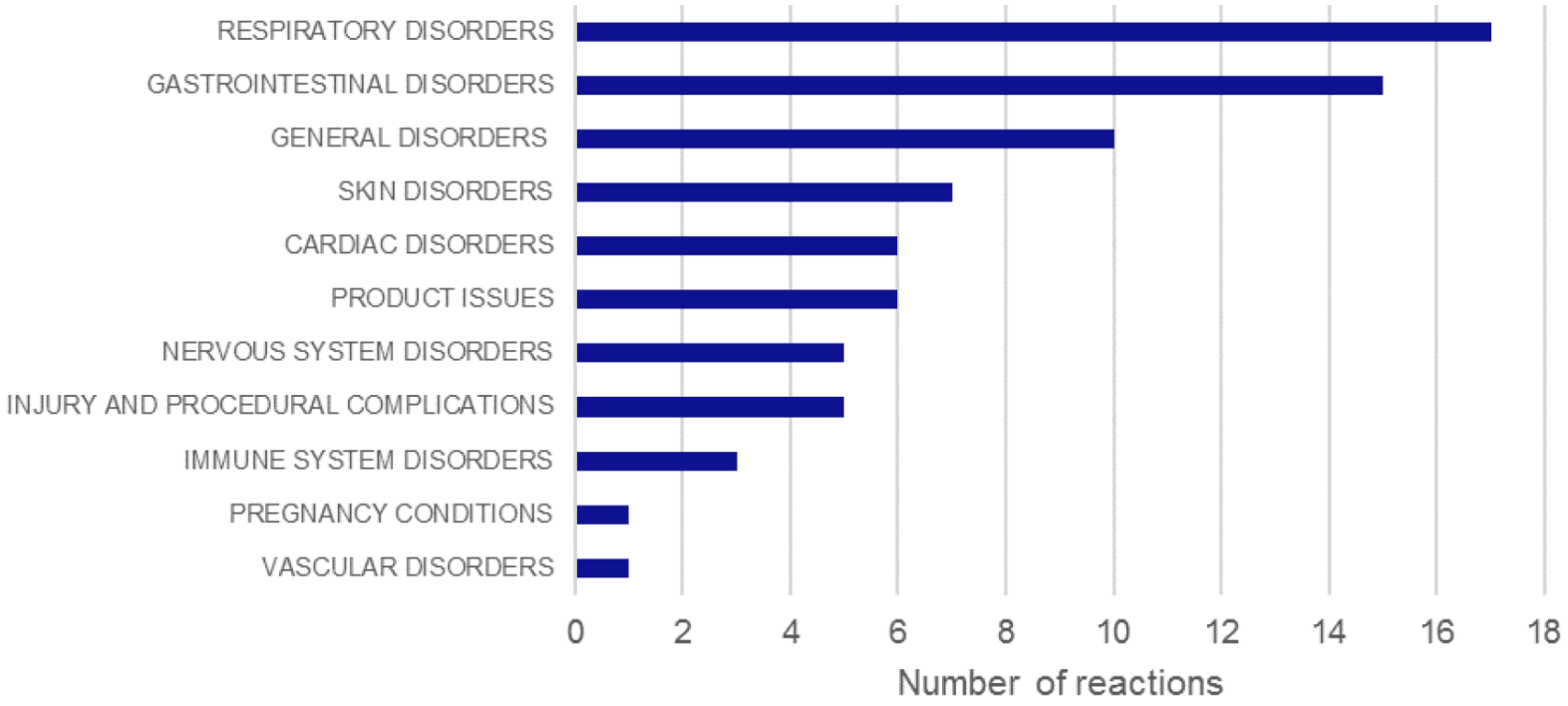
Safety in use

- Yellow Card reporting

- Low number of reports – raising awareness
- Liaison with company where problem identified
- Product complaints - Trading Standards action

Reporting in the first year

Graph 1 - Number of reactions associated with e-cigarettes, reported via the Yellow Card Scheme, broken down by MedDRA System Organ Class



Medicines – encouraging applications

- General medicines guidance on MHRA webpages – quality, safety and efficacy
- Specific guidance recently updated
- Scientific advice meetings
- Potential for mutual recognition in EU

Clinical research on e-cigarettes

Check the MHRA algorithm: https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#when-a-clinical-trial-authorisation-cta-is-needed

The algorithm is a set of questions that determine:

- whether the product being tested counts as a medicinal product
- whether the trial counts as a clinical trial within the scope of the relevant EU directive

There are mock examples on the same page

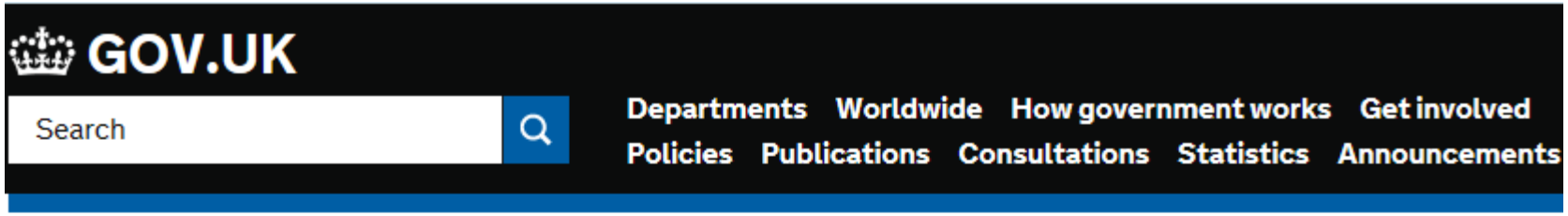
– **now updated with examples for e-cigarettes**

In general…

An e-cigarette which is a consumer product regulated by the Tobacco Products Directive 2014/40/EU (TPD) is **not a medicinal product** and this product would not be considered an investigational medicinal product (IMP) in health / clinical research.

This does not mean that a study that includes a TPD regulated e-cigarette would not require a clinical trial authorisation (CTA) in some circumstances.

Information and advice



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Guidance

E-cigarettes: regulations for consumer products

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