Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Implementing article 20 of the EU Tobacco Products Directive (TPD)

Beryl Keeley

Purpose

The regulatory framework introduced by the TPD is intended to provide:

- minimum standards for safety and quality of all e-cigarettes and e-liquids
- information to consumers so that they can make informed choices
- an environment that protects children from beginning to use these products

TPD notification scheme

- TPD requires producers of e-cigarettes and refill containers to submit a notification to the competent authority
- Existing products on the market must notify by 20 November 2016
- Data will be published (except confidential information)

Product requirements

- Ingredient standards – banned substances, submission of toxicology data
- Emissions testing – formaldehyde, acetaldehyde, acrolein, metals depending on device
- Packaging requirements – child resistant closures, leak-free filling, health warning, leaflet

Notification scheme

Reliance on:

- Declaration of conformity with Article 20 requirements
- Declaration that manufacturer and importer bear full responsibility for the quality and safety of the product when placed on the market and used under normal or reasonably foreseeable conditions

Non-compliant products

- May not be manufactured or imported into EU after 19 Nov 2016
- Producers may only continue to sell if they submit a notification by 19 November
- Retail sell-through until 19 May 2017

Safety in use – company role

- Contact in EU to receive information – on leaflet
- Responsibility of manufacturer to monitor reports
- Investigate potential non-compliance or safety issues
- Report outcome and actions taken to MHRA at TPDsafety@mhra.gsi.gov.uk

Safety in use – MHRA role

- Yellow Card reporting

- Reports routinely sent to company and to local Trading Standards team
- Liaison with company where problem identified
- Provisional action and European co-ordination

Medicines – evaluation

Demonstration of safety, quality and efficacy – positive risk : benefit balance

- Quality – product data must be submitted
- Safety and efficacy – bridge to licensed reference product by means of a pharmacokinetic study
- Separate device – CE marking (class IIa)

Any questions?

Further information:

E-cigarettes: regulations for consumer products

https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products

Register to be kept informed of developments in our implementation of the regulations

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