



Medicines & Healthcare products
Regulatory Agency



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

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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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