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UK's detailed TPD plans suggest light-touch approach

Written by **Barnaby Page** || 8 January, 2016 || **Regulatory news analysis** ↶ | 🔒



The shape of future e-cigarette regulation in the UK became clearer today with the release of the

government's response to one major public consultation, and the launch of another on the issue of fees.

While there could theoretically still be changes, the Department of Health's statement on the completed consultation suggests that the government favours light-touch regulation when it legislates to transpose the European Union's Tobacco Products Directive (EU TPD) before the 20th May deadline.

Among the major [points that the ministry makes](#) are:

A transition period for products not compliant with the TPD will allow them to remain on sale until 20th May 2017.

Cross-border sales of e-cigarettes by foreign companies to UK consumers will continue to be permitted, with the government believing it would be “disproportionate” to ban them, and acknowledging that international sales are more important for e-cigs than for combustible tobacco products.

However, vendors from other countries will be obliged to register with UK authorities, and nominate an individual to be responsible for verifying that products comply with UK regulations. Domestic mail-order sales will not be subject to this requirement.

Nicotine-free e-liquids will not be affected by the UK’s legislation implementing the TPD, and will continued to be regulated under the General Product Safety Regulations.

E-cigarettes and refill containers will have to bear the **warning statement** “This product contains nicotine which is a highly addictive substance”, but not the additional sentence “It is not recommended for use by nonsmokers”, which the government had originally wanted.

Two reasons the Department of Health offers are that “the shorter statement would be more appropriate for the small refill bottles; and avoid any possible confusion amongst ex-smokers using these products who may view themselves as non-smokers, who we do not want to see turn back to smoking”.

The secretary of state for health, in effect the Department of Health, will have “the power to take measures including action to **prohibit the supply** of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public

health”.

E-cigarette businesses will *not* be required to nominate a specific individual as the person in charge of **collecting information** on any “adverse incident”. However, there will be an obligation to report any such incident to the authorities.

The legislation transposing the TPD into Britain’s domestic law will use the **TPD’s definitions** of “e-cigarette” and “refill container”.

The people have spoken

The e-cigarette industry appears to have been highly active in the Department of Health’s two-month consultation, which ran from 2nd July last year, and much of which concerned detailed questions relating to tobacco packaging and warnings.

Of the 709 responses the ministry received, although the vast majority (75%) came from the general public, the next-highest proportion (8%) derived from the e-cig business. That was twice as many as from the tobacco industry, and indeed more than from any other group, including stakeholders in public health and retail.

The regulations outlined in the consultation response are likely to apply to Scotland, Wales and Northern Ireland as well as to England, although there may also be other e-cigarette regulation introduced by those countries’ own legislatures covering areas not encompassed by the TPD – for example, public vaping.

The Department of Health, which strictly is responsible

solely for England, was given the task by the three other countries that make up the UK of handling TPD transposition on their behalf.

It plans to achieve transposition by revoking and replacing the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002.

Costing compliance

Almost simultaneously with the release of the health ministry's consultation response, the British pharmaceutical regulator launched its own [consultation on the fees](#) for notifying e-cigarette products to it, as required under the TPD.

The Medicines and Healthcare Products Regulatory Agency (MHRA) plans to charge:

- £220 (€290, \$320) for the first notification of an e-cigarette product.
- £60 (€80, \$90) per year for each product thereafter.
- £110 (€145, \$160) for notifying a modification to an existing product, although businesses which expect to frequently change their products can pay a fixed fee covering several alterations – therefore, it would seem, getting a bulk discount on modification fees.

Notification will be required for products that “contain, or could contain nicotine in the form of e-liquid”, meaning that “equipment such as mouthpieces [and] batteries” will not be subject to the notification requirement or the associated fees.

The government agency expects the total cost to the industry to be less than £1m (€1.3m, \$1.45m) a year, although it acknowledges that “low, smaller sellers are likely to be more affected than larger ones by the proposed fees”.

“However,” the MHRA adds, “we consider that there is no viable alternative in order to cover the cost of these functions.” It stresses that “the MHRA scheme is a direct transposition of the EU Directive, without gold plating”.

It expects setting up the notification system to cost it about £600,000 (€800,000, \$870,000) in the first year of operation, thanks both to fixed expenses such as the deployment of IT systems and to the large number of notifications anticipated. In subsequent years it anticipates the programme costing around £100,000.

All e-cigarettes and affected components on the market on 20th May will need to be notified within six months.

Responses to the consultation are required by 29th January.

What This Means: As was to be expected in the light of relatively liberal regulation to date and the now-famed endorsement of e-cigs by [Public Health England](#), the UK’s proposals for TPD implementation and notification fees are gentle on the industry.

Many of the TPD’s requirements that e-cig suppliers – and vapers – find distinctly unwelcome, such as the limits on nicotine concentration and refill container size, will of course still be imposed in Britain. The EU directive gives member states no discretion to vary those.

But in those areas where the UK government has had a genuine decision to make, the industry should find little to complain about.

– Barnaby Page and Pablo Cano Trilla *ECigIntelligence* staff

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Contact Us

info@ECigIntelligence.com
+44 (0) 203 289 8185

UK
ECigIntelligence
(Tamarind Media Limited)
5 St John's Lane
London EC1M 4BH
United Kingdom

SPAIN
ECigIntelligence

(Tamarind Media Limited)
Portaferrissa nº 8 Principal-1
Barcelona - 08002
Spain

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