Death by paperwork: consultation on EU e-cigarette notification regime

written by Clive Bates | 8 September 2015

Death by paperwork: no estimate has been made of the damage that paperwork burdens will do

Under the Tobacco Products Directive Article 20(2), e-cigarette and e-liquid manufacturers or importers will have to notify the authorities of any product they want to place on the market. A low-key (to put it mildly) UK consultation run by MHRA on the data requirements for notification closed on 3 September. Of course most of it was already settled when the directive was agreed without any consultation whatsoever and cannot be changed by humble objections from those who bear the burdens.

I was on holiday, so only put in a short response from my temporary HQ in the mountains of Sardinia. However, I think it is important to take every opportunity to register despair at the way the TPD Article 20 on e-cigarettes was negotiated and to try to reduce the damage it will do. It will be interesting to see if anyone cares.

These were the documents circulated by MHRA for comment: Commission Decision on TPD Implementation / Annex: E-cigarette Data Description. Here's my response:

Common notification portal for e-cigarettes

Consultation response – Clive Bates, Counterfactual

1. Defective process. The relevant provision in the TPD, Article 20(2) or anything remotely like it, was never subject to consultation, impact assessment or regulatory scrutiny in the course of its negotiation. It is a piece of *de novo* legislation created in the closed and political triologue process, rather than through the Ordinary Legislative Procedure. It is unlawful to make EU law in this way and British ministers and officials should not have agreed to it. Even the present consultation has no impact assessment so it is not always clear what burdens are associated with providing each piece of data – for example, do they require pharmacokinetic testing?

2. Poor legislation. There is no clearly defined problem to which this notification regime is a response, and it is unclear what action will be based on the collected data, if any. The risks involved are minimal, the burdens disproportionate, it does not support free movement of goods in the EU internal market and the notification regime far exceeds the requirements placed on manufacturers of cigarettes – so the regime is also discriminatory. Again, the underpinning directive is unlawful when tested the major principles required in the EU treaties, and British officials and ministers should not have accepted it.

3. Applying the Regulators' Code. The failures in designing the provisions of the original directive 2014/40EU suggest that as competent authority, MHRA should be proactive in using any flexibilities or ambiguities in the body of the directive text to bring the notification as far as possible into compliance with the principles of good regulation in the Regulators' Code, especially principle 1.1:

> ***1. Regulators should carry out their activities in a way that supports those they regulate to comply and grow***
>
> *1.1 Regulators should avoid imposing unnecessary regulatory burdens through their regulatory activities and should assess whether similar social, environmental and economic outcomes could be achieved by less burdensome*

> *means. Regulators should choose proportionate approaches to those they regulate, based on relevant factors including, for example, business size and capacity.*

It would be a welcome innovation for MHRA to describe how it will apply the principles of the Regulators' Code to its regulatory role with e-cigarettes, and use this to inform its approach to the Commission, while recognising those parts of the directive that were irrevocably fixed without regulatory scrutiny or challenge.

4. Product combinations. The designers of the notification portal have not attempted to build a system that would minimise burdens and have not designed the reporting requirements with any apparent insight into how the market functions – by offering thousands of combinations of ingredients, diluents, nicotine strengths and container sizes. The notification burdens will favour large producers of narrow standardised product ranges, penalise SMEs and probably reduce the variety of products available to consumers – leading fewer to switch from smoking.

5. Notify products *ranges*. The design appears to involve vast duplication and dead-weight costs. The appropriate unit to record is a *product range*, not an individual product, because there are thousands of possible flavour, strength and size combination. The notification regime appears to require every combination to be notified separately. A much lower burden design would specify a product range and list the elements that can be combined, without a separate entry for each combination.

6. Testing requirements. Where testing is required to supply data for notification, the only reporting requirement should apply to the maximum concentration used in any range, as this poses the greatest of the trivial risks posed by these products.

7. PK testing. There should be no requirement for pharmacokinetic testing and reporting under any circumstances. It is expensive for producers and pointless data for regulators to collect. Tobacco manufacturers do not do this, and it is a function of user and device interaction providing nothing useful. Consumer preferences and market forces determine which products provide satisfactory experience, not regulators. Firms may wish to undertake PK testing for commercial and innovation purposes – but that should be their call, not a

notification requirement.

8. Dose. The concept of a device providing a 'dose' is grounded in conceptual error – these are not metered drug delivery systems and to force them function that way that would compromise their functioning as alternatives to smoking. These devices supply vapour on demand and under the control of the user via sensory feedback.

9. Emissions testing and reporting. Reporting of emissions serves no purpose, and is completely pointless if there is no standardised puffing regime specified. All the important safety concerns are addressed for liquids by testing and reporting the constituents of the liquids prior to heating. All the important safety concerns in relation to devices should be dealt with through specification of standards for leaching of materials etc.

10. Information on devices / gold plating. The requirements for notifying devices should be kept to the legally compliant minimum. This is not the case in the present specification. MHRA should make a detailed analysis of any gold plating of the directive's requirements in the notification regime, publish its assessment and use it to oppose excessive burdens introduced by the consultant consortium.

11. Commercial data. There should be no requirement to report any commercial data – including launch or withdrawal dates. The notification regime creates a right to place a compliant product on the market in the EU – once done there should be no need to report launch dates other commercial information.

12. Impact assessment. There should be an impact assessment and modelling of the costs and burdens that will be applied to particular business models in the sector. Questions so far unanswered (and unasked): will this notification regime discriminate in favour of the subsidiaries of tobacco or pharmaceutical multinationals at the expense of others, and for what public value in return? Will it render SME specialised vape emporia commercially unviable? Will it force internet retailers stocking a wide range of products to change their business and offer a narrower product range?

Yours sincerely

Clive Bates

Counterfactual