Because you're worth it – are there ideas from cosmetics regulation useful for e-cigarettes?

written by Clive Bates | 26 July 2013

I have been pretty scathing in a number of posts about how wrong it would be to regulate e-cigarettes as medicines (see, for example: The case for regulating e-cigarettes as medicines; 10 reasons not to regulate e-cigarettes as medicines; Medicines regulation for e-cigarettes – when caution can kill – and pointed out it is probably illegal, not least because they are not medicines. I've also stressed the significant body of legislation that already applies to e-cigarettes, and suggested how the tobacco products directive can be amended to take better advantage of this.

Can any more be done…? Well perhaps we can learn from the approach taken to regulating cosmetics in the European Union.

Why look at cosmetics regulation?

Similarities between cosmetics and e-cigarettes. This is a useful area to explore for e-cigarettes, not because e-cigarettes can be classed as cosmetics (they obviously are not cosmetics), but because they have some interesting characteristics in common. If they have similar characteristics, perhaps they would be regulated in a similar way.

- Both are fast moving consumer goods;
- Both are marketed as lifestyle products;
- Both are capable of making claims (eg. of eternal youth) that need justification;

- Both have potential human health and safety risks;
- Both are in contact with to the human body;
- Both industries have many vendors, different business models and long supply chains;
- Both markets rely on rapid innovation, short product cycles, and 'creative destruction';
- Both are functional and have to work properly (eg. makeup must not run, change colour etc);
- Both sets of consumers expect products to be the same each time they buy;
- Both have diverse ranges – colours and textures for cosmetics, flavours for e-cigs;
- The cosmetic market is huge, the e-cig market will become huge;
- Neither are foods or medicines (or tobacco products) and neither fit into regulatory frameworks designed for other products

An evolving purpose-built regulatory framework since 1976. So given these similarities, what can we learn from how cosmetics are regulated? In the case of cosmetics, legislators have taken the trouble to create a bespoke regime that is fit for purpose (ie. it has been designed to regulate cosmetics, not something else). With e-cigarettes legislators are trying to cut corners by hammering e-cigarettes into the most convenient and risk averse regulatory framework to hand, namely the medicines directive – an approach that is poor from a regulatory perspective and almost certainly unlawful. Since the 1970s there has been an evolving system of regulation for cosmetics at EU level. Until this month, cosmetics had been regulated by a 1976 cosmetics directive (76/786/EEC) – this was amended in 1982, 1983, 1988, 1989, 1993 and 2003 and finally replaced in 2013. It also had nine related directives. This is important: they didn't get there in one go. A new purpose built regulatory regime can be seen as a destination or direction – not something achieved at the outset.

The current regulation. Cosmetics are now covered by a purpose-built EU regulation: Regulation (EC) No 1223/2009 on cosmetic products. This was agreed in 2009 and entered into force on 11 July 2013 (note, a good long lead time). It also draws on evolving standards – for example ISO 22716 was introduced in 2007 to provide a Good Manufacturing Practice standard appropriate for cosmetics, and this is different to that used for pharmaceuticals. It shows that the EU is capable of developing a purpose built regulatory regime if it chooses to. Given the conceptual similarities above, it turns out that cosmetics regulation has many of the features we would might eventually expect in an e-cigarette regime. It shouldn't be blindly replicated either – this regulation has been a long time in

the making and operates in a mature market. But it has several potentially useful features:

- It respects the internal market. Manufacturers and distributors are required to comply with the regulation, but do not need pre-market authorisation.
- It establishes a 'responsible person' in each manufacturer or distributor operating in the EU – and places obligations on them
- It requires each product to have a safety assessment to a common format and for a product file to be kept
- It requires proper labelling and product descriptions
- It has lists of prohibited and permitted substances
- It sets out what must happen if problems arise with products

In other words, it establishes the regulatory platform for a highly competitive innovative market.
See European Commission legislative overview for more detail and below for an outline of the articles in the regulation.

What does this tell us for the Tobacco Products Directive?

It means that the full challenge of e-cigarettes does not have to be addressed finally, once and for all in the TPD. We can take time (as with cosmetics) to get it right – there is no health emergency, consumer crisis or rioting among users that demands an draconian regulatory response. Existing provisions (like the RAPEX system) are picking up faulty or dangerous products and there is scope to apply the existing consumer protection legislation more effectively. At this point we should concentrate on avoiding damaging and costly errors, imposing inappropriate regulation, creating needless legal vulnerabilities. Here's what to do:

1. Reject medicines regulation for e-cigarettes – it is a 'quick fix' and not appropriate for these products [see here and here] – and allow this only where a therapeutic claim within the meaning of the medicines directive is made.
2. Use the directive to require member states to more robustly apply and enforce the body of safety and consumer protection regulations that already exists [see here] and require the member states to report on compliance and enforcement activity and bring in this quickly (ie without

the long lead in time needed for very disruptive regulation)

3. Establish a new evidence based regulatory development process aimed at creating bespoke fit for purpose regulation of e-cigarettes and, potentially, other low risk alternatives to smoking. This requires scientific advice, a technical review, options development and appraisal, legal underpinning, consultation with users and producers etc.

A new regulatory regime does not have to be concluded now – progress can and should be made, bad choices rejected, and a good direction set. Achieve that modest ambition, and MEPs, ministers and officials can be proud of taking a proportionate, non-discriminatory, lawful, evidence-based, ethically sound approach to tobacco harm reduction. But that does require a change of direction in the final months of this year.

Appendix: Structure of the cosmetics regulation

The articles of regulation EC 1223/2099 cover the following:

1. Scope and objective (internal market with high level of health protection)
2. Definitions
3. Safety (a broad responsibility to be 'safe')
4. Responsible person (designation of a responsible person for each product)
5. Obligation of responsible person (to ensure compliance with the regulation and general duties)
6. Responsibilities of distributors (general duties and responsibilities – eg. regarding labelling and product shelf life)
7. Identification within the supply chain (traceability in the distribution chain)
8. Good manufacturing practice (requirement to meet a quality standard for manufacturing – in practice ISO22716)
9. Free movement (asserts basic right of free movement in the single market subject to compliance with the regulation)
10. Safety assessment (an assessment to be made to a standard set out in Annex I)
11. Product information file (a dossier on the product, safety profile etc)
12. Sampling and analysis
13. Notification (important – this requires notification of the Commission, not an *authorisation* process)
14. Restrictions on substances listed in Annexes (refers to annexes II-VI)

15. Substances classified as CMR materials (restrictions on carcinogenic, mutagenic, reprotoxic substances)
16. Nanomaterials
17. Traces of prohibited substances (a *de minimus* clause for unintended traces of harmful substances)
18. Animal testing
19. Labelling (ingredients, shelf life etc)
20. Product claims (duty to be truthful)
21. Access to information by the public (right to know what is in the product and any known safety risks)
22. In market control and surveillance (duty of memeber states to monitor compliance)
23. Communication of undesirable effects (responsibility to notify authorities etc)
24. Information on substances (how to act when in doubt about safety)
25. Non-compliance by responsible persons
26. Non-compliance by distributors
27. Safeguard clause (powers for competent authority to intervene)
28. Good administrative practice (application on 25-27)
29. … to 40 co-operation, administrative and final provisions etc

Annex I Cosmetic product safety report
Annex II List of substances prohibited
Annex III List of substances restricted
Annex IV List of colorants permitted
Annex V List of preservatives permitted
Annex VI List of UV filters permitted

Competent authority. The ‘competent authority‘ for cosmetics in the UK is the Department for Business Innovation and Science and the Laboratory of the Government Chemist.