Consumation

Consumer information design

Response to European Commission Public Consultation

Legal Proposal on Information to Patients

Summary of response

- High-quality information on medicines is desirable for patients – and also for others
- Any provider of such information will have a bias – industry, government, charity – but users can usually identify a bias when the source is clear
- Putting patients' interests first is more difficult than it sounds
- Push and pull provision and monitoring arrangements are not clearly delineated in the proposals
- The multi-stakeholder groups proposed are vital to regulatory arrangements, and must include communication professionals.

Consumation is a leading health information design consultancy. We specialise in the production and user testing of highly readable information about health and medicines

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- **High-quality information on medicines is desirable for patients – and also for others**

  Information is now recognised as a vital ingredient of medicines. It can influence decisions on whether to take medicines; what to do in case of no effect, or unwanted effects; and it can affect the likelihood of people abandoning their prescribed medicines. Indeed, patient information shapes the expectations of medicine users and this (like the shape of a capsule or tablet) can greatly affect the acceptability of the medicine.

  It is often forgotten that patients may not be the only or even the main readers of medicines information. Healthy people contemplating medication; people caring for medicine takers; parents of children taking medicines; friends or relatives of those with visual problems or cognitive impairment – none of these are patients but all have a developed interest in clear and accessible information.

  Nor are lay people the only readers. Many health professionals have told us in our research that they will often need to scan the "patient information leaflet" to build up their knowledge of a treatment. For example, hospital nurses may be given only brief training in administering injectables, and often say that they consult the patient information sheets as they find health professional information too formal or complex.

- **Any provider of such information will have a bias – industry, government, charity – but users can usually identify a bias when the source is clear**

  Undoubtedly, the pharmaceutical industry struggles to be impartial when it comes to giving information about its own products. But any source of information will have its own bias, whether or not it is acknowledged. Medical doctors, national health departments and designers of health information also have their own 'axe to grind' – own values, peculiar biases and characteristic blind spots.

  The good news is that these are usually easy to guard against by identifying the source of the information. A positive message about a medicine, brought to you by the company that makes it, will be more sceptically viewed than the same message from a leading medical specialist. This is so obvious that it is sometimes neglected as a consumer protection measure.

  Although it may be obvious, the question of sourcing is not simple. If the leading medical specialist is also a shareholder in the manufacturing company, our view of her testimony might be affected – but we would need to know about it. And if we watch a television programme about a medicine, or read a press article, we also need to know its provenance. Not just its direct provenance (the production company), but its underlying funding – how and why it came to be made. New rules need to prevent (for example) companies setting up web sites disguised as patient advocacy services.

▪ Putting patients' interests first is more difficult than it sounds

It is encouraging to read that the forthcoming proposal will put the interests of patients first. Certainly, it will be the first piece of legislation to achieve this ambitious aim. The experience of regulatory guidance and actual assessment practice in the field of medicine package leaflets has not been encouraging here. Perhaps lessons can be learned from that.

The requirements of the Directive are to provide clear and understandable information for medicine users, which reflects consultation with target patient groups. The practice of regulators – national and central – has been to replace such tried and tested, user-friendly material, and replace it with "alternatives" which are complex, full of jargon and sometimes misleading. New written guidance has been enormously delayed, old and discredited templates have been left in place and national and central assessors have been responding based on criteria that have never been published.

In short, many of the Directive's requirements on patients' interests are regularly broken by regulators themselves. Many regulatory demands on patient information are in effect unlawful, as for instance when they require changes to text that has been clarified at the suggestion of users.

Of course most of these replacements and changes are done with the best motives by scientific assessors who think that their version is right (and that the "company's" version is wrong – by this stage in licensing, it has become a two-sided game). A pharmaceutical company is unlikely to challenge such regulatory demands, because it is interested in a obtaining a licence.

The voice that is missing? That of the medicine user, or "patient". They did have their say, some time earlier in the process, but (despite European law) the system ensures that the debate on technical terms comes to be seen as more important than patients' understanding.

If the forthcoming proposal builds a system to put that patient's interests first, it may be worth considering what has happened to the European licensing system for patient information.

▪ Push and pull provision and monitoring arrangements are not clearly delineated in the proposals

Section 3.3 of the proposals envisages push and pull modes in information giving. This is a relevant distinction, but one that is not rigorously followed up in sections 3.3.1, 3.3.2 and 3.3.3 – they have a slightly different wording and structure. The latter sections perhaps provide a more useful framework: data received by citizens; data gathered and evaluated by citizens; and direct questions asked by citizens. "Passive" receiving of (for example) TV programmes is arguable, as fewer and fewer people gaze uncritically at their TV. In some member states, TV offers almost as broad a choice as the internet.

At this early stage of the proposal, it is hard to understand the nature of the co-regulatory oversight envisaged here: for example, the body *should monitor*

the contents [of web sites] without validating ex-post or ex-ante specific actions. Again: *replies by industry to enquiries from citizens through written solicited posting or email should be monitored based on complaints.* No doubt the details will be clarified in any forthcoming proposal.

- **The multi-stakeholder groups proposed are vital to regulatory arrangements, and must include communication professionals.**

  Having been instrumental in setting up several multidisciplinary working groups in the field of patient information, I am convinced that they are the only way to find consensus, and the Commission is to be warmly congratulated on adopting this model.

  Alternative approaches – such as separate working groups for industry and patients – too often work against universally acceptable solutions, and promote loose compromise. A multi-stakeholder group that takes responsibility for its output and is accountable for its decisions, is the only serious forum for the proposed co-regulation arrangements.

  One common problem with patient, professional or industry representation is the natural tendency to appoint articulate and highly literate people, who are well suited to committee work. Unfortunately, they are much better able to understand and process information than the average patient. As with the regulatory assessors mentioned elsewhere in this document, any such group of individuals is likely to confuse its own knowledge and goodwill with the thinking of people in world outside, and may overestimate the public's ability or willingness to deal with medicines information.

  One way to counteract this tendency is to introduce communication researchers into such a group – those whose job is to interact with people and observe and record their use of information. I need to declare an interest, as an information designer who sat on the UK Committee on Safety of Medicines' working group on Patient Information. There were others on that group, from academic and commercial organisations, who contributed to the notable "feet-on-the-ground" approach of the subsequent document, *Always Read the Leaflet*.