European Commission Public Consultation: Legal Proposal on Information to Patients

Dr DK Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

D.K.Raynor@leeds.ac.uk

Thank you for the opportunity to respond to this proposal. I am contributing as an academic pharmacist with research and practice expertise in the area of consumer medicines information.

1. About the Consultation

1.1 The EC is preparing a legal proposal on information to patients to ensure good quality, objective, reliable and non-promotional information.

- It is important to note that no information about medicines will be fully objective, regardless of its source.
- Information written by a Government or health management source will be perceived by some to be written from a particular stand-point. Equally, information written by a patient organisation will have its origins in its own particular stand-point.
- The key is to ensure that all information is very clearly identified with its source (see below).

2. Introduction

2.1 The quality of information currently is currently very variable, in particular in view of the internet.

- I am pleased to see no mention of the use of a quality "kite mark" for Internet sites. There is no evidence that all consumers would take notice of a kite mark and monitoring and maintaining such a system would be unmanageable.
- A much better option to educate consumers to be their own gatekeepers when looking at any information, whether from the internet or elsewhere.

The Commission's declared intention that healthcare professionals should remain the primary source of health information.

- Our recent systematic review of research into written medicines information confirms that spoken information from healthcare professionals remains the priority for patients.[1]

[1] Raynor, DK, Blenkinsopp A, Knapp PR et al. *A systematic review of quantitative and qualitative research on the role & effectiveness of written information available to patients on individual medicines.* **Health Technology Assessment 2007;** 11: 1-177. www.ncchta.org/execsumm/summ1105.shtml

2.2 The forthcoming proposal will put the interests of patients first

- It is worth noting that the systematic review of research found that consumers do want a range of sources of information. However, the research evidence does show that there is some distrust of pharmaceutical company information which some may regard as healthy [1]. This can only work in patients favour if it is always clear to them when they are reading information which comes from the industry.

Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality, and non-promotional information about the benefits and the risks of their medicines

- It is worth noting that most current package leaflets include mostly information about risks, but less about benefits. This needs to be addressed in the future. Research shows that people do want a balance of information about benefits and risks [1].
- There is a strong argument to say that the package leaflet which comes with all medicines should remain a key focus as this is the only piece of information that all patients get and that is supplied closely linked to the medicine concerned. The fact that this is now readability tested to ensure usability is another argument for it remaining a key focus.

3. Key ideas of the forthcoming proposal

A major part is to present a clear distinction between advertising of and information provided on prescription medicines.

- This is likely to be difficult. Again, I would recommend that very clear reference to the source, prominently placed on all pieces of information.
- This will help consumers determine for themselves whether the information they are reading is advertising in any way.

3.2 Information should be compatible with approved SmPC and patient information leaflets and it should not contradict or go beyond the key elements specified in them.

- This statement appears to be contradicted by the next sentence which talks about other limited medicine related information which could be given. This needs clarifying.
- As mentioned above, it would helpful if any information included more on the benefits of the medicines concerned.

In addition, specific quality criteria should be defined and respected

- Such criteria must include reference to the readability of the information concerned. Applying checklists of quality criteria would have some benefits, but would not give the comfort that readability testing does to patients leaflets. There is an argument that the same benefits of readability testing through consultation with target patient groups should be applied to other forms of information that industry provides to patients.

3.3.1 For the pharmaceutical industry to disseminate information on prescription only medicines through TV and radio programmes.

- It is unclear why specific reference is made to TV and radio programmes. I am aware of no evidence that consumers are calling for information from industry through such media, nor that it has been shown to be beneficial in any way.
- There is a strong argument that the information allowed to be distributed by industry be restricted to material through printed media, audio visual and written material provided to patients by healthcare professionals, and "pull" information on the Internet.

A mechanism should be set up to ensure that the information providers inform national co-regulatory bodies about their activities before action is taken

- The workload of the national co-regulatory bodies which are proposed would be overwhelming - this could result in scores of such notifications per month. I believe these bodies would not provide sufficient protection for the public.

3.3.3 Replies by industry ..... should be monitored based on complaints

- This would not give consumers comfort that this mechanism was working properly. I would recommend sampling or spot checks as an additional measure.

4. Quality criteria

The information provided should be "objective and unbiased, patient orientated, evidence based, up-to-date, accessible, transparent, relevant and consistent with approved information".

- The latter phrase needs to be clarified to note that additional, acceptable information, not in the approved information is allowable.
- In addition, I would recommend that although the terms "patient orientated" and "accessible" are noted here, the word '**readable'** needs to be included.

5. Proposed structure for monitoring and sanctions

- I would recommend that the National Co-regulatory bodies, if set up, include academics who have expertise in the area of consumer medicines information.
- It seems wholly inappropriate that only repeated and severe cases of non-compliance should be referred to the competent authorities to apply sanctions.

6. Table

The comments below relate to final column **"Quality criteria of provided information".**

Objective and unbiased – based on facts and not influenced by prejudices or personal perceptions.

- This needs re-wording to state "- based on facts – writers should work hard to **minimise the influence** of prejudice or personal perceptions".

Patient oriented

- The entry needs to include the word "**readable**", i.e. "Patient oriented – Patient centred and readable (can people find and understand the information they

need) and taking into account patients needs and expectations in order to empower patients."

Up-to-date

- All information should be dated with a date when it is going to be revised.

Understandable

- This heading includes no further information.
- I suggest that this should say "**Understandable – can people find and understand the information they need**".
- Mandatory package leaflets need to be tested for readability i.e. so that they meet the needs of patients. There is an argument that the same benefits of testing should be applied to other forms of information that industry provides to patients, under the terms of this proposal.

Consistent with approved product information:

- This, again, needs to be clarified to allow additional non-promotional benefit information.

7 Other points

- A key issue which is not addressed in the document is the fact that web-based information will clearly be available across the countries of the EU and if the National Co-regulatory bodies come up with different guidance then this could lead to inconsistencies and problems.
- Our systematic review of medicines information for patients found little existing research evidence associated with web-based medicines information[1]. Such research should be commissioned by the EU.

Statement of Interest

Professor Raynor is Director of LUTO Research Limited which is a University spin-out company which provides information testing services to the pharmaceutical industry.

DKTR 070408