EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

PUBLIC CONSULTATION

LEGAL PROPOSAL ON INFORMATION TO PATIENTS

A Response by *Dr. Lindy Williams, PhD., BSc., ARCM April 6th 2008*

Preamble

This document contains no hard information and there are no references for any of the bald statements.

This report should make clear from the outset that this proposal, such as it is, relates principally to relaxing the regulations concerning direct-to-consumer information by the pharmaceutical industry on prescription only medicines. The industry is only mentioned on page six of the document.

There is nothing in the document that shows that the proposal is in the interests of patients or of the citizens of the European Union. It is quite clear that the proposal is intended to help the pharmaceutical industry expand its markets. Claims that the proposals will be patient-centred and will take account of patientsô needs and expectationsô are not compatible with the pursuit of profit. It is hard to see how the industry knows what these expectations might be.

The document is so vague as to criteria, regulation and to precisely what distinguishes advertising from information, that it has not been possible to make constructive suggestions. For the most part I have asked questions, although I have also pointed to some glaring omissions and some lack of logic.

I hope that the Directorate-General Enterprise and Industry will realise that it is in the public interest to recall this consultation and bring it back to the public when it has done some serious background work involving matters of health and not purely those of commerce..

1. About the Consultation

In how many languages is this available? In 2007 the ódraft Report On Current Practice With Regard To Information To Patients On Medicinal Products was available only in Englishô.

1.1. The purpose of this consultation

How will the feedback be used? It will be difficult to see how this has been done if the comments are not published on the website.

In 2007 following the ódraft Report On Current Practice With Regard To Information To Patients On Medicinal Productsô, it was expected that all comments and responses were to be published on the site and this was not the case. It is in the public interest for such information to be openly available. What guarantee is there that this will be adhered to this time?

2.1. What are the reasons for the proposal?

ñthe Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liabilityñ.

Should this read ó<u>reliability</u>ô? If not, it should be added. What will govern whether or not the proposals are put forward?

'....evidence shows that the rules and practices on what information can be available still vary significantly among Member States, which results in unequal access of patients, and the public at large, to information on medicinal products.'

There is no reference for this evidence. It is not possible to comment without having some hard evidence for this claim. Furthermore since the proposal, as I understand it, is to increase the amount and sources of information available to the public it is hard to see how increasing the amount of information will ensure more equal information throughout member states.

'The quality of information is currently very variable, in particular in view of the Internet where the providers have no or limited accountability toward EU citizens'

How will this be altered by allowing more information? How will the industry be regulated in this respect? Who will monitor it?

'The forthcoming proposal would amend Directive 2001/83/EC and, in keeping with the scope of this directive, would set rules on the provision of information by marketing authorization holders This would be without prejudice to the provision of information by other actors and the Commission's declared intention that healthcare professionals should remain as they are today, the primary source of health information.'

This whole paragraph reads like a get-out clause designed to protect the industry.

Who will these ó*authorization holder's* be?

'……..intention that healthcare professionals should remain as they are today, the primary source of health information.'

How will this be guaranteed? Who will guarantee it? The promotion of information by pharmaceutical companies will undermine the integrity of doctors and others in the forefront of healthcare provision. It is not necessary for the industry to intervene.

2.2. Objectives and impact assessment

The forthcoming proposal will put the interests of patients first and with this perspective should aim at reducing differences in access to information and should ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products.

There is no evidence that the proposal will do anything to put patientsô interests first. This is in part also because the role of the Directorate-General, Enterprise and Industry is to promote the interests of industry, not those of the public.

The following main policy objectives are pursued:

1. 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, and which maintains the confidence of citizens, regulators and healthcare professionals.

2. Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information'.

There is neither evidence cited nor explanation given as to how information from pharmaceutical companies can be other than promotional. I suggest that this is because there is no real difference. What is essential is that, before putting forward this proposal, clear details are given of what is deemed to constitute advertising and in contrast, information. Only at that point might it be worth asking the public to comment.

3. Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation. On the basis of these objectives, DG Enterprise and Industry is preparing an assessment of the possible impacts. This includes an analysis of the likely impacts of the main options and an examination of possible synergies and trade-offs. The results from the impact assessment and the public consultation together will be carefully considered and used in the preparation of the legal proposal on information to patients.'

It is dubious in this instance whether less bureaucracy equates with better regulation. There is confusion between quality and quantity. It is good business practice to undertake assessments of all kinds before embarking on any new course of action, in the same way as producing a business plan is essential to any new venture. The impact assessment should have been accomplished already, before making these rather wooly proposals, which have all the markings of a complete cover-up for promoting greater consumption of medicines and use of medicinal products. Only with some specific information can any real comments be made. It must be asked whether there are any circumstances in which this proposal will not be put forward.

3. Key ideas of the forthcoming proposal

Key ideas under consideration for the forthcoming legal proposal on information to patients are explained below and summarised in the Table (at the end of the document).
A fundamental objective of the legal proposal should be to provide rules that harmoniseactices on information provisions to patients in Member States. A major part is to present a clear distinction between advertising of and information provided on prescription medicines. This distinction as well as the quality criteria, the content and means of the information provided, together with the proposed structure for the monitoring of the quality of the information, should create a framework for the industry to provide certain information on their medicines to the public. The proposal should enable EU citizens to get objective information from reliable sources. The following key ideas for a legal proposal by the Commission are put forward for consultation:

This paragraph represents confused thinking. ó*Fundamental objective'* and *'a major part*ô. What is the priority? Is the objective to harmonise practices between states, to present a clear distinction between advertising and information or to give citizens more information?

Firstly I suggest that there is no point harmonising if the practices are sub-standard in the first place. Secondly if objective information is required, then this could, and should, be provided by independent bodies rather than by those with vested interests. This is where it becomes clear that the place for this discussion is not, with respect, the DG Enterprise and Industry, but should rather be under the aegis of health. Only then would the public have confidence in the neutrality and public interest ethos of the proposal.

3.1. Provisions on advertisement
The current rules ban advertisement of prescription medicines to the general public. At the same time they allow advertisement of over the counter medicines. These rules should not be changed.

3.2. Scope, content and general principles of the new legal provisions
The revision should clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. Basically, communication not covered by the definition of advertisement, should be regarded as information. Clear criteria should distinguish the information that is allowed from the information that is not allowed.

The rules are not being revised they are being changed fundamentally. In order to comment on the proposals it is essential that these revisions are delineated publicly. Similarly criteria must be shown clearly before comments can be made. The directorate is showing remarkable lack of openness and also reveals lack of trust in members of the public.

Information should be compatible with approved summaries of product characteristics and patient information leaflets, and it should not contradict or go beyond the key elements specified in them. Other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying measures to medical treatments, prices). In addition, specific quality criteria should be defined and respected.

If in essence the information is not to change from what is in already permitted and/or required in patient information leaflets, the proposal lacks overt purpose.

I should point out that a vaccine is not a disease.

It is not possible to comment constructively on ó*specific quality criteria'* unless they are clearly stated. Furthermore simply asking for such criteria to be respected lacks rigour: they should be adhered to with tough penalties imposed on those who break the rules.

3.3. Type of actions, content and monitoring of information

A distinction should be made between the cases where the patient is passively receiving the information ("push") or actively searching for the information ("pull") in terms of the monitoring mechanism.

This is ludicrous market-speak and has no place in a public consultation document, nor in any other self-respecting paper.

3.3.1. Information passively received by citizens
Under the clear safeguard that all advertisement to the public is banned, it should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in

printed media or through audiovisual and written material provided to patients by healthcare professionals.

ó*...should be possible…'* but almost certainly would not be. How would television material differ from advertisements for, say, shampoo? What safeguards would be in place should a company advertise first a non-prescription drug, as is permitted, followed immediately by information on a prescription drug by the same company? It would be very hard to make such a distinction, so the prescription drug information would appear to be an advertisement. Since when has the pharmaceutical industry been engaged in public service broadcasting?

Doctors and nurses have a busy enough workload without having to dish out leaflets on behalf of the industry.

'To facilitate the monitoring of the information provided, a mechanism should be set up to ensure that the information providers inform national co-regulatory bodies about their activities before action is taken'.

In what sort of detail? Who will scrutinize it? What precisely does this paragraph mean?

3.3.2. Information searched by citizens
Further, when industry disseminates information on prescription medicines through Internet websites or verbally, it should announce such information activities to a national co-regulatory body which should monitor the contents without validating ex-post or ex-ante specific action.

What sort of language is this? How much detail would be provided?

3.3.3. Answering requests from citizens
'Citizens often have questions to pharmaceutical companies'.

Neither evidence nor a reference is provided to confirm this statement.

'Replies by industry to enquiries from citizens through written solicited posting or e-mail should be monitored based on complaints'.

This sentence is rather meaningless, but it is hard to see how this could not be achieved without invasion of privacy.

4. Quality criteria
All information provided to citizens should fulfil specific criteria concerning the quality of the information. The information provided should be objective and unbiased, patient oriented, evidence-based, up-to-date, accessible, transparent, relevantconsistent with approved information. Comparisons between medicinal products should not be allowed.

Any information should also be <u>complete.</u> The pharmaceutical industry has a poor record in this respect, with several recent examples having been revealed in recent months. The notion of the

information being patient-orientated is a fallacy, specially in this field; the most likely result of attempts in this area would be to make people more disease-aware, more anxious about possible diseases which they do not have and increase dependency on drugs.

What is meant by ó*approved information'?* By whom is it to be approved?
Is every word to be approved for every promotion/information pack/ television item/ website posts? This is not practicable.

5. Proposed structure for monitoring and sanctions

The structure of enforcement could take place on three different levels.

Figure. Proposed structure for monitoring

EU Advisory Committee	*-give opinions on national code of conduct* *-settle possible disputes between national co-regulatory bodies*
National Competent Authorities	*-oversight over national co-regulatory bodies* *-penalties*
National co-regulatory Bodies	*-public authorities and a mix of stakeholders, including healthcare professionals, patient organisations and the pharmaceutical industry* *- monitoring of information providers* *-adopting the national code of conduct* *-informing about non-compliant information* *-advising and monitoring activities of industry*

a) Each Member State could set-up a national co-regulatory body, consisting of public authorities and a mix of stakeholders, including healthcare professionals, patient organizations and the pharmaceutical industry. These co-regulatory bodies could be responsible for:

- *adopting a code of conduct on information to patients;*
- *monitoring and following up of all information activities by the industry.*

There is no point in having ó*the pharmaceutical industry'* involved in regulating itself by being part of a co-regulatory body. Suggesting that such a body ó*could be responsible for'* the two items shows that there would be no real regulation at all. Despite the fact that these proposals are tantamount to allowing advertising of prescription drugs, there would have to be safeguards in place to protect the public and to stop the industry drifting

into overt advertising. If the co-regulatory bodies do not make themselves responsible for regulation, then who to whom would the industry be answerable?

b) Each Member State could charge its competent authorities to act in the case of repeated and severe cases of non-compliance and apply sanctions.

Once again, use of a conditional verb implies that there would be no true regulation of these activities if the proposal is implemented. It should be encumbent upon competent authorities to act and impose penalties. Furthermore this should not simply be for ó*repeated and severe cases of non-compliance'*, but should be enforced for any transgression.

*c) On the EU level, an **Advisory Committee with no Comitology powers**, chaired by **the Commission**, could be given the task to oversee the work of national co-regulatory bodies and authorities. The Committee would have to be consulted before adoption of any national code of conduct and would deal with all questions on information to patients with a Community dimension existing Pharmaceutical Committee could be tasked with this role. While the EMEA could contribute to the work of the committee, the Agency should not have any further role as no scientific assessment of information will be necessary (2).*

Commitology is an EU-invented word whose meaning is not entirely clear. It should not be used. There should be a regulatory committee, not an advisory one, it should have powers to act and should have clear outline criteria for national bodies. Why mention ó*an Advisory Committee with no Comitology powers'* and then suggest the ó*Pharmaceutical Committee'* whose interests lie purely with the industry?

Table: Key ideas of the forthcoming proposal on information to patients

The table is incomprehensible because it uses acronyms without explanation. This is appallingly bad practice and I condemn it without reservation.
In addition to this, there is considerable market/human resources language in the table, much of which is meaningless. The table still says nothing about what the specific details of the criteria would be for this information, it fails to give any safeguards against

misinformation and also, because the national co-regulatory bodies are only a suggestion rather than a requirement, do not clarify who has powers of sanctions.

A major issue here is who is responsible if a patient receives some of this information, visits a doctor who prescribes the medicine after badgering by the patient, further information reveals serious adverse effects of the drug, and this patient becomes ill as a result? This needs clarifying. Failure to do so might well result in large class action legal challenges to drug companies, but this after damage has been done and unlikely to affect the companies in any major way.

This whole document is a disgrace in its lack of hard information on which to base comments. Almost all my comments relate to what is missing from the document rather than what is in it. I ask that this exercise goes back to the beginning and looks properly at its aims, its methods and potential outcomes. Without that the proposal should not be considered.

Dr. Lindy Williams, PhD., BSc., ARCM April 6th 2008
willowwarbler@phonecoop.coop