Consultation response

DG Enterprise & Industry
Unit F2 'Pharmaceuticals'
European Commission

DATE: 07 April 2008
TO: Ulla Närhi
RESPONSE BY: Kate Webb

RE: PUBLIC CONSULTATION ON LEGAL PROPOSAL ON INFORMATION TO PATIENTS

INTRODUCTION

1 Which? is an independent, not-for-profit consumer organisation with around 700,000 members. Based in the UK, it is the largest consumer organisation in Europe. At EU level we are members of Beuc, the Bureau Européen des Unions de Consommateurs. Entirely independent of government and industry, we actively campaign on behalf of consumers and are funded through the sale of our Which? range of consumer magazines and books.

2 Which? campaigns on a wide range of health issues, and through our work we seek to make individuals as powerful as the organisations they have to deal with in their daily lives. In considering our response to this consultation, we have drawn on the research and analysis that supports our long-standing interest in patient information and medicines regulation.

3 Thank you for the opportunity to comment on the legal proposal on information to patients. We have considerable concerns about the proposals and feel strongly that the Commission is in danger of exacerbating the current problems rather than taking this opportunity to make practical improvements for consumers as patients. We firmly hope that the Commission will address these problems before rushing to present any formal legislative proposals in this area to Parliament.

SUMMARY

> We fully support the drive for more and better information for consumers about health, disease, treatments and medicines via education about health promotion and prevention as well as information about medicines.
> But we are very concerned that these proposals in practice may only serve to exacerbate the problems and issues that they have been designed to address.

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- Which? calls on the Commission to produce an information strategy, as requested by the Parliament in Directive 2004/27/EC, before making any detailed and specific legislative proposals.
- We do not believe that these proposals will help to maintain the ban on direct-to-consumer advertising.
- We urge the Commission to adopt a consumer-centred approach to solving the problems of lack of harmonisation and unequal access across the European Union and in making proposals and devising an information strategy, building on successful approaches that are already indicated by research or experience.

AN INFORMATION STRATEGY?

4 Article 88a of Directive 2004/27/EC is cited by the Commission as the prompt for these proposals:
'the 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 liability'

5 In our view, these legal proposals provide industry with a framework to provide information directly to consumers, as patients, but do not fulfil the requirement to provide an information strategy. Rather they are a narrow and partial response to earlier discussions and consultations and in our view they represent a disappointing response by the Commission to debates in this area.

6 Which? believes meeting the commitment in article 88a of Directive 2004/27/EC to set out an information strategy to ensure 'good-quality, objective, reliable and non-promotional information' fails if it does not include proposals for improvements that can be made to patient information leaflets provided by marketing authorisation holders, for example, those outlined in *Always read the leaflet.*[i]

7 Which? calls on the Commission to reconsider these proposals as they fail to deliver the improvements that consumers as users of medicines are looking for, and furthermore to produce an information strategy, as requested by the Parliament in Directive 2004/27/EC, before making any detailed and specific legislative proposals.

MEETING AIMS AND OBJECTIVES

8 These proposals assert some clear aims and objectives. For example:

- 'Maintaining the ban on direct-to-consumer advertising'
- 'Reducing the differences in access to information'
- 'Avoiding unnecessary bureaucracy'

In our view, the specific details of this proposal will work against the successful attainment of these aims and objectives.

Maintaining the ban on direct-to-consumer advertising

9 Our analysis of these legal proposals leads us to believe that their success or failure will hinge on working with a distinction between advertising prescription-only medicines, and providing 'non-promotional information' about these products. Such a distinction would be essential for the Commission to maintain its position, which we endorse, that the ban on direct-to-consumer advertising of prescription-only medicines should continue.

10 Current pharmaceutical legislation offers some examples of what 'advertising of medicinal products' includes, but in our view it does not provide a definition of advertising. Other EU directives use other definitions of advertising, suggesting it is very difficult to work with a single, accepted definition.

11 We would suggest that in the absence of an agreed definition of advertising it is impossible to work with a framework, as stated by the proposal that 'basically, communication not covered by the definition of advertisement, should be regarded as information'.

12 These proposals suggest that pharmaceutical companies would be permitted to 'push' information directly to consumers, as patients, through TV, radio, printed media and other channels. In the absence of consensus on the distinction between information and advertising, we believe this is nearly identical to the examples of advertising in Article 86 of 2004/27/EC, and in practice these proposals will allow exactly the direct-to-consumer advertising it is seeking to prohibit.

13 The Commission should not be proposing to change legislation on the promise of a distinction — it is essential that the pre-work and analysis of an advertising—information distinction is done, at least to see if such a distinction can be agreed and is feasible in this context — before proposing

it as the basis for legislative change. Such work was recommended by the G10 group, but as yet the Commission has failed to act.

14 We are concerned that such a policy line is impractical and will lead to considerable and distracting confusion as arguments ensue about whether material is advertising or information. At worst these proposals will, in practice, effectively undermine the ban on direct-to-consumer advertising.

15 Given this, it is impossible to see how the Commission's explicitly stated policy objective to preserving the ban on direct-to-consumer advertising of prescription-only medicines, which we wholeheartedly support, can be sustained.

Reducing the differences in access to information

16 The Commission states that a fundamental aim of the legal proposal is to provide rules that harmonise practices on information provisions to patients. We agree that the variety of current practices seen in member states would be a cause for concern. However, with regards to the proposal to establish new co-regulatory bodies in each member state to monitor and oversee the framework, such harmonisation will be impossible to achieve in practice. National reinterpretation of key aspects of the plans, such as the quality principles, and the lack of a workable distinction between advertising and information will act against this goal.

Avoiding unnecessary bureaucracy

17 The legal proposal also seeks to avoid unnecessary bureaucracy. However, on examining the detail this is hard to justify when the Commission proposes each member state supports the proposed framework with a new co-regulatory body with a very limited range of available sanctions, backed by competent authorities (the medicines regulators) in each member state, further supported by a new EU Advisory Committee. The plans for a three-tier system of overlapping remits between national and EU bodies, coupled with national reinterpretation in a potentially confusing policy framework of distinctions and principles that can be very subjective and difficult to define, will be far from burden-free.

MAKING REAL IMPROVEMENTS TO MEDICINES INFORMATION

18 We fully support the drive for more and better information for consumers about health, disease, treatments and medicines via education about health promotion and prevention as well as information about medicines.

19 We also believe that any European-level action around information to patients should seek to add value, to consumers, health professionals and national bodies, and not compromise this situation with potentially confusing developments.

20 We urge the Commission to adopt a consumer-centred approach to solving the problems of lack of harmonisation and unequal access across the European Union and in making proposals and devising an information strategy, building on successful approaches that are already indicated by research or experience.

21 These proposals state they are putting the interests of patients first, but we would question this. For example, recent research by Northumbria University has shown that consumers are reluctant to use pharmaceutical industry websites: Professor Pamela Briggs commented that, '… people question the authors' motivation and agenda. The issue of impartiality is quite crucial in building trust.'[ii]

22 Research carried out for Which? in 2002 found that of all the sources we asked about (GP, hospital doctor, pharmacist, NHS Direct, patient or voluntary group (local or national), internet, drug company) drug companies were considered the least trustworthy. Thirty-one per cent said they thought drug companies were trustworthy sources of information, compared to 92 per cent who felt GPs were trustworthy sources.[iii]

23 Given what is known about consumers' mistrust of information provided by the pharmaceutical industry, we strongly question the Commission's approach in these proposals.

24 Which? believes that added value at the European level would be delivered through a programme of work that combines the strength of European expertise in medicines regulation – through the data collected by European Medicines Agency (EMEA) – and in raising standards, developing the concept of the quality principles to raise the abilities of other organisations to deliver high-quality information for patients.

25 Using the existing legal framework, we urge the Commission to consider a number of alternative policy actions:

- enable the EMEA to be a central and impartial source of information about medicines

- make statutory information equally available, on-line and off-line, in all Member States
- take forward the 2005 recommendation of the EU's Health Policy Forum for a comprehensive mapping exercise to identify all initiatives and policies on health information
- conduct an EU-wide survey on consumers' information needs around medicines from all sources, not just the industry.

Only when armed with a real overview of the situation, and consumers' needs across the EU, should proposals be tabled, and can the Commission confidently claim their actions are taken with consumers', as patients, needs in mind.

26 If legal changes are to be considered we would strongly argue that the Commission should seek to improve the provision of statutory information, especially the form, style and content of patient information leaflets as recommended by Which? in *Patient information: what's the prognosis?* and the report, *Always read the leaflet*, published by the UK's Medicines and Healthcare products Regulatory Agency.[iv] This action should include:

- A commitment to continual improvement in patient information leaflets, beyond the strict demands of regulation, based on experience of user testing and evidence gathered from independent research.
- Improvements in content and presentation of patient information leaflets, changing the order of information, improving information on side effects, headlining key messages, providing short statements on benefits and risk.
- Improving access for those consumers who currently have difficulty using traditional patient information leaflets, for example children and young people, and those with specific communication needs.
- Providing consumers with easy access to patient information leaflets through the EMEA website and the EU health portal (http://ec.europa.eu/health-eu/index_en.htm)

For further information please contact Kate Webb, Principal Policy Adviser (kate.webb@which.co.uk)

References

[i] MHRA. Always read the leaflet. 2005

[ii] ESRC press release: Prescriptions for health advice online. Published 7 March 2007. http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/PO/releases/2007/march/health.aspx?ComponentId=1864

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[iii] Which? surveyed 1818 adults aged 15+ in Great Britain in April 2002. Results were weighted to be representative of GB adults aged 15+.

[iv] Consumers' Association. Patient information: what's the prognosis? 2003; MHRA. Always read the leaflet. 2005