EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 19 October 2007
ENTR/F/2/RSI/lc D(2007) 34327

DRAFT REPORT ON CURRENT PRACTICE WITH REGARD TO PROVISION OF INFORMATION TO PATIENTS ON MEDICINAL PRODUCTS

in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use

Summary of the public consultation responses

This document summarises responses from the public and stakeholders to DG Enterprise and Industry's public consultation on the above document conducted between 19 April and 30 June 2007.

Responses received can be grouped into the following categories:

(a) Patient organisations;

(b) Consumer and citizen organisations;

(c) Pharmaceutical industry organisations and companies;

(d) Healthcare professional organisations;

(e) Regulators;

(f) Individual citizens;

(g) Social insurance organisations;

(h) Media and others.

In Appendix I a full list of all respondents is provided.

Breakdown of Responses

In total, 73 responses were provided. The breakdown of these responses by type of respondent is shown in the table below.

Category	Number of responses
Patient organisations	14
Consumer and citizen organisations	4
Pharmaceutical industry organisations and companies	18
Healthcare professional organisations	16
Regulators	9
Individual citizens	3
Social insurance organisations	2
Media and others	7
Total	**73**

Individual responses varied from short emails or letters to more in-depth papers.

Patient Organisations

1.1 Views from patient organisations varied. Many of these responses were broadly supportive of the draft report, although a few were critical.

1.2 All respondents in this category appeared to be in favour of improving information provision to patients, and nearly all of those that commented on the issue were opposed to direct-to-consumer advertising. An exception was a contribution recommending that direct-to-consumer advertising should be allowed, albeit with a good validation mechanism.

1.3 Patient organisations were generally supportive of allowing the pharmaceutical industry a greater role in the provision of information with reasons given including that industry has the best knowledge of its products. However, there were a few respondents who were opposed.

1.4 While responses generally recognised the Internet to be an important channel of communication, several highlighted the fact that not everyone has Internet access and that other channels of communication should be considered as well.

1.5 Most responses which commented on the issue saw some sort of role for the Commission in improving information provision, although there was no consensus as to whether or not new EU legislation was necessary.

1.6 Other points made included the importance of health literacy and the potential role that patient organisations could play in providing information.

Consumer and Citizen Organisations

1.7 Responses were received from two consumer organisations and two citizen organisations.

1.8 All the responses were in favour of improving information provision to patients, and all those who commented on the issue were opposed to direct-to-consumer advertising.

1.9 In general, consumer organisations did not support the views in the draft report whereas the citizen organisations were neutral or supportive.

1.10 The two consumer organisations expressed opposition to the pharmaceutical industry as a source of patient information. In contrast, one of the citizen organisations argued that pharmaceutical companies should be given greater freedom to provide information on the grounds that they have the best knowledge of their products.

1.11 In general, responses were cautious about relying on the Internet as the only channel for providing information to patients.

1.12 One citizen organisation sent the results of a survey of 114 civic organisations from 24 countries which gathered their views on the provision of medicines information to patients.

Pharmaceutical Industry Associations and Companies

1.13 Responses were received from both pharmaceutical industry associations and individual pharmaceutical companies.

1.14 Responses in this category were generally supportive of the draft report, although a few criticised the absence of concrete proposals for an information strategy.

1.15 The pharmaceutical industry is strongly in favour of improving information provision to consumers, and sees the pharmaceutical industry as a legitimate source of information. Views expressed by respondents in this category included the view that the quality of information was more important than the source, and that the pharmaceutical industry has greater knowledge of the medicines which it produces than anyone else. On the other hand, all of the respondents in this category which mentioned the issue stated that they were against the introduction of direct-to-consumer advertising in the EU.

1.16 Many of the responses from the pharmaceutical industry were in favour of self-regulation, with some responses stating that self-regulation has been proven to be effective. However, one company suggested an alternative approach in which information provision would be monitored by an independent panel.

1.17 Views were divided on whether there was a clear distinction between information and advertising, with some suggesting the distinction is something which needs to be clarified.

1.18 Generally, responses in this category saw a need for new legislation at EU level. For instance, one company believes that legislative proposals are needed to lift current legal barriers to the provision of health information, and one industry association suggests legislative amendments to allow users to access more information through the outer packaging of non-prescription medicines. However, another industry association argued that there was no need to change European legislation on information provision or advertising but to focus on its implementation.

Healthcare Professional Organisations

1.19 Responses were received from a range of bodies, including organisations representing doctors, pharmacists, nurses and medical students.

1.20 Overall, attitudes to the Commission's draft report were mixed, with some responses offering support and others taking a critical stance.

1.21 All responses in this category were in favour of improving information provision and (where the issue was mentioned) against relaxing the prohibition on direct-to-consumer advertising.

1.22 Several responses expressed opposition to giving the pharmaceutical industry greater freedom to provide information. Others offered qualified support – for instance, provided that strict regulatory controls were in place. Of those responses which mentioned the issue of industry self-regulation, nearly all were opposed. However, one response accepted a role for self-regulation alongside other enforcement mechanisms.

1.23 Generally, healthcare professionals did not think that there was a clear distinction between information and advertising.

1.24 Responses typically supported the use of the Internet, but saw a need to use other channels of communication as well, given the fact that not everyone has internet access.

1.25 Views were fairly evenly divided on whether or not there was a need for new EU legislation.

1.26 Other points made by responses in this category included the primacy of the interaction between patients and healthcare professionals, and the role of health literacy. One respondent argued that nurses should have the same access to information as physicians and pharmacists.

Regulators

1.27 A few responses in this category consisted purely of suggested corrections to some of the factual information in the Commission's draft report. Others offered more substantive comments on the policy issues raised by the consultation.

1.28 Among those respondents who addressed the substantive policy issues, there were mixed reactions to the Commission's draft report, ranging from supportive to critical.

1.29 There was general agreement that information provision to patients should be improved, while retaining the current prohibition on direct-to-consumer advertising. However, regulators in different Member States had widely differing views on how best to improve information provision. On the one hand, several responses supported greater information provision by the pharmaceutical industry, with one contribution going further and expressing support for industry self-regulation in the case of non-statutory information. On the other hand, some other regulators were opposed to a greater role for industry in providing information to patients.

1.30 Generally responses in this category did not comment on whether new EU legislation is needed, although one respondent took the view that no legislative change was necessary.

1.31 A Member State stated that it could not accept any form of prior control of information material by national authorities as this would be considered censorship and thereby a constitutional infringement.

Individual Citizens

1.32 There were three responses in this category.

1.33 Two of the respondents are critical of the draft report and argue against considering the pharmaceutical industry as a source of patient information. The third respondent focuses on the pharmaceutical industry as a source of information to doctors rather than patients.

1.34 One of responses argues that the draft report is out of line with the position adopted by the European Parliament in 2003 during the revision of European legislation on medicines.

1.35 The one the response which commented on the issue was cautious about relying on the Internet to provide information.

Social Insurance Organisations

1.36 Only two responses were received in this category, one from a national organisation and another from a European organisation representing 32 organisations in 13 different Member States.

1.37 One response is very critical of the Commission's draft report, claiming that the draft report is of poor quality, lacks transparency, lacks accessibility and is not unbiased, neutral nor balanced. It argues that the draft report overemphasises the benefits of more information and fails to fulfil the obligation in Article 88a of Directive 2004/27/EC to examine the risks of information.

1.38 The same respondent is strongly in favour of retaining a strict ban on direct-to-consumer advertising, and does not see any need to change current EU legislation. Instead, it recommends that the Commission should:

(a) Improve awareness and access to existing sources of high-quality, evidence-based and patient-centred information.

(b) Set up a network of competent authorities in Member States to exchange good practices and existing information.

(c) Undertake a feasibility study for setting up a national or European label for good quality information.

1.39 The other response in this category criticises the draft report for discussing the provision of health information in general, rather than focusing on the specific question of information on medicines. It also argues that information provided by the pharmaceutical industry is by definition promotional in nature.

Media and Others

1.40 This category contained a mix of respondents, comprising:

(a) Five organisations dedicated to the dissemination of health information;

(b) Two organisations representing magazine publishers.

1.41 Responses in this category varied in their attitude on the draft report, with some offering qualified support and others voicing criticism.

1.42 All responses were supportive of improving information provision to consumers. At the same time, nearly all of the respondents which commented on the issue of direct-to-consumer advertising were opposed to any relaxation of the current ban.

1.43 Several of the responses in this category were in favour of the pharmaceutical industry acting as a source of information, with some going further and voicing support for industry self-regulation.

1.44 Those responses in this category which commented on the issue did not see a clear distinction between advertising and information.

1.45 The responses from the two organisations representing magazine publishers emphasise the benefits of print media as a channel for communicating information to patients, and argue against relying exclusively on the Internet.

APPENDIX 1: LIST OF RESPONSES

	Respondent
Patient organisations	
1	Alliance for Health and the Future
2	Alzheimer Europe
3	Association des malades des syndromes de Lyell et de Stevens-Johnson (AMALYSTE)
4	European Cancer Patient Coalition (ECPC)
5	European Heart Network (EHN)
6	European Organisation for Rare Diseases (EURODIS)
7	European Patients' Forum (EPF)
8	European Public Health Alliance (EPHA)
9	Finnish Diabetes Association
10	Health Action International Europe (HAI)
11	International Diabetes Federation (IDF)
12	International Patient Organisation for Primary Immunodeficiencies (IPOPI)
13	Picker Institute Europe
14	Scottish Association for Mental Health (SAMH)
Consumer and citizen organisations	
15	Active Citizenship Network (ACN)
16	European Consumers Organisation (BEUC)
17	German Seniors League
18	Which?
Pharmaceutical industry organizations and companies	
19	Amgen
20	Association of the British Pharmaceutical Industry (ABPI)
21	Association of the European Self-Medication Industry (AESGP)
22	Agipharm
23	AstraZeneca
24	European Association for BioIndustries (EuropaBio)
25	European Federation of Pharmaceutical Industries and Associations (EFPIA)
26	European Generic Medicines Association (EGA)
27	Europharm SMC
28	French Pharmaceutical Companies Association (Leem)
29	GlaxoSmithKline (GSK)
30	Irish Pharmaceutical Healthcare Association (IPHA)
31	Johnson and Johnson
32	Novartis
33	Pfizer

	Respondent
34	Pharmaceutical Research and Manufacturers of America (PhRMA)
35	Roche
36	Sanofi Aventis
Healthcare professional organisations	
37	Austrian Medical Chamber (ÖÄK)
38	British Medical Association (BMA)
39	CEPLIS Health Working Group
40	European Association of Hospital Pharmacists (EAHP)
41	European Health Management Association (EHMA)
42	EMEA Human Scientific Committees' Working Party with Patients and Consumers' Organisations (PCWP)
43	European Medical Students' Association (EMSA)
44	European Society for Medical Oncology (ESMO)
45	European Respiratory Society (ERS)
46	International Federation of Nurse Anesthetists (IFNA)
47	Model Group
48	National Council of Pharmacists
49	Pharmaceutical Group of the European Union (PGEU)
50	Royal College of Nursing (RCN), UK
51	Royal Pharmaceutical Society of Great Britain
52	Standing Committee of European Doctors (CPME)
Regulators	
53	The Bavarian Department of State for Environment, Health and Consumer Protection
54	Federal Institute for Drugs and Medicinal Devices (BfArM) in co-operation with Paul-Ehrlich-Institut (PEI), Federal Office of Consumer Protection and Food Safety (BVL) German Institute of Medical Documentation and Information (DIMDI) and German Ministry of Health
55	French Health Products Safety Agency (Afssaps) and French Association of People Suffering from Obsessive Compulsive Disorder (AFTOC)
56	German Ministry of Health
57	Medicines and Healthcare Products Regulatory Agency (MHRA), UK
58	Medical Products Agency, Sweden
59	Ministry of the Interior and Health, Denmark
60	National Authority of Medicines and Health Products (INFARMED, IP), Portugal
61	Norwegian Medicines Agency, Section for Pharmacovigilance
Individual citizens	
62	Anne Ferreira
63	Carlo Piria
64	Lindy Williams, PhD
Social insurance organisations	

	Respondent
65	European Social Insurance Platform (ESIP)
66	Main Association of Austrian Social Security Institutions
Media and others	
67	Association of German Magazine Publishers (VDZ)
68	Cambridge Health Informatics
69	Datapharm Communications
70	European Federation of Magazine Publishers (FAEP)
71	Health Communications Council (HCC) of European Association of Communications Agencies (EACA)
72	Health Library Group (HLG)
73	TeleSana