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Consumer goods
Pharmaceuticals

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KEU IDEAS OF A LEGAL PROPOSAL ON INFORMATION TO PATIENTS

SUMMARY OF THE PUBLIC CONSULTATION RESPONSES

Introduction

The European Commission is preparing a legal proposal on information to patients to ensure good-quality, objective, reliable and non-promotional information on prescription-only medicinal products to citizens and to harmonize the existing situation in Member States in this area.

DG Enterprise and Industry launched on 5 February 2008 a public consultation on the key ideas of the forthcoming legal proposal. Contributions were invited until 7 April 2008.

This report gives a summary of the comments to the public consultation.

Responses received can be grouped into the following categories:
- Healthcare professionals and organisations
- Patient organisations
- Regulators
- Pharmaceutical industry organisations and companies
- Research and others
- Consumer organisations
- Media and patient information organisations
- Social insurance organisations

In Annex 1 there is a full list of all contributions provided. The individual responses of those respondents who did not make a specific request for confidentiality will be published on the "Pharmaceuticals" website.

Breakdown of responses

We were provided with 185 responses and in addition, we received 7 supportive comments. Total, we were provided with 192 contributions. The breakdown of the responses by type of respondent is shown in the Table 1.

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Table 1: Breakdown of responses

Category	Responses	
	n	%
Healthcare professionals and organisations	59	32
Patient organisations	40	22
Regulators	28	15
Pharmaceutical industry organisations and companies	26	14
Research and others	10	5
Consumer organisations	9	5
Media and patient information organisations	7	4
Social insurance organisations	6	3
Total	**185**	**100**

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

About a third (32%) of the responses came from healthcare professionals and about a fifth (22%) came from patient organisations. The category "Research and others" covers, for example, responses from research organisations and citizens.

General overview of the responses

There was an overall consensus that there is a need to provide citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their prescription-only medicines. The great majority of the respondents had a view that the ban on direct-to-consumer advertising of prescription-only medicines should be maintained, making sure that there is a clear distinction between advertising and non-promotional information. However, it was agreed that such a distinction is not easy to establish.

The respondents agreed that unnecessary bureaucracy should be avoided, in line with the principles of Better Regulation. It was also acknowledged in general, that there is a need to harmonize the existing situation in Member States in the provision of patient information of prescription-only medicines.

Many of the respondents focused on patient information in general, not only about prescription-only medicines, which was the focus of the public consultation. The problems related in the current situation of patient information were discussed in many responses. Considering information about prescription-only medicines, the two most highlighted issues were the role of pharmaceutical companies as information providers and the role of TV and radio in disseminating the information.

Information provision

One of the key ideas would be to clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. The respondents had mixed views on this issue (Table 2).

Almost half (48%) of the respondents had a view that pharmaceutical industry is not an appropriate source of prescription-only medicine information in general, mainly because there may be a conflict of interest relating to the financial interests. The payers (social institute organisations) and healthcare professionals were mostly suspicious, while responses from media and patient information organisations and pharmaceutical industry mostly supported pharmaceutical companies as information providers. Some (14%) of the contributors had a view that if there would be a clear distinction between advertising and information, pharmaceutical companies would be a valuable source of prescription-only medicine information, because they know the product.

However, while the majority of the respondents did not accept pharmaceutical companies as providers of general information, they did agree that the companies could be allowed to disseminate information that is approved by authorities (e.g. summaries of product characteristics and patient information leaflets).

Table 2: Overview of the respondents' comments regarding pharmaceutical industry as an information provider about prescription-only medicines.

Category	Pharmaceutical industry as a provider of prescription-only medicine information			
	Yes (%)	No (%)	Mixed (%)	No comment (%)
Healthcare professionals and organisations	7	70	15	8
Patient organisations	25	50	10	15
Regulators	11	46	29	14
Pharmaceutical industry organisations and companies	96	0	0	4
Research and others	20	30	0	50
Consumer organisations	0	56	44	0
Media and patient information organisations	72	14	0	14
Social insurance organisations	0	100	0	0
Total	**26**	**48**	**14**	**12**

*"**Yes**" refers to opinions that highlighted the role of pharmaceutical companies as information providers, because, for example, nobody knows the product better than its producer*
*"**No**" refers to opinions that declined the role of pharmaceutical companies as information providers, because, for example, the information that comes from the producer can not be neutral*
*"**Mixed**" refers to responses that accused that there is a lack of a coherent distinction between advertising and information*
*"**No comment**" refers to responses that did not take out this issue*

"Push" and "pull" information

In the public consultation document, there was a distinction between the cases where the patient was passively receiving the information ("push") or actively searching for the information ("pull"). This came particularly out in an issue to disseminate information on prescription-only medicines through different channels.

TV and radio

Among the responses, only seven per cent supported TV and radio as channels to disseminate information about prescription-only medicines (Table 3). A majority (36%) of the contributors – including pharmaceutical industry – did not support TV and radio. According to their opinions, TV and radio would not be suitable channels because of the nature of the media. Information that passively comes to the patient, for example by TV and radio, would not be beneficial for the individual patient. Consumer and patient organisations highlighted the difficulties to make a distinction between advertising and information and the possibility to misuse TV and radio in information provision.

Respondents from media and patient information organisations supported TV and radio as useful channels to disseminate the information. However, about half (52%) of the respondents did not give their comment on this issue.

Table 3. Overview of the respondents' comments regarding TV and radio as channels to disseminate information about prescription-only medicines.

Category	TV and radio as channels to disseminate information about prescription-only medicines			
	Yes (%)	**No (%)**	**Mixed (%)**	**No comment (%)**
Healthcare professionals and organisations	3	36	2	59
Patient organisations	7	38	5	50
Regulators	0	23	24	53
Pharmaceutical industry organisations and companies	19	50	0	31
Research and others	11	22	0	67
Consumer organisations	0	44	56	0
Media and patient information organisations	25	0	12	63
Social insurance organisations	0	67	0	33
Total	**7**	**36**	**5**	**52**

*"**Yes**" refers to comments that considered TV and radio as valuable channels in information provision of prescription-only medicines*
*"**No**" refers to comments that had views that TV and radio would not be suitable*
*"**Mixed**" refers to comments that highlighted the advantages of this media but also disadvantages considering their nature*
*"**No comment**" refers to contributions that did not take out this issue*

Printed media and the Internet

In some responses, the printed media as a channel of disseminating information was compared to TV and radio. It can be misused, but also be a valuable source for patients who have no possibilities to use the Internet.

According to the responses, the role of the Internet will increase. Internet offers many advantages from the perspective of availability, reach and price.

It was highlighted that patients in the EU should have the possibility to get good quality information about the treatment, including medicines, also by the Internet. As well, industry should be allowed to provide information on prescription-only medicines to patients who actively seek it. According to the responses, this could mean that information about a specific medicine should be available on the company website in a format that can be downloaded and this should be monitored by relevant authorities. However, especially patient organisations highlighted that it should be ensured that there would not be unnecessary restrictions on people accessing information on the Internet.

Content of the information

It was agreed that pharmaceutical companies should be allowed to publish summaries of product characteristics (SPCs) and patient information leaflets (PILs) for example on their websites. Considering disseminating of other limited medicine-related information, many respondents especially among healthcare professionals and regulators had a view that this information from the industry could be focused on new medicinal products since stronger economic interests exist in these. Information about ongoing studies shall by no means be communicated to the public, as they are likely to create massive uncertainty in patients. Also a further clarification with regards to the content of other-medicine related information, including scientific studies, was applied.

It was mainly agreed that information to patients should not be able to go beyond the key elements specified in the regulatory documents. However, responses from media and patient information organisations mostly highlighted that information to patients should be able to go beyond the key elements, as long as this reflects a clear clinical consensus. They questioned the benefit of producing further information if it cannot present anything different than that already contained within PILs.

Pharmaceutical companies proposed the following categorization of the non-promotional information:

1) "Pro-active information" ("Push"), which is provided unsolicited to the public, should be limited to general information on diseases, e.g. covering awareness, prevention etc. but not mentioning specific medicines.
2) "Reference information" on diseases and medicines ("Pull"), which is sought by patients and citizens as in a library, e.g. through the Internet.
3) "Reactive information" on medicines, which is supplied in response to spontaneous enquiries received from patients and citizens.
4) "Support information", which is supplied with or subsequent to a prescription for a specific medicine, e.g. to support concordance with the prescribed medicine.

Views considering the comparisons between products were mixed. On the one hand, pharmaceutical industry should not be allowed to provide information that compares different products, but on the other hand, comparisons could be very useful for patients and help them to take more responsibility of their health care.

Quality criteria

There was a consensus that criteria for ensuring a good quality of the information are needed. All the information provided to patients, not depending on the provider of the information, should fulfil the criteria.

Some additions to the criteria were proposed. Many responses highlighted that the criteria "unbiased" should be included separately. Consumer and patient organisations presented that the one of the most important criteria is that the information should be patient friendly. The criteria “understandable – can people find and understand the information they need” was proposed by healthcare professionals. As well, there should be a very clear reference to the source of the information.

Monitoring mechanism

It was suspected by regulators that the proposed mechanism for monitoring would create an amount of a new regulatory work. The system with co-regulatory mechanism can be costly and lead to different codes of conduct in the different Member States. The significance of the competent authorities in monitoring was highlighted especially by payers. Nevertheless, Member States should be free to decide what form, composition and executive powers the co-regulatory body – or any type of body – would have.

One of the most important tasks of the EU Advisory Committee could be to provide a model code of conduct using the quality criteria, upon which national models could be based. This came out mainly by consumer and patient organisations.

The EU Advisory Committee should be composed of key stakeholders, including in particular the representatives of the target users themselves – patients. However, especially according to responses by pharmaceutical industry, the proposed model could potentially lead to a "patchwork" of very different interpretations and implementations in national laws.

Other issues

It was agreed by the majority of the responses that healthcare professionals are and should be the first source of information to patients. Dialogue between health professionals and patients remain the central point. However, information about environmental issues considering medicinal products should also be available for patients.

Examples about ongoing public private partnerships in patient information were provided. Public private partnerships – were for example authorities and pharmaceutical industry are included – have been created for example in Sweden and in the United Kingdom. It was also suggested that other medicine-related information that could supplement the information by SPCs could be provided by public private partnerships where the overseeing bodies may define acceptable additional sources of evidence.

Annex 1. List of responses

Healthcare professionals and organisations

Acade'mie Nationale de Pharmacie, France
Association of Democratic Pharmacists, Germany
Austrian Chambre of Pharmacists
Austrian Medical Chamber, Austria
Barrera Linares Ernesto, Spain (not to be public)
Belgian Centre for Pharmacotherapeutic Information (BCFI)
Both Hans-Joachim, Holdorff Bernd
British Medical Association
British Pharmacological Society
Deymunck Hilde
Drug Commission of the German Medical Association
Dutch Institute for the Proper Use of Medicine
European Federation of Neurological Associations (EFNA)
European Hospital and Healthcare Federation (HOPE)
European Public Health Alliance (EPHA)
European Society for Medical Oncology (ESMO)
Evgenidis Dionissios, Greece
Executive committee of the Swedish Association of Clinical Pharmacology and the Department of Clinical Pharmacology in Sahlgrenska University Hospital, Sweden
Federal Union of German Associations of Pharmacists (ABDA), Germany
Finnish Pharmacists' Association
Gemeinsamer Bundesausschuss (Joint Federal Committee), Germany
German Network for Evidence-based Medicine
German Society of Social Medicine and Prevention
Guild of Healthcare Pharmacists (GHP), UK
Health Care Without Harm Europe
Heller Francis, Belgium
International Federation of Anthroposophic Medical Associations (IVAA)
Jonitz Gunter, Germany
Keeley Duncan, UK
Latvian Hospital Ass.
Lehmkuhl Dieter, Germany
M.K. Laker, UK
Madurga Sanz Mariano, Spain
Márquez-Calderón Soledad, Spain (no to be public)
Mintzes Barbara, Canada
National Association of Pharmacies (ANF), Portugal
Neonatal & Paediatric Pharmacists Group (NPPG), UK
Odre National des Medicines, France
Pareskivi Sakka (Athens Alzheimer's Association)
Penkkila Kari, Finland
Pettit-Mills Richard, UK
Pharmaceutical Group of the European Union (PGEU)
Raynor DK Theo, UK
Royal College of General Practitioners, UK

Royal College of Nursing (RCN), UK
Royal College of Physicians of Edinburgh, UK
Royal College of Physicians, UK
Royal College of Psychiatrists, UK
Royal Dutch Medical Association (KNMG), The Netherlands
Royal Pharmaceutical Society of Great Britain
Sidiropoulou Anna, Greece
Standing Committee of European Doctors (CPME)
Stockholm County Council and Apoteket AB, Sweden
Swedish Collegium of Chairmen of the Drug and Therapeutics Committees, Sweden
Swedish Medical Association
Vergnoux Odile, France
Williams Lindy
Wonca Europe

Patient organisations

AAA-VAM, France
AFTOC
AIM, HAI Europe, ISDB, Medicines in Europe Forum: Open Letter
Algemeen Syndicaat van Geneeskundigen van België (ASGB)
Alzheimer Europe
AMALYSTE, France
British Heart Foundation (BHF)
Deutsche Rheuma-Liga Bundesverband, Germany
Diabetes UK
European Cancer Patient Coalition (ECPC)
European Disability Forum (EDF)
European Federation of Crohn's and Ulcerative Colitis Associations
European Federation of Patients' Associations for Anthroposophic Medicine (EFPAM)
European Heart Network (EHN), supported by
- Italian Heart Foundation
- Finnish Heart Association

European Men's Health Forum
European Older People's Platform (AGE)
European Organisation for Rare Diseases (EURORDIS)
European Patients Forum (EPF)
- European Federation of Allergy and Airways Diseases Patients' Associations (EFA)

Family Planning Association (fpa), UK
Federation of Polish Patients
Finnish Diabetes Association
Flemish Patients Platform (VPP)
Gemeinsamer Bundesausschuss (G-BA, patient representatives), Germany
German Association of Self-Help Groups (DAG SHG)
German Pain League
German Seniors League
Health Action International (HAI)
International Alliance of Patients' Organizations
International Diabetes Federation European Region

International Patient Organisation for Primary Immunodeficiencies (IPOPI)
Irish Platform for Patients' Organisations, Science and Industry (IPPOSI)
Long-term Conditions Alliance (LTCA)
Mind, UK
National Coordination of Associations of the Chronically Sick (Cittadinanzattiva), Italy
Picker Institute Europe, supported by
- Plamping Diane, PhD
- Griffith David, MB FRCP
Polish Diabetes Association
Public and Patient Involvement (PPI) Forum
Swedish Rheumatism Association
UNIAMO, Italy
ZoZie Patient Advocacy, The Netherlands

Regulators

Austrian Ministry of Health, Family and Youth
Dutch authorities
European Medicines Agency (EMEA)
Federal Agency for Medicines and Health Products, Belgium
Federal government, Germany
German Federal Environment Agency
French authorities
Icelandic Medicines Control Agency
Infarmed, Portugal
Irish Medicines Board (IMB) (not to be public)
Italian Medicines Agency
Medical Products Agency (MPA), Sweden
Ministerio de Sanidad y Consumo, Spain
Ministry for Health and Prevention, Denmark
Ministry of Health of the Republic of Latvia
Ministry of Health, Hungary
Ministry of Health, Welfare and Sport, The Netherlands
Ministry of Social Affairs and Health, Finland
National Health Service (NHS), UK
Non-EEA Regulatory Agency (not to be public)
Norwegian Medicines Agency
Regional Drug and Therapeutic Committee in Stockholm (Läksak), Sweden
Regionala läkemedelsrådet I Västra götalandsregionen, Sweden
Senate Department for Health, the Environment and Consumer Protection of the land of Berlin, Germany
State Instuitute for Drug Control of the Czech Republic
Swedish Associations of Local Authorities and Regions
Swedish Council on Technology Assessment in Health Care
UK Government

Pharmaceutical industry organisations and companies

Amgen
Association of International Pharmaceutical Research Group (AGIPHARM)
Association of the British Pharmaceutical Industry (ABPI)
Association of the European Self-Medication Industry (AESGP)
AstraZeneca
Baxter
Biogen Idec
European Association for Bioindustries (EuropaBio)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
European Medicines Group (EMG), UK
French Pharmaceutical Companies Association (LEEM)
Genzyme
GlaxoSmithKline
H. Lundbeck A/S
Irish Pharmaceutical Healthcare Association (IPHA)
Johnson & Johnson
Merz
Nefarma
Novartis (not to be public)
Pfizer
Pharmaceutical Reseaech and Manufactures of America (PhRMA)
Plasma Protein Therapeutics Association (PPTA)
Procter & Gamble Pharmaceuticals
Roche
Sanofi Aventis
Shire

Research and others

Below Detlef, Germany
BUKO Pharma-Kampagne (supported by IPPNW, Germany)
Cancer Research, UK
European Pharmaceutical Law Group
Good Clinical Practice Alliance (GCPA)
Steinbrueck HJ, Germany
Surridge Avril, UK
Task-force in Europe for Drug Development for the Young (TEDDY)
van der Waarde Karel, Belgium
Vapaavalta Teppo, Finland

Consumer organisations

Altroconsumo, Italy
BEUC
Consumer Centre Federal association, Germany
Consumers International

European Research into Consumer affairs (ERICA)
Finnish Consumers' Association
Health Consumer Powerhouse
Swedish Consumers Association
Which? UK

Media and patient information organisations

Consumation, UK
Datapharm Communications, UK
European Federation of Magazine Publishers (FAEP)
Health Communications Council (HCC) of the European Association of Communications Agencies (EACA)
Medicines Information Project (MIP), UK
Patient Information forum (PiF)
Verband Deutscher Zeitschriftenverleger (VDZ), Germany

Social insurance organisations

Association Internationale de la Mutualite (AIM), supported by
- General Health Insurance Company, Slovakia
- Dutch Health Care insurers

Der Paritätische Gesamtverband, Germany
Finnish Social Insurance Institution
Main Association of Austrian Social Security Institutions
National Federation of Mutual Insurance Societes in France
The European Social Insurance Platform and the Medicine Evaluation Committee (MEDEV) of the European Social Health Insurance Forum