

Pre-meeting document

**Prevention and control of viral hepatitis: the
role and impact of patient and advocacy
groups in and outside Europe.**

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Introduction:

Scientific publications dealing with the role and impact of patients groups are scarce, if the focus is limited to liver or viral hepatitis patient groups almost nonexistent. As lessons can be learned from other fields the literature search, results presented in part I of this background document, was not restricted to viral hepatitis or prevention.

Part I provides selected abstracts from a ERL WebSPIRS search on **(patient adj association?) or ((patient adj group?) and (advocacy)) or (patient adj organi*ation)** in Health Sciences and Social Sciences and Humanities Databases and a ISI Web of Knowledge search on **("patient organi?ation" OR "patient association" OR "patient movement") AND (advocacy OR support OR policy OR "public health")**.

Abstracts are ranged per year of publication, from recent to old, and within each year in reversed alphabetical order of the first author.

In Part II a copy of recent Viewpoints on Patient organizations and public health by M Naiditch and Patient organizations and prevention in the Netherlands by I Van Bennekom Stompedissel are enclosed. Also a copy of the **European Federation of Pharmaceutical Industries and Associations: EFPIA code of practice on relationships between the pharmaceutical industry and patient organizations** is attached.

PART I

M. Vermeulen and J. Bouma. Invloed van de farmaceutische industrie in patientenverenigingen. [The influence of the pharmaceutical industry in patient organisations]. *Ned Tijdschr Geneeskd.* 2007; 151(44):2432-4

Most patient organisations have no objection to sponsoring by the pharmaceutical industry. Only 5% of all organisations are against sponsoring. When patient organisations were asked whether or not their activities could continue without sponsoring, 42% answered no, 6% yes, and 52% felt that they might continue, but restricted. In a report of the public health inspector on the subject, transparency is considered to be a remedy for the entanglement between patient organisations and the pharmaceutical industry. However, the authors doubt that this is effective. The government should provide sufficient support for patient organisations so that they can become independent from the industry.

I. van Bennekom Stompedissel. Patient organizations and prevention in the Netherlands. *Eur J Public Health.* 2007; 17(6):545 (see Part II of this document)

D. Stakisaitis, I. Spokiene, J. Juskevicius, K. P. Valuckas and P. Baiardi. Access to information supporting availability of medicines for patients suffering from rare diseases looking for possible treatments: the EuOrphan Service. *Medicina (Kaunas).* 2007; 43(6):441-6

Currently in Europe, approximately 30 million people suffer from rare diseases, and a major problem is that many patients do not have access to quality healthcare for their disorders. Moreover, there is also a lack of quality information and a networking system aimed at supporting interaction among patients, clinicians, researchers, pharmaceutical industries, and governmental bodies. The purpose of this article is to inform physicians, public health care professionals, and other health care providers about EuOrphan service, the aim of which is to ensure easier access to quality information on rare diseases and their treatment. A set of web-based services is available at www.euorphan.com where information for target-users on treatments and products available worldwide for rare disease care as well as indications about healthcare centers are provided. Moreover, the service aims at providing consultancies for pharmaceutical companies to ultimately support the European legislation in bringing new drugs of a high ethical standard to the market and to exert a positive impact on the large population of patients suffering from rare diseases in Europe. The services provided by EuOrphan can facilitate concrete networking among patients, patient associations, doctors, and companies and also support the organization of

clinical trials. In this perspective, EuOrphan could become a very valuable tool for globalizing the information about the availability of treatment (authorized or under development) of orphan patients.

S. Sanger, F. Brunsmann, G. Englert, B. Quadder and G. Ollenschlager. Patientenbeteiligung am Programm für Nationale VersorgungsLeitlinien - Stand und Konsequenzen. [Participation of patients in the program for national disease management guidelines--current state and implications]. *Z Arztl Fortbild Qualitätssich.* 2007; 101(2):109-16

Patient involvement has been implemented in the Program for National Disease Management Guidelines since 2005. Currently patient/consumer participation is being incorporated in terms of patients' comments of consultation papers on National Disease Management Guidelines (NDMG) and in the development of NDMG-based patient guidelines (PG). The editorial activities in patient guideline development from the beginnings to its publication are conducted in close cooperation with the patient representatives appointed by the Patient Forum. Between June 2005 and September 2006, three NDMG and three patient guidelines on asthma, chronic obstructive pulmonary disease (COPD) and chronic coronary artery disease (CAD) were produced by including patients in the guideline development process. The information provided in these guidelines is freely accessible at <http://www.versorgungsleitlinien.de>. The present contribution focuses on the development of patient guidelines. It describes the current state of patient involvement and joint work and indicates the implications that can be derived from patient participation in the NDMG Program. Accompanying the involvement procedures, experiences resulting from previous NDMG and PG development activities are continuously investigated for the possibility of further methodological development of consumer participation by a work group of the Patient Forum in coordination with the patient organizations involved. In particular, the procedures resulting from more intensive patient participation in patient guideline development are to be examined as to their relevance for the expansion of patient involvement in NDMG development.

R. I. Overberg, L. L. Alpay, J. Verhoef and J. H. M. Zwetsloot-Schonk. Illness stories on the Internet: what do breast cancer patients want at the end of treatment? *Psycho-Oncology.* 2007; 16(937-944)
The study aims to elicit user requirements for internet-based applications disclosing fellow patients' illness stories for the benefit of breast cancer patients. Twenty-six breast cancer patients, recruited via the Dutch Patient Organization for Breast Cancer, were interviewed about their preferences with regards to content, appearance, and search options concerning fellow patients' illness stories online. The interviews were analysed quantitatively (SPSS) and qualitatively (NVivo). Participants were mainly interested in fellow patients' experiences about how to cope with emotions, the impact of cancer in daily life, and physical discomforts. Most participants preferred a section of an illness story in text format about a specific topic; some of them wanted to be able to click on to the corresponding complete story, comprising of text alone or supported by voice or video clip. A majority of participants wanted to be able to select illness stories on the basis of several authors' features, i.e. treatment underwent, age, presence of metastases, time since diagnosis, and whether or not caring for children. Participants gave arguments for their preferences. The findings of this study will be used for designing an online trial with breast cancer patients aiming at refining the user requirements. Copyright (C) 2007 John Wiley & Sons, Ltd.

O. O'Donovan. Corporate colonization of health activism? Irish health advocacy organizations' modes of engagement with pharmaceutical corporations. *International Journal of Health Services.* 2007; 37(711-733)

This article is based on a study that aimed to shed light on the "cultures of action" of Irish health advocacy organizations, and particularly their modes of engagement with pharmaceutical corporations. Debates about what some interpret as the "corporate colonization" of health activism provide the backdrop for the analysis. The empirical dimension of the study involved a survey of 112 organizations and in-depth study of a small number of organizations that manifest diverse modes of engagement with the pharmaceutical industry. The varying modes of interaction are plotted along a continuum and characterized as corporatist, cautious cooperation, and confrontational. Evidence is presented of a strong and growing cultural tendency in Irish health advocacy organizations to frame pharmaceutical corporations as allies in their quests for better health. The analysis of four constitutive dimensions of organizations' cultures of

action can reveal the legitimating logics underlying their diverging positions around pharmaceutical industry sponsorship. While the research shows that pharmaceutical corporations have largely succeeded in defining themselves as a philanthropic force and rightful players in Irish health activism, it cautions against a simplistic conclusion that this is evidence of corporate colonization.

M. Naiditch. Patient organizations and public health. *Eur J Public Health.* 2007; 17(6):543-5 (See Part II of this document)

C. Lavery and U. Ramaswami. Supporting the patient and family with mucopolysaccharidosis disorders: the role of patient organizations. *Acta Paediatr Suppl.* 2007; 96(455):87

A. Kent and C. Oosterwijk. A patient and family perspective on gene therapy for rare diseases. *J Gene Med.* 2007; 9(10):922-3

The authors describe the view of patients and patient organisations on gene therapy research and gene therapy regulations. In particular, the added value of partnership between scientists and patient organisations, and patient involvement in the gene therapy field, are addressed. Copyright 2007 John Wiley & Sons, Ltd.

T. Hudson and L. J. Denis. Europa Uomo: the European Prostate Cancer Coalition. *Recent Results Cancer Res.* 2007; 175(267-71

Europa Uomo is a patient-led, non-governmental association (NGO), launched formally in Milan in 2004 with a legal base in Antwerp. As a coalition of prostate cancer patient groups with representation in 18 European countries, the NGO focusses on awareness, early detection, optimal treatment, multi-professional care and, above all, quality of life and patient advocacy. In the majority of European countries prostate cancer is the most commonly diagnosed cancer affecting men beyond middle age. The incidence and substantial mortality rises with age, peaking in the seventh decade. Standards of diagnosis and treatment vary across Europe and attitudes differ. Information about the early detection and awareness of prostate cancer available to the public leaves much to be desired. Since 2002, involved individuals, patient support groups, patients, family members, physicians, urologists, oncologists and nurses joined in the formation of an independent, international, non-profit association of patient-led prostate cancer support groups from European countries known as Europa Uomo, the European Prostate Cancer Coalition. This Coalition was legally established as an NGO in June 2004 in Milan with the headquarters and secretariat in Antwerp, Belgium. Its membership represents 18 countries by the national or regional groups listed in Table 16.1 with their respective contact persons. The coalition is led by a steering committee under the control of the annual general assembly. The steering committee members and their co-ordinates are listed in Table 16.2. Scientific advice is given by a scientific committee chaired by Prof. H. Van Poppel as the liaison officer with the European Association of Urology (EAU). The support for EAU guidelines appears on the Web site and will be linked to all members in their own language (www.cancerworld.org/europauomo). The goals and activities of Europa Uomo have been condensed in a series of slides at the request of the Eurocan+Plus collaboration to facilitate international collaboration. These slides have been listed in Tables 16.3, 16.4 16.5, 16.6, 16.7, 16.8, 16.9, 16.10, 16.11, 16.12, 16.13 and 16.14. It should be noted that membership includes supporting activities for patients and adherence to our 10 objectives listed in the manifest (Tables 16.4-16.6). The bottom line is that the coalition focuses on peer-to-peer support, information and education, as well as partnership with professional associations. We in Europa Uomo hope to see the decrease in over-treatment and mortality of prostate cancer by the clinical activities, trials and research of the professional organizations. We have the great opportunity to be supported and sponsored by the European School of Oncology (ESO) and its director Dr. A. Costa. The European Society of Medical oncology (ESMO), the International Consultation of Urological Diseases (ICUD) and the International Prostate Health Council (IPHC) support our advice on scientific data. It is quite natural that all of our members have joined the European Cancer Patients Coalition (ECPC) to speak for all European patients with one voice. We are a young association but ambitious enough to launch several projects in addition to the Web site, such as the Prostate Passport, a

global coalition of patient support organizations, and a series of patient symposia. In this way we are able to show our support and collaboration with all health workers, including nurses, social workers, nutritionists and psychologists. We like to conclude this contribution with a list of questions to the experts from our participation in the 6th International Consultation of Urological Diseases (ICUD) symposium in Paris (Hudson et al. 2006).

C. Goss and C. Renzi. Patient and citizen participation in health care decisions in Italy. *Z Arztl Fortbild Qualitatssich.* 2007; 101(4):236-40

In recent years there has been a growing recognition in Western healthcare systems of the importance of considering preferences of patients and the public in tailoring health services and treatment plans. The active collaboration between doctor and patient has recently been encouraged through the shared decision-making model. Aim of the present contribution is to describe the current state of patient and public participation in healthcare in Italy. First, we will briefly outline the organization of the Italian National Health Service; second, we will describe the governmental and institutional initiatives regarding participation; third, some examples of associations and initiatives promoting patient participation will be provided; fourth, we will report on research projects on patient participation published in peer-reviewed journals; and finally, we will provide some examples on training activities promoting patient participation. The Italian National Health Plan and many regional and local health authorities in Italy explicitly recognize the importance of patient/citizen participation in healthcare decisions at the macro, meso and micro level of decision-making. However, application of a shared model is still at an early stage in Italy. The reported experiences have yielded positive results and have shown that particular attention should be dedicated to more disadvantaged subgroups of the population, involving patient organisations, enhancing patient/citizen knowledge and adopting approaches that take the specific context into account.

A. Coulter. Time for a change. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy.* Vol. 2007; 10(3):209-210

The first issue of *Health Expectations* appeared in June 1998. Since then we have published 36 issues containing more than 250 papers from around the world on a wide variety of topics. The theory and practice of shared decision-making and the use and effects of patient decision aids has been a very strong theme, but other issues such as lay involvement in service development and priority-setting, the activities of patient organizations, information and communications, and patient participation in research have attracted a large number of high quality submissions. We have learnt a great deal since the journal was launched. The task is not over, however. There are still many gaps in our collective knowledge and many opportunities for innovative research in this important field. We must pay greater attention to the problems of translating research evidence on shared decision-making into practical strategies for implementation in the real world of mainstream clinical practice. (PsycINFO Database Record (c) 2008 APA, all rights reserved) DOI: doi:10.1111/j.1369-7625.2007.00461.x

F. Brunsmann, R. von Gizycki, A. Rybalko, A. G. Hildebrandt and K. Ruther. Patientenselbsthilfe und seltene Erkrankungen : Mitgestaltung der Versorgungsrealität am Beispiel seltener Netzhautdegenerationen. [Patient participation in medical care, taking rare retinal degenerations as examples.]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz.* 2007; 50(12):1494-501
Eight rare retinal degenerations were chosen to exemplify self-organisation and involvement of patient self-help groups in medical care. They were studied and supported in their development on the following levels: disease-specific groups (level 1), patient organisations (level 2), umbrella organisation (level 3). Databases of defined needs and concerns ("Themenspeicher") of disease-specific patient groups and of patient organisations with respect to care, research and patient networking were established. Priority concerns were implemented in the following areas: specialised medical care; quality assurance; quality management; expert panel with international dialogue of patients and physicians (including consensus statement on treatment recommendations); glossary internet portal; criteria for patient-oriented disease descriptions; structured documentation of patient experiences; patient management of health care records (paper bound and electronic health records). Apart from disease-specific approaches, interdisciplinary disease approaches were also applied, e.g. by contributing to the establishment of the

German Alliance for Rare Diseases (ACHSE). This umbrella organisation has substantially improved chances for cooperation and patient advocacy. Patient participation was promoted by a federal regulation in 2004 ("Patientenbeteiligungsverordnung"). The example of rare retinal degenerations demonstrates the advantage of strong patient and umbrella organisations. Further development of qualified selfhelp resources is required for patient participation in rare diseases.

Y. Bartholomee and H. Maarse. Empowering the chronically ill? Patient collectives in the new Dutch health insurance system. *Health Policy*. 2007; 84(2-3):162-9

On January 1, 2006, the Dutch government instituted major reforms to the country's health insurance scheme. One of the features of the new system is the opportunity for groups to form collectives that may negotiate and enter into group contracts with health insurers. This article discusses one particular type of collective, namely patient collectives. The purpose of this paper is to investigate if, and to what extent, patient collectives empower chronically ill patients. The results of the study show that some patient groups were able to contract collective agreements with health insurers, whereas others were not. The eligibility of a group's disease for compensation through the risk equalisation fund (which subsidises the costs for many but not all disorders) seems to determine whether or not a patient organisation is able to successfully negotiate a collective contract for its members. Another key factor for success is the presence of a large membership whose constituents have similar healthcare needs. If both of these factors are present, insurers are more likely to develop specific products for particular groups of patients, as is the case for people with diabetes. Furthermore, the presence of patient collectives accords patient associations with a new role. It may be possible for them to become powerful players in the health insurance market. However, this new role may also lead to tensions, both within and between associations.

M. Wastfelt, B. Fadeel and J. I. Henter. A journey of hope: lessons learned from studies on rare diseases and orphan drugs. *J Intern Med*. 2006; 260(1):1-10

Rare diseases are frequently life-threatening or chronically debilitating and the impact on the quality of life of affected patients and their family members is thus significant. However, drug development for these conditions has been limited by a lack of understanding of the underlying mechanisms of disease and the relative unavailability of subjects for clinical trials, as well as the prohibitive cost of investing in a novel pharmaceutical agent with poor market potential. Nevertheless, the introduction of Orphan Drug legislations has provided important incentives for the development of orphan drugs (i.e. drugs that have been abandoned or 'orphaned' by major drug companies). Moreover, recent studies on rare diseases, including inherited immunodeficiencies and metabolic disorders, have served not only to alleviate the plight of patients with rare diseases, but also yielded valuable information on biological processes of relevance for other, more common conditions. These lessons, along with the crucial importance of cooperation between academic institutions, pharmaceutical companies, patient advocacy groups and society in the elucidation of rare diseases, are highlighted in the present review.

J. W. Walsh, G. L. Snider and J. K. Stoller. A review of the alpha-1 foundation: its formation, impact, and critical success factors. *Respir Care*. 2006; 51(5):526-31

Patient-advocacy organizations have proliferated because they can be an effective method to advance research and clinical care for those with the index condition, and can produce substantial benefits for the affected community, especially when the condition is uncommon. To clarify critical success factors in organizing a patient-advocacy organization and to provide a blueprint for others, including the respiratory-care advocacy community, this report examines features of one highly successful organization, the Alpha-1 Foundation, which is committed to helping those with the genetic condition alpha-1 antitrypsin deficiency. Features of the Alpha-1 Foundation that underlie its success include: consistently creating partnerships with key stakeholders, including the scientific and clinical communities, government, and pharmaceutical manufacturers; bringing passion to the cause (eg, by assuring that organizational leadership is provided by individuals affected by alpha-1 antitrypsin deficiency); and developing strategic business partnerships, as with a company that administers alpha-1 antitrypsin treatment (so-called intravenous augmentation therapy) and employs individuals with alpha-1 antitrypsin deficiency. Funds

allocated by the company help to underwrite the foundation's research-funding commitment. The foundation also recruits and retains talent, including alpha-1 patients, to leadership roles (eg, on the board of directors) and has a voluntary group of committed scientists and clinicians. We believe that attention to these factors can help assure the success of patient-advocacy groups.

D. J. van Leeuwen and J. L. Bernat. Ethical, social and legal implications of genetic testing in liver disease. *Hepatology*. 2006; 43(6):1195-201

Advances in molecular genetics challenge the hepatology community to understand and implement genetic knowledge. Despite excitement about the potential benefits of new genetic information, concerns have been raised about the inappropriate use of genetic testing, clinicians' incorrect ordering and misinterpretation of test results, and discrimination in employment and insurability based on tests results. Among the public there is fear and mistrust, in part based on horrifying historical events that were gross violations of medical ethical standards. Clinicians, scientists, patient advocacy groups, and government agencies worldwide are debating the optimal legal protections to prevent abuse. In addition, these groups are developing clinical guidelines for optimal use. Traditional ethical and legal standards of confidentiality between physicians and their patients are under scrutiny. A new principle, "the duty to warn," is emerging that has applications specific to genetic testing and may conflict with the duty to maintain patient confidentiality. Emerging ethical, legal, and social issues involve the appropriate use and protection of confidential data in tissue and serum banks. Education of the profession and the public at many levels will increase the likelihood that the unraveling of the human genome will maximally benefit society. If fear of genetic testing can be alleviated, selection bias in research could be reduced. Professional and lay organizations concerned with liver disease should consider a more active role in the public and professional debate, and foster education at all levels.

P. Radin and K. Landzelius. "To me, it's my life": Medical communication, trust, and activism in cyberspace. *Social Science and Medicine*. Vol. 2006; 62(3):591-601

This paper studies the conversations and activities of an online support group for breast cancer sufferers and survivors and their supporters. Using communications medium theory and social capital theory, it examines the mundane and profound exchanges, the poignant self-disclosures, the creative expressions of solidarity, and the minor but not-insignificant political actions of people--initially strangers--who come together as a 'virtuous circle,' not only to assist with medical issues but also to meet emotional and even material needs. Sponsored by the Canadian nonprofit organization Breast Cancer Action Nova Scotia (BCANS), this virtual community has logged over a half million messages since 1996. Not every BCANS participant is an activist--many are just trying to grapple with their disease--but some find ways to shatter the professional "information monopoly," and to press for healthcare improvements. The study illustrates the scope, passion, and complexity of peer-to-peer medical communication in a virtual environment that promotes "thick trust". BCANS participants discuss with candor, warmth and even humor such painful topics as death and dying and the crises in intimate relationships brought about by a terminal illness. The sharing of confidences and fears enables participants to pool their 'collective intelligence' about many things, from how to cope with swelling, to how to think about end-of-life issues, to how to improve social policy. (PsycINFO Database Record (c) 2007 APA, all rights reserved) (journal abstract) DOI: doi:10.1016/j.socscimed.2005.06.022

V. Rabeharisoa. From representation to mediation: the shaping of collective mobilization on muscular dystrophy in France. *Soc Sci Med*. 2006; 62(3):564-76

How, and to what extent, do patient organisations renew traditional forms of social participation and protest? This question is examined, drawing on a socio-historical case study of the Association Francaise contre les Myopathies--French Muscular Dystrophy Organisation (AFM). The originality of the AFM is that it has not been content to endorse the classic role of representation of people with muscular dystrophy (MD) and their families. It has also articulated and structured different social spaces that allow people suffering from genetic diseases and severe disabilities to be considered as fully-fledged human beings, persons, and citizens within those spaces. Based on quantitative data and methods, this paper aims to characterize this reconfiguration of social spaces that the AFM has undertaken. My contention is that it

has given shape to a different form of collective mobilization, one in which the patient organisation is a mediator between different social actors, as much as a patients' representative. It helps a new issue, here MD, to emerge so that the largest possible collective designate it as a general public concern. As we shall discuss, this renews the question of patients' collective identity and citizenship.

N. Oudshoorn and A. Somers. Constructing the digital patient: Patient organizations and the development of health websites. *Information, Communication and Society*. Vol. 2006; 9(5):657-675
In order to understand the constraints and challenges of realizing the democratic potentials of the Internet, this paper focuses on the attempts of three Dutch patient organizations to develop health websites. The authors describe how these patient organizations had to overcome specific barriers to develop their digital services. All three organizations faced certain constraints that had negative consequences for the plans they wanted to realize. Lack of financial resources and manpower were the main reasons why these patient organizations could not develop interactive parts of their website or provide personal advice services. Other barriers the patient organizations had to overcome were getting access to digital expertise to build the websites. The paper shows that the development of a website is a very demanding task, even for patient organizations that have in-house expertise with computers and Internet. Moreover, the paper shows that patient organizations do not consider the involvement of patients as crucial for the design of health websites. This research thus confirms previous research findings that users, in this case patients, are largely absent from the design process of information and communication technologies Finally, the paper shows how patient organizations' websites contribute to a redefinition of the patient from being a passive actor towards one who is an active participant in his or her care. (PsycINFO Database Record (c) 2007 APA, all rights reserved) (journal abstract) DOI: doi:10.1080/13691180600965666

K. Landzelius. Introduction: Patient organization movements and new metamorphoses in patienthood. *Soc Sci Med*. 2006; 62(3):529-37
In this introduction, we examine health activism as one expression of an emergent 'politics of vitality' or flurry of activity around health matters that includes: advances in technoscientific medicine, healthcare restructurings, and a re-thinking of science-society contracts. In querying politicized mobilizations around 'health matters and the mattering of health,' we provocatively entitle our discussion 'patient organization movements'. This marks an invitation to interrogate (in reverse order) each term along the way, pausing in our concluding discussion to turn our attentions to the patient. The figure of the patient is thematized as an historical inscription and a formidable dimension of personhood under modernity/late modernity. Moreover, we argue that conventional categorizations of the patient are undergoing accelerated processes of change at the present time. We characterize three transformational trends: moves to author and authorize patienthood, mutiny from patienthood, and mutations in the category of the patient. Such metamorphoses in patienthood represent both reflections and repercussions--at once consequences and catalysts--of the proposed politics of vitality. We explore the pluralization of the patient's persona via a closer look at the 11 empirical studies of health activism that comprise this collection.

I. Hollander. Viagra's rise above women's health issues: An analysis of the social and political influences on drug approvals in the United States and Japan. *Social Science and Medicine*. Vol. 2006; 62(3):683-693

In the United States, Viagra was approved in less than 6 months of its application to the Food and Drug Administration, while the medical abortion pill was approved 4 years after its application, and 17 years after research was first permitted. Congruently, the Ministry of Health in Japan legalized Viagra in 6 months, while oral contraceptives were approved 35 years after the ministry received initial applications. The pharmaceutical review agencies in each country are founded on safety and efficacy standards, in which objective decisions arise from science and clinical investigations. Analyses of these recent drug approvals demonstrate that conclusions may not have been based simply on science and health concerns. Instead, agency actions and application of pharmaceutical law appear to have been influenced by social and political pressures surrounding the products under scrutiny. Pharmaceutical regulations were effectively ignored or manipulated in the United States during the review process for medical

abortion, and were applied inconsistently in Japan--ultimately yielding results that happened to conform to contemporary sociopolitical beliefs. Such disregard of legislation holds serious ramifications for public health, national consumer trust and the pharmaceutical industry. It is imperative that external pressures remain outside the scope of drug approval processes. (PsycINFO Database Record (c) 2007 APA, all rights reserved) (journal abstract) DOI: doi:10.1016/j.socscimed.2005.03.046

C. Carlsson, M. Nilbert and K. Nilsson. Patients' involvement in improving cancer care: experiences in three years of collaboration between members of patient associations and health care professionals. *Patient Educ Couns.* 2006; 61(1):65-71

OBJECTIVE: The aim of this study was to explore how members of patient associations (PACPs) and health care professionals (HCPs) experience collaboration in a network initiated by the health care system and aimed at improving cancer care. METHODS: The participants were asked to describe, after 1 and 3 years, their experiences of collaboration. Data collected were in the form of a written answer to a single, open-ended question, and the answers were analysed using inductive content analysis.

RESULTS: The analysis revealed four themes: the impact of processes that occur within the network, the impact of learning, the impact of innovation and development in cancer care, and the impact of PACP members' personal cancer experience. Statements about the impact of the processes that occur within the network dominated at both occasions. CONCLUSION: This study of experiences of collaboration provides new data on the importance ascribed to such efforts between patients in an organised association and HCPs. PRACTICE IMPLICATIONS: We suggest that differences in perceptions and expectations should be taken into account in future collaborations between representatives of patient associations and of health care systems in order to reach out and to influence developments in cancer care.

S. Blume. Anti-vaccination movements and their interpretations. *Social Science and Medicine.* Vol. 2006; 62(3):628-642

Over the last two or three decades, growing numbers of parents in the industrialized world are choosing not to have their children vaccinated. In trying to explain why this is occurring, public health commentators refer to the activities of an anti-vaccination 'movement'. In the light of three decades of research on (new) social movements, what sense does it make to attribute decline in vaccination rates to the actions of an influential anti-vaccination movement? Two sorts of empirical data, drawn largely from UK and the Netherlands, are reviewed. These relate to the claims, actions and discourse of anti-vaccination groups on the one hand, and to the way parents of young children think about vaccines and vaccination on the other. How much theoretical sense it makes to view anti-vaccination groups as (new) social movement organizations (as distinct from pressure groups or self-help organizations) is as yet unclear. In any event there is no simple and unambiguous demarcation criterion. From a public health perspective, however, to focus attention on organized opponents of vaccination is appealing because it unites health professionals behind a banner of reason. At the same time it diverts attention from a potentially disruptive critique of vaccination practices; the critique in fact articulated by many parents. In the light of current theoretical discussion of 'scientific citizenship' this paper argues that identifying anti-vaccination groups with other social movements may ultimately have the opposite effect to that intended. (PsycINFO Database Record (c) 2007 APA, all rights reserved) (journal abstract) DOI: doi:10.1016/j.socscimed.2005.06.020

J. Barbot. How to build an "active" patient? The work of AIDS associations in France. *Social Science and Medicine.* Vol. 2006; 62(3):538-551

"What is an "active" patient?" is a question that arises in most medicine and illness-related social science research. This article examines the normative work carried out by AIDS associations in France to define an "active" patient in healthcare and research. While the fight against AIDS is often presented as being homogenous, we look at the diversity of opinion between different associations (Aides, Act Up-Paris, Actions Traitements and Positifs). We find four different cases: the patient as manager of his illness, the empowerment of patients, the science-wise patient and the experimenter. Systematic comparison of these cases shows that these perceptions of the "active" patient, in terms of the same pathology, are based upon different ways of seeing: the nature of the relationships between the different types of

knowledge of the illness (scientific knowledge, clinical knowledge, experience of the illness) and the distribution of roles and powers among the various actors in the healthcare system (the government, pharmaceutical companies, the medical profession, the patients). This article highlights the historical dynamics which allow us to have a better understanding of these differences, especially the major distinction between two generations of associations, which adopted different positions with regard to their public identity. (PsycINFO Database Record (c) 2007 APA, all rights reserved) (journal abstract) DOI: doi:10.1016/j.socscimed.2005.06.025

D. E. Ball, K. Tisocki and A. Herxheimer. Advertising and disclosure of funding on patient organisation websites: a cross-sectional survey. *BMC Public Health*. 2006; 6(201

BACKGROUND: Patient organisations may be exposed to conflicts of interest and undue influence through pharmaceutical industry (Pharma) donations. We examined advertising and disclosure of financial support by pharmaceutical companies on the websites of major patient organisations. METHOD: Sixty-nine national and international patient organisations covering 10 disease states were identified using a defined Google search strategy. These were assessed for indicators of transparency, advertising, and disclosure of Pharma funding using an abstraction tool and inspection of annual reports. Data were analysed by simple tally, with medians calculated for financial data. RESULTS: Patient organisations websites were clear about their identity, target audience and intention but only a third were clear on how they derived their funds. Only 4/69 websites stated advertising and conflict of interest policies. Advertising was generally absent. 54% of sites included an annual report, but financial reporting and disclosure of donors varied substantially. Corporate donations were itemised in only 7/37 reports and none gave enough information to show the proportion of funding from Pharma. 45% of organisations declared Pharma funding on their website but the annual reports named more Pharma donors than did the websites (median 6 vs. 1). One third of websites showed one or more company logos and/or had links to Pharma websites. Pharma companies' introductions were present on 10% of websites, some of them mentioning specific products. Two patient organisations had obvious close ties to Pharma. CONCLUSION: Patient organisation websites do not provide enough information for visitors to assess whether a conflict of interest with Pharma exists. While advertising of products is generally absent, display of logos and corporate advertisements is relatively common. Display of clear editorial and advertising policies and disclosure of the nature and degree of corporate donations is needed on patient organisations' websites. An ethical code to guide patient organisations and their staff members on how to collaborate with Pharma is also necessary, if patient organisations are to remain independent and truly represent the interests and views of patients. As many organizations rely on Pharma donations, self-regulation may not suffice and independent oversight bodies should take the lead in requiring this.

J. M. Traulsen and A. B. Almarsdottir. Pharmaceutical policy and the lay public. *Pharm World Sci*. 2005; 27(4):273-7

Almost every national and supranational health policy document accords high importance to the need to listen to and 'empower' patients. The relationship between pharmaceutical policy and the lay public is not direct but mediated by several actors, including health care workers, patient organisations, industry and, most recently, the media. Although the overall aim of health and pharmaceutical policy is to address the needs of all citizens, there are only a few, well organised groups who are actually consulted and involved in the policymaking process, often with the support of the industry. The reasons for this lack of citizen involvement in health and pharmaceutical policymaking are many, for example: there is no consensus about what public involvement means; there is a predominance of special interest groups with narrow, specific agendas; not all decision makers welcome lay participation; patients and professionals have different rationalities with regard to their views on medicine. Because the lay public and medicine users are not one entity, one of the many challenges facing policy makers today is to identify, incorporate and prioritise the many diverse needs. The authors recommend research which includes studies that look at: lay attitudes towards pharmaceutical policy; lay experiences of drug therapy and how it affects their daily lives; the problem of identifying lay representatives; the relationship between industry and the consumers; the effect of the media on medicine users and on pharmaceutical policy itself. The authors acknowledge that although lay involvement in policy is still in its infancy, some patient organisations have been successful and there are developments towards increased lay involvement in pharmaceutical

polycymaking.

A. Ternhag, T. Asikainen and J. Giesecke. Size matters -- patient organisations exaggerate prevalence numbers. *Eur J Epidemiol.* 2005; 20(8):653-5

Patient organisations serve their members with information and support concerning a specific disease. In many cases they also contribute to research funding and lobby to improve the situation for their members. The larger group of patients an organisation claims to represent, the bigger their potential influence. Our hypothesis is that patient organisations exaggerate the number of persons affected with a specific disease. Prevalence figures from patient organisations in Sweden were collected via their own web sites. About 93 patient organisations were identified, 29 of which presented the estimates of disease occurrence used in this study. We calculated the probability for a person to have at least one disease and the proportion of the population not having any of the diseases listed. About 60% of the Swedish population have at least one disease covered by our sample of patient organisations. Nine tenths (87%) of the population would be ill if one assumes that an individual could only have one disease. Our rough estimates suggest that patient organisations exaggerate the number of ill persons. To render other messages on their agenda more trustworthy, we propose that some patient organisations moderate their prevalence and/or incidence figures.

B. Richter and E. Bandeira Echtler. Patientenbeteiligung in der Cochrane Collaboration: Wie können sich Patienten/Consumer aus aller Welt aktiv in einer Cochrane Reviewgruppe beteiligen? [Patient participation in the Cochrane Collaboration: how can patients/consumers actively participate in a worldwide Cochrane Review Group?]. *Z Arztl Fortbild Qualitatssich.* 2005; 99(6):373-5

In Cochrane Review Groups, consumers are usually involved in every phase of the production of systematic reviews, as patient-oriented outcomes are expected to be integral part of all review projects. A further enlargement of participation consists of a new project aimed at contacting patient organizations worldwide, in order to identify particular socio-cultural preferences and needs and to integrate them in the work of the Review Groups. As a first step, information about healthcare issues from people suffering from metabolic and endocrine disorders is gathered by means of structured questionnaires. These activities should be able to detect new research areas, and to draw the attention of the sponsors to a possible western-focused bias in the preparation of systematic reviews.

T. Nijsten, T. Rolstad, S. R. Feldman and R. S. Stern. Members of the national psoriasis foundation: more extensive disease and better informed about treatment options. *Arch Dermatol.* 2005; 141(1):19-26
OBJECTIVE: Patient advocacy groups such as the National Psoriasis Foundation (NPF) serve as representatives of those affected by disease and provide information about the condition. Our objective was to assess the extent to which NPF members differ from nonmember patients with psoriasis in their knowledge and use of therapies. PARTICIPANTS: Using random-digit dialing, we identified and interviewed patients with psoriasis in the general US population. Randomly selected NPF members were also interviewed. MAIN OUTCOME MEASURES: Multivariate logistic regression models were used to estimate differences (odds ratios and 95% confidence intervals) in demographic and clinical characteristics and in awareness and use of therapies between members and others diagnosed as having psoriasis. RESULTS: Of 601 individuals with psoriasis identified from the general population survey, 185 provided a second interview and were defined as nonmembers. We interviewed 289 randomly selected members of the NPF. Although members were significantly older and wealthier and had more extensive disease, they reported the disease to be significantly less of a burden and were more satisfied with therapy than others affected. Compared with nonmembers, members were significantly more likely to have heard of and used most of the 10 therapies assessed. However, the proportion of respondents who were aware of a therapy and who also used it did not differ between groups. CONCLUSION: Members of the NPF are better informed and more satisfied with available treatment options than nonmember affected patients.

A. Garcia Sempere and J. J. Artells. Organizacion, funcionamiento y expectativas de las organizaciones representativas de pacientes. Encuesta a informadores clave. [Organization, functioning and expectations of organizations representing patients. Survey of key informants.]. *Gac Sanit.* 2005; 19(2):120-6

OBJECTIVES: To explore patient organizations and their scope in terms of patient and user participation in decisions affecting their health. **METHODS:** Semi-structured questionnaire survey of key informants from 21 patient organizations. **RESULTS:** Most of the patient organizations were regional or national private organizations. Their main objectives include improving quality of life and representing the interests of patients and their families, developing information triage and dissemination activities, and providing additional services not offered by the public health service. The main methods of communicating with members were electronic mail, open meetings and forums. Most patient organizations considered health professionals to be the most important group of stakeholders. The sources of funding most frequently quoted were membership fees, public grants and contributions from the pharmaceutical industry. The most important factor for enhancing patient co-responsibility was considered to be involving patients in health care as a way to improve the quality of the health services. The proposed future scenario that received the most support was the creation of a legal forum in which the patient's voice could be heard and demonstrably taken into account. **CONCLUSIONS:** Patient organizations can play an important role in providing patients and health professionals with information, promoting self care and improving the effectiveness of health care. These features require visible commitment by the health authorities to facilitate opportunities for patient decisions and choice within the system.

B. Sang. Choice, participation and accountability: assessing the potential impact of legislation promoting patient and public involvement in health in the UK. *Health Expectations.* 2004; 7(3):187-190

Recent legislation enabling increased patient and public involvement in health decision-making will increasingly interact with the maturing independent patient movement to open up accountability systems across healthcare. Lay people will develop new roles, building on learning from the independent advocacy sector, self management, and wider active participation. Inevitably, this means a profound cultural challenge for healthcare organizations, and for citizens, as they begin to understand the implications of the new policies, including patient choice.

D. Pink and C. Prior. Long-term condition ideas. Power to the people. *Health Serv J.* 2004; 114(5917):16-7

We are on the brink of a revolution in patient involvement, but partnerships involving the NHS and support groups must keep pace with 'patient power' if people with chronic medical conditions are to get the best services

A. Nelis, G. De Vries and R. Hagendijk. 'Stem geven' en 'publiek maken': Wat patientenverenigingen ons kunnen leren over democratie. *Krisis.* 2004; 5(3):25-40

This paper offers a pragmatist interpretation of the role of patient organizations in public debates about medical-ethical issues. Analyzing the role of Parkinson disease societies in the United Kingdom and the Netherlands in recent stem-cell debates, we argue that interpretations based on models of democracy that focus on deliberation and inclusion fail to single out the exclusive role of patient organizations. These models welcome patient organizations in democracy because of their role in representing and giving voice to people who are at danger of being excluded from the democratic processes. Patient organizations use a variety of techniques not available to the medical professionals. These techniques are analyzed along lines set out by Latour in his seminal work in science studies. (edited)

E. Mezza, G. Soragna, V. Consiglio, S. Putaggio, M. Burdese, E. Maddalena, M. Bravin, M. Gai, D. Motta, F. Tattoli and G. B. Piccoli. Asclepiad's cock: a patient-physician association is a useful tool for educational programs in nephrology, dialysis, and transplantation. *Transplant Proc.* 2004; 36(9):2546-9

BACKGROUND: The negative impact of the mass media, the lack of information, and the request for in-depth knowledge are the basis for the present need for educational programs on transplantation, brain

death, and chronic kidney diseases end-stage renal disease; (ESRD). The aim of the present article was to critically review the activities performed by Il Gallo di Esculapio, a nonprofit association, in the education on the different phases of ESRD. The associates are physicians and patients, and the activities are integrated institutionally. **METHODS:** This report is a narrative review of the material produced and performed by Il Gallo di Esculapio ONLUS in 1996-2004. **RESULTS:** The two main activities developed were book writing and an educational program. Eight books for patient education were written on different aspects of dialysis, transplantation, and ESRD. Most were designed as theses of the Medical School. Cooperation with patients was important in all cases and fundamental for the collection of interviews. **EDUCATION:** A 4-hour educational program on transplantation started in 2000-2001 (1 high school was involved). The checklist originally included only transplantation and organ donation, but progressively gave space also to dialysis, ESRD, and social health care problems. In 2003-2004 the program involved 67 high schools. The association coordinated progressive patient involvement. **CONCLUSION:** Small, nonprofit patient-physician associations linked with the University allow enrolling resources for educational activities to often-neglected parts of the medical profession.

A. M. Fabius, K. C. Cheung, C. J. Rijcken, C. H. Vinkers and H. Talsma. Direct-to-consumer communication on prescription only medicines via the internet in the Netherlands, a pilot study. Opinion of the pharmaceutical industry, patient associations and support groups. *Pharm World Sci.* 2004; 26(3):169-72

OBJECTIVE: Investigation of the current application of direct-to-consumer (DTC) communication on prescription only medicines via the Internet in the Netherlands. **METHOD:** Questionnaires were sent by e-mail to 43 Dutch innovative pharmaceutical industries and 130 Patient Association and Support Groups (PASGs). **RESULTS:** In this pilot study, the response of the pharmaceutical industry was rather low but the impression is that they were willing to invest in DTC communication. The majority of the websites of PASGs did not link to websites of pharmaceutical companies. The PASGs had no opinion whether patients can make a good distinction between DTC advertising and information on websites of the pharmaceutical industry nor about the quality. PASGs did not think unambiguously about the impact on the patient-doctor relationship. **CONCLUSION:** The impact of DTC communication on prescription only medicines via the internet is not yet clear in the Netherlands.

P. J. M. v. de Mheen and J. Kievit. Response to "Patient organisations should also establish databanks on medical complications". *Journal of Medical Ethics.* Vol. 2004; 30(6):609-610

Comments on the article, "Patient organisations should also establish databanks on medical complication," by D.O.E. Gebhardt (2003). The author pleads for patient organisations to establish databanks on medical complications. Given the references and the lack of argumentation, there is substantial danger of misinterpretation of the current situation, which in turn may frustrate the process of increased transparency. We would therefore like to respond to this by giving background information and reasons for some of the choices that were made with respect to the registry of complications mentioned by Gebhardt. First, a distinction needs to be made between an error and an adverse outcome, which are often confused. Secondly, with respect to confidentiality, this is relevant in particular for the initial years of such a registry during which it is thoroughly tested and accuracy of the registration may vary widely between participants. Finally, what does the patient want? International research has shown that patients do not use public information on performance of hospitals or doctors for making a choice of treatment or hospital because, among other reasons, they do not understand and do not trust these data. Patients are more interested in the experience of doctors or hospitals to treat certain diseases or to perform certain operations, since the question they want answered is "What is the best place to go to for this type of problem?". It is essential that there is an increased mutual trust between the medical profession and patients' organisations that supports a combined effort to improve the quality and availability of patient information. Such initiatives will benefit both patients and doctors and are too important to be frustrated by references to "powers that must be kept under control". (PsycINFO Database Record (c) 2007 APA, all rights reserved)

V. Rabeharisoa. The struggle against neuromuscular diseases in France and the emergence of the

"partnership model" of patient organisation. *Soc Sci Med.* 2003; 57(11):2127-36

The past few decades have witnessed the increasingly active participation of patient organisations in research activities concerning them. They contribute substantially to the funding of scientific and clinical research. More importantly, certain patient organisations take strategic decisions concerning that research, and contribute to the production of knowledge on their diseases. In France, the AFM (Association Française contre les Myopathies-French Muscular Dystrophy Organisation), is a striking illustration. The paper argues that the model of the AFM's engagement in research-the "partnership model"-is original insofar as it renews the power relations between patients and professionals found in two classic models: the "auxiliary model" and the "emancipatory model". Based on a long-term study of the French Muscular Dystrophy Organisation, this "partnership model" is characterised and its implications discussed in three respects: the possible generalisation of the mode of relations it establishes between patients and professionals; its effects on the steering of research; and its consequences for the dynamics of patient organisations movements.

M. A. Balinska. Vaccination in tomorrow's society. *Lancet Infect Dis.* 2003; 3(7):443-7

An international workshop organised by the Merieux Foundation with the co-sponsorship of Aventis-Pasteur and the European Vaccine Manufacturers (Annecy, France; Feb 26-28), assembled policy makers, paediatricians, and journalists as well as representatives from industry, patient advocacy groups, research agencies, international organisations, non-governmental organisations, and coalitions to discuss "vaccination in tomorrow's society: new information pathways". The purpose of the workshop was to identify problems inherent to the social acceptance of vaccination, and ways of enhancing information sources and exchange of data. The discussions revealed three key areas for action: improving benefit and risk assessment tools, attentiveness to public concerns, and education and timely information for health-care professionals. For all these areas, it was agreed that greater financial and human resources commitment is needed.

E. M. Vogt. Effective communication of drug safety information to patients and the public: a new look. *Drug Saf.* 2002; 25(5):313-21

Recent parallel developments in the fields of medicine and the social sciences are providing us with new insights and resources that have the potential for improving the effectiveness of drug safety communication and decision-making. These developments include medicine's new look at patient safety with its emphasis on complex adaptive systems, education's new appreciation for learning as an internal change process and risk communication's evolving recognition that relevant knowledge may not be the exclusive property of 'experts'. Eight principles are drawn from this analysis: there cannot be a safer drug until there is a safer system; all stakeholders are equal partners and have an equal voice in all deliberations; paternalism must be eliminated; the expertise for determining acceptable benefit and risk is dispersed throughout society; patients and all stakeholders serve as both teachers and learners; all stakeholders are involved in the identification of their learning needs, processes and evaluation of outcomes; in a complex adaptive system all individual actions are interconnected and; patients must be involved in the continuous feedback and redesign of the evolving drug safety information system. The conclusion is that we are not asking the right questions; 'what information should we communicate?' and 'how do we communicate more effectively?' should be reframed to ask 'how do we provide an equal voice for patients with the other stakeholders in the determination and communication of benefit-risk information?' Some patients are not waiting. The International Alliance of Patient Organizations (IAPO), the Database of Individual Patient Experience (Dipex) and the Self-Help Group Clearinghouse are examples of international patient driven efforts to actively participate in their own care. The author suggests that the emerging discipline of inter-active management can contribute methodologies for creating citizenship models to generate the collective wisdom and translate it into action. A future research agenda calls for creating new models of public accountability that support these evolving systems of engaging the entire community in benefit-risk determination, communication and management.

J. Legemaate. The development and implementation of patients' rights: Dutch experience of the right to information. *Med Law.* 2002; 21(4):723-34

Many initiatives have been taken to advocate, develop and emphasize patients' rights. The existence of legislation, case law or charters in the area of patients' rights does not guarantee that these rights are or will be successfully implemented in everyday practice. The implementation of patients' rights requires specific actions and expertise. It is important to develop strategies to enhance the successful implementation of patients' rights. This is illustrated by using the example of the developments in the Netherlands regarding the patient's right to information. This development shows that legal interventions, such as legislation, will always have to be embedded in and/or supplemented by non-legal policy measures. This calls for a broad and well-considered implementation policy, including items at various levels (legislation, patient and patient organizations, health providers and health institutions, contextual conditions). Such a strategy calls for a multidisciplinary approach, involving input from the areas of law, ethics, medicine, the sciences etc.

E. Lecimbre, R. Gagnayre, A. Deccache and J. F. d'Ivernois. Le role des associations de patients dans le developpement de l'education therapeutique en France. [Role of patient associations in the development of therapeutic education in France]. *Sante Publique.* 2002; 14(4):389-401

The aim of this survey conducted among patient associations is to define the role and the position that they have with regard to the development of therapeutic education in France. 124 associations were solicited (out of over 500 existing), and 68 replied. 17 indicated that the survey was not relevant for them. 51 answered the 43 questions related to the conception and implementation of educational programmes, their goals and objectives, the choice and selection of educational activities, the target audiences and pedagogical principles of reference. The results obtained demonstrate the predominance of informational activities and psychological support. The responding associations declared that sometimes they conduct educational activities which rather resemble informational activities. Only three associations declared having implemented and managed formalised educational programmes based on pedagogical methods. The aims and objectives most frequently targeted were focused on increasing the patients' knowledge on their disease and its treatment. These educational programmes are usually delivered by members of the association's office staff. However, overall most of the responding associations indicated that it is relatively difficult to provide precise data on the pedagogical methods of the activities undertaken. In light of the results, it is therefore necessary to consider the totality of the activities conducted by the associations as a mechanism for building educational resources in which the place of formalised educational programmes remains marginal, even quasi-absent, for the moment. Associations believe that patient education is an important issue for their development. It is highly likely that the emergence of such programmes will only be possible if the associations show some degree of autonomy in relation to the health care sector and assert a point of view specific to patients, above and beyond that of health care users.

A. van der Zeijden. The patient rights movement in Europe. *Pharmacoeconomics.* 2000; 18 Suppl 1(7-13) Phrases such as 'patient centred healthcare' and 'putting patients first' are becoming common in healthcare discussions in Western society. This makes patient rights an issue. Patient rights are nothing but a modification of general human rights. These have been established in several international documents, such as the main articles of the Standard Rules (resolution 48/96) of the United Nations and the Principles of the Rights of Patients in Europe, which includes a model for a Declaration on the Rights of Patients. What is involved in understanding a patient in the patient rights movement? Patients, seen as people with a long term medical condition, have a relationship with illness which is different from that of healthy people. If we really wish to include this perspective in our discussions and dealings with patients, we have to listen to the patient and the patients' organisations. This approach respects the right of the individual patient to be treated as a human being, but is also about the right of their organisations to be involved in policy-making and decision-making processes at every level. In order to acquaint readers with the main actors in the patient rights movement in Europe, this article discusses the viewpoint of the chronically ill on healthcare, as well as the role of patients' organisations in representing that viewpoint to the healthcare system, providers and society in general.

P. Laredo and B. Kahane. Research policies and organizational choices of the AFLM (French patient association on cystic fibrosis). *Sciences Sociales Et Sante*. 1998; 16(3):97-128

This article deals with the involvement in research of the French patient association on cystic fibrosis and distinguishes two phases. In a first phase, the adoption of a classical approach to the management of public research was successful in creating a dedicated scientific community. It also drove to a progressive diversification of types of research activities. Four types have been identified which require, in order to progress towards therapies, different forms of support by the Association. This diversification entails new requirements for the management of its research effort by the association, for weighing the relative importance given to each type, for the definition of the forms adapted to each action and for their real time monitoring. This has driven the Association to rethink its organisation, thus defining a new approach which departs from both the public and industrial models of research management.

I. C. Linse. The patient union: a partner in Dutch patient education. *Patient Educ Couns*. 1996; 28(1):57-67

This article is a review of the principles, values and activities of the Dutch patient unions. Attention is paid to the historical development of the patients' organizations in the Dutch policy, the activities, patients expertise and their perspective, and the content of the patient education by the patient unions. Furthermore the obstacles and prerequisites in the cooperation between patient organizations and health care providers are described. Also the way of cooperation of patient organizations in the patient education activities in health care institutions is presented. Conclusions are drawn on the advantages of the role of patient unions in Dutch patient education.

J. C. M. van Haastregt, L. P. de Witte, S. J. Terpstra, J. P. M. Diederiks and et al. Membership of a patients' association and well-being: A study into the relationship between membership of a patients' association, fellow-patient contact, information received, and psychosocial well-being of people with a neuromuscular disease. *Patient Education and Counseling*. Vol. 1994; 24(2):135-148

Studied the relationship between membership in a patients' association, information received, fellow-patient contact, and psychosocial well-being. Data were collected from 349 people with myotonic dystrophy and spinal muscular atrophy. 201 Ss were members of a patients' association for people with a neuromuscular disease. No direct relationship was found between membership in the patients' association and well-being. Membership was positively related to the number of fellow patients with whom a S had personal contact and to the amount of information received about the disease and related factors. Having personal contact with more fellow patients was related to better well-being in the Ss who had a relatively low level of physical functioning. There were no indications that receiving information led to better well-being. (PsycINFO Database Record (c) 2007 APA, all rights reserved) DOI: doi:10.1016/0738-3991%2894%2990007-8

PART II

M. Naiditch. Patient organizations and public health. *Eur J Public Health*. 2007; 17(6):543-5

I. van Bennekom Stompedissel. Patient organizations and prevention in the Netherlands. *Eur J Public Health*. 2007; 17(6):545

European Federation of Pharmaceutical Industries and Associations: EFPIA code of practice on relationships between the pharmaceutical industry and patient organizations.

Viewpoints

Patient organizations and public health

Introduction

In a stimulating paper in the *British Medical Journal*,¹ Show and Baker described the turmoil produced 15 years ago in the medical profession by what has since then been coined the 'expert patient'; a patient whose specific knowledge about his disease challenges the power of the medical profession to decide alone the nature and the way his care should be organized. Several alternative models of the clinical encounter have emerged, focusing on the ability of a patient to cope actively with his disease, and emphasizing the 'patient empowerment' which is facilitated by the specific knowledge which the patient draws from his experience.²

A 'patient collective identity' sometimes emerges from the experiences shared between members of the same disease group. Patient organizations (POs) have been a strong factor in shaping these identities. As a recent special issue of *Social Science and Medicine* shows, some of these POs have got involved in activities (e.g. medical research or health planning) previously considered a professional prerogative.³

The community of public health researchers has not yet fully appreciated the impact these developments may have on their activities. While a recent viewpoint in this Journal seems to reflect a certain awareness of this 'blind spot', when it acknowledges the fact that 'a new partnership to involve the whole society in reorienting health policies' is necessary,⁴ POs are not mentioned as potential stakeholders.

Dynamics of patient organizations

Sharing patients' experiences with a specific disease has been the basis of the action of many POs. Until the 1980s, POs were frequently dominated by professionals in their boards or scientific councils, so they lacked the capacity to develop specific knowledge and shape their actions autonomously. Two sets of closely related factors can be considered as major drivers towards a better institutional recognition and autonomy.

The first, fuelled by various crises (Bovine Spongiform Encephalitis), scandals (contaminated blood; asbestos) and

controversies (Genetically Modified Organisms), is linked to the perception by the public of growing health threats. These threats cast doubt on the capacity of scientists, health professionals and politicians to frame the political decision process. Building on the perception that voices from all stakeholders were necessary ingredients to fuel a more open and transparent decision process, POs claimed the recognition of their specific form of expertise.⁵

Their political ability to put patients' expectations at a higher level in the political agenda was facilitated by a second factor linked to the evolution of democratic societies: a growing individualism which entitles each consumer to take responsibility for decisions impacting on his life. Long before POs began their fight for more autonomy, core health institutions had started to take these elements into account: Successive European regulations since 1948 have promoted patients as partners, raising them to the same (formal) level of responsibility as professionals and regulators, while setting out some principles and instruments to implement this new policy.⁶ In 2000, the fifth recommendation of the ministerial council of the European Union stipulated that 'consumers and patients should participate in the process of defining goals for the health system'.

Patient association involvement in the fields of research and health care policy

POs' involvement in biological and clinical research offers a first striking illustration of their expanded role. Not only have POs sometimes influenced the process of research, but also decision making on research. In France, in the context of the AIDS epidemic, by creating a new balance of power between patients and professionals, POs succeeded in redesigning the methodology of clinical trials in order to take into account patients' disease experiences and rights. Considered as 'new experts', they were active partners in the selection of the population to be included in trials.⁷ In the United States, the 'Women's coalition for breast cancer', in order to tackle the

medical uses of oral contraceptives, had a critical role in the launching of randomized clinical trials, and continues to be active in the controversies related to their results. In the field of rare diseases, research design and orientation were directly tackled by POs: Rabeharisoa has shown how the French Association against Neuromuscular Diseases, boosted by their fund raising capacity, turned the research community in another direction. This was called a 'distributed knowledge acquisition process' in which each partner recognizes and gives equal value to the specific knowledge of the other.⁸

It is worth paying attention to two elements. First, while working with professionals, patients have demonstrated their ability in assessing, formalizing, staging and distributing knowledge drawn from their specific experiences. Also, in parallel with their fight for 'patients' rights', they have challenged medical practices such as diagnostic processes, medical consultations and the side-effects of drugs. So today 'lay expertise' can be described as a 'body of hybrid knowledge in-between patients' experience and professionals' expertise'.⁸ Secondly, in various institutions, we are witnessing the development of initiatives aimed at integrating patients' experiences and knowledge into experts' groups. In France, the non-governmental drug agency investigates and circulates patients' experiences on drugs and therapeutics, while HAS (the French agency equivalent of the British NICE) involves PO representatives in groups working on clinical recommendations, hospital certification or clinical paths for chronic conditions.

What remains a partly open question is why POs sometimes succeed in establishing patients' authority and legitimacy vis-à-vis the medical and political arena, and sometimes not. Why were they able to strongly impact the organization of health care for neuromuscular diseases and cystic fibrosis, as it happened in France, and has their influence tended to be weaker in the field of cancer?

Patient associations, collective interest and equity

Alongside their traditional role, POs also act as 'mediators' between the various

actors involved in the 'war against disease', endorsing new social responsibilities and gaining political leverage for negotiations with decision makers.

European coalitions of POs represent a powerful instrument not only in sharing collective knowledge between national POs, but also in their effective voicing of citizens' claims at a European level. By mobilizing public opinion in favour of research, EURORDIS, the patients' coalition for rare diseases, succeeded in passing the European Orphan Drug Act. It was also a key player in the development of an effective market approach, gaining the support of pharmaceutical firms for setting up medical trials involving patients and their representatives.⁸

Coalition formation among different patient groups also offers a pragmatic answer to the following ethical issue: how can a specific organization, which captures resources to the detriment of others, act in order to represent common interests? Other examples are the mobilization of NGOs leading to AIDS treatment access in developing countries in which POs had an important role,⁹ and the 'European patient forum' acting as a powerful lobby in Brussels. In France, a coalition (CISS) brought together organizations of patients, disabled, consumers and the elderly in a joint fight for a 'consumer and patient oriented health information system', the creation of a specific indemnity process for people having experienced adverse health events, and the development of a more effective hospitals risks management process.¹⁰

So one of the more robust results is that POs are not only to be considered as powerful resources in shaping patients' strategies to face the consequences of their illness, but also as major instrument to help them organize their life as citizen or consumer.

What can public health learn from these facts?

Some public health researchers, facing issues involving competing sources of evidence and heterogeneous public expectations, may be willing to move toward new methods allowing 'lay people' more power in the research process or in designing public health programmes. But others may be reluctant to do so for two reasons.

First, the institutions informing and framing the decision-making process were always professionally led and staffed by experts. So it seemed inappropriate to involve the wider community of citizens, as public judgement

was considered to be influenced by misunderstandings, prejudices, emotions or self-interests. The fact that the decision-making process requires the weighing up of information of a specialized and technical nature, and often leads to potentially contentious priority choices, reinforced the opposition to lay involvement. Even in cases where the decision process incorporated the opinion of lay persons, it usually relied on methodological assumptions defined solely by health care professionals with no real direct lay input, thus potentially misrepresenting public opinion.

Secondly, experts may be reluctant because they do not know how to work with groups of patients in a problem solving perspective. The answer lies in the application of existing methodologies which have been built in order to help lay persons participate in a transparent, accountable and inclusive decision-making process, even if the latter involves complex and multifaceted issues, and competing pressures and interests. Examples of such methodologies include citizen's jury, Danish consensus conferences, deliberative conferences, and scenario framing.¹¹ As they require a complex approach that goes far beyond the provision of information or the solicitation of public opinion, they are not straightforward to set up, and success is not guaranteed.¹²

They share the capacity to allow participants to take a broader view of the issues at stake, because participants are provided with elements underpinning the trade-offs inherent in potential responses and solutions. So participants are brought in a position to engage collectively around the issues, to reflect on what they have been provided with, to weigh up information and data, to reason with the issues, and to refine their opinion through discussion with peers and experts. This is what transforms 'public opinion' into 'public judgement', and what fosters a genuine dialogue between professionals and lay people.

Researchers working on the quoted cases confirmed that it was precisely this kind of dynamic that made these experiments successful: in fields where professional expertise seemed previously unquestionable, when patient-specific knowledge was carefully embedded in the process of knowledge acquisition, they did contribute, together with the scientific expertise, creating a common knowledge and tracking new pathways for problem solving.

This happened also in the field of environmental health. The contamination of air by particles and the way it affects the population at large, with differentiated impacts across space and

social groups, is a concern for public health experts. In parallel, a number of 'air crises' have shown the inadequacy of current conceptions of knowledge and of public action to provide adequate responses in terms of decision-making processes. In a recent paper, Brown *et al.* give an example of how minority activist groups, in their struggle to reduce pollution, tried to influence the decision-making process by creating a coalition with asthmatic patients. Building on the controversy about the role of external environmental factors in causing or triggering asthma and using as a 'moral argument' the socially unequal health impact of the distribution of particles, they set up a strong partnership with academic researchers and then succeeded in enforcing more stringent local but also national regulations. The research showed how their work on environmental factors lead to a collective form of illness experience in which minority people with asthma were able to make direct links with social determinants of their health.¹³

I am not saying here that all public health researchers should transform themselves into health activists, but only that the experiences cited may convey new understandings on how to build better research and design more efficient public health programmes by considering the unexplored creative capabilities of patients, consumers and citizens. While I am aware of the difficulties for many public health researchers in moving towards this kind of partnership with POs and community groups, as it represents a 'cultural shock', I believe they nevertheless should engage themselves in this direction, which has been efficient in other closely connected fields.

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Patient organizations and prevention in the Netherlands

The paper 'Patient Organizations and Public health by M. Naiditch' highlights the importance of patients' experiences and knowledge for health research and policy. The analysis also applies to developments in the Netherlands of the past 20 years, in which individual patients and consumers have founded hundreds of patients' organizations. Some of these are organized around a specific disease or illness; others focus on broader issues related to the position of patients and consumers, like information and quality of care. In the early nineties the need was felt for an umbrella organization. The Netherlands Patient and Consumer Federation (NPCF) was founded in 1992 to represent common interests at a national level, creating one voice on subjects such as patients' rights and access to care and public health programmes. The NPCF represents more than 3 million people: 3 million health care consumers. Jointly with its member organizations it promotes common interests towards influential parties in the field of healthcare, policy makers, healthcare providers, insurance companies as well as in the field of research. It develops and implements programmes to strengthen the position of the patient. Like other European

countries, the Netherlands is confronted by a number of autonomous trends and developments that affect and challenge the health care system such as: increasingly demanding citizens, rising public expectations, an ageing population and rapid technological changes. Furthermore, the Netherlands is facing increasing pressures in terms of cost containment and financing, access to services and the quality and sustainability of health care.

A sustainable society calls for a sustainable health care system. Therefore, it is necessary to innovate the health care system based on the needs and demands of citizens. It is those needs that the NPCF tries to identify and promote. The main question is: do citizens receive the care that meets their needs and demands? In every 'normal' market it is said that the customer is always right. This means that he receives a good product that meets his needs, and that he is being serviced to his satisfaction. The NPCF works on a long-term strategy on the position of consumers, in order for them to become the so-called third party in our health care system, or better still, the first party in the long run!

This strategy does not only apply to the patients' position in negotiating the

cure and care packages of healthcare. The NPCF encourages investments in national preventive programmes and makes an appeal for including prevention in health insurance packages. It promotes patient participation in research and in the development of intervention strategies. Today, patient and consumer organizations are in a position to negotiate collective contracts with healthcare insurers not only to get a lower premium, but also to have preventive programmes included in the contracts.

The NPCF critically follows the political process and the health care research programmes from a patients perspective. Today, 'the patient' has become a respected and honoured participant in the political discussion and decision-making process in the Netherlands. This strong position can and will be used to promote improved treatment services as well as improved prevention services.

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European Federation of Pharmaceutical
Industries and Associations

**EFPIA CODE OF PRACTICE ON RELATIONSHIPS
BETWEEN THE PHARMACEUTICAL INDUSTRY AND
PATIENT ORGANISATIONS**

Adopted by EFPIA*

* As adopted by EFPIA Board on 05/10/2007.

Introduction

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of thirty countries in Europe and over forty leading pharmaceutical companies. EFPIA's primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in bringing to market medicinal products which improve human health.

The pharmaceutical industry recognises that it has many common interests with patient organisations, which represent and/or support the needs of patients and/or caregivers.

In order to ensure that relationships between the pharmaceutical industry and patient organisations take place in an ethical and transparent manner, EFPIA has adopted the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

This Code builds upon the following principles that EFPIA, together with pan-European patient organisations, last updated in September 2006:

1. The independence of patient organisations, in terms of their political judgement, policies and activities, shall be assured.
2. All partnerships between patient organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value.
3. The pharmaceutical industry shall not request, nor shall patient organisations undertake, the promotion of a particular prescription-only medicine.
4. The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged.
5. The pharmaceutical industry welcomes broad funding of patient organisations from multiple sources.

Scope

This EFPIA Code covers relationships between EFPIA member companies and their subsidiaries/contracted third parties and patient organisations which operate in Europe.

Patient organisations are defined as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.

Applicability

The EFPIA Code sets out the standards which EFPIA considers must apply. In a manner compatible with their respective national laws and regulations, member associations must adopt provisions in their national codes which are no less rigorous than the provisions contained in the EFPIA Code.

Pharmaceutical companies must comply with the following applicable codes ('Applicable Codes') and any laws and regulations to which they are subject:

1. If the company is located within Europe, the industry code of the country in which the company is located or, if the company is located outside Europe, the EFPIA Code;

AND

2. **a)** in the case of partnerships and activities taking place in a particular country within Europe, the industry code of the country in which the activity takes place; or
b) in the case of cross-border partnerships and activities, the industry code of the country in which the patient organisation has its main European location.

The requirements apply to activities or funding within Europe. 'Europe' as used in this EFPIA Code, includes those countries in which the EFPIA member associations' codes of practice apply.

The Applicable Codes that will apply must be specified in a written agreement between the company and the patient organisation. In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions shall apply. For the avoidance of doubt, the term 'company' as used in this EFPIA code, shall mean any legal entity that provides funds or engages in activities with patient organisations covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation. 'Activity' as used above, shall mean any interaction covered by an Applicable Code, including the provision of funding.

Provisions

Article 1

Non-promotion of prescription-only medicines

EU and national legislation and codes of practice, prohibiting the advertising of prescription-only medicines to the general public, apply.

Article 2 **Written agreements**

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Each pharmaceutical company should have an approval process in place for these agreements.

A template for a written agreement is available in Annex I.

Article 3 **Use of logos and proprietary materials**

The public use of a patient organisation's logo and/or proprietary material by a pharmaceutical company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Article 4 **Editorial control**

Pharmaceutical companies must not seek to influence the text of patient organisation material they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.

Article 5 **Transparency**

- a) Each company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a short description of the nature of the support. This information may be provided on a national or European level and should be updated at least once a year.¹
- b) Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

¹ The provision of the information required in article 5a must be made for the first time by member companies no later than the end of the first quarter of 2009 (covering activities commenced as of or ongoing on 1 January 2008)

Article 6
Single company funding

No company may require that it be the sole funder of a patient organisation or any of its major programmes.

Article 7
Events and hospitality

All events sponsored or organised by or on behalf of a company must be held in an appropriate venue that is conducive to the main purpose of the event, avoiding those that are 'renowned' for their entertainment facilities or are 'extravagant'.

All forms of hospitality provided by the pharmaceutical industry to patient organisations and their members shall be reasonable in level and secondary to the main purpose of the event, whether the event is organised by the patient organisation or the pharmaceutical industry.

Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees.

No company may organise or sponsor an event that takes place outside its home country unless:

- a. most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
- b. given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

Article 8
Enforcement

Attached to this EFPIA Code as Annex II, are "Implementation and Procedure Rules" which are binding upon member associations and companies and set forth the framework for the implementation of this EFPIA Code, the processing of complaints and the initiation or administration of sanctions by member associations.

Member associations shall provide guidance on the meaning of the terms 'appropriate', 'significant', 'major', 'reasonable', 'renowned' and 'extravagant' as used in this code.

This Code of Practice will be effective from 1 July 2008.

Annex I Model template for written agreements between the pharmaceutical industry and patient organisations

Annex II Implementation and Procedure Rules

ANNEX I Model template for written agreements between the pharmaceutical industry and patient organisations

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement.

Below is a model template, which may be used in its entirety or adapted as appropriate, setting out key points of a written agreement. It is intended as a straightforward record of what has been agreed, taking into account the requirements of EFPIA' s Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

- Name of the activity
- Names of partnering organisations (pharmaceutical company, patient organisation, and where applicable, third parties that will be brought in to help, as agreed by both the pharmaceutical company and the patient organisation)
- Type of activity (e.g. whether the agreement relates to unrestricted grant, specific meeting, publication, etc.)
- Objectives
- Agreed role of the pharmaceutical company and patient organisation
- Time-frame
- Amount of funding
- Description of significant indirect/non-financial support (e.g. the donation of public relations agency's time, free training courses)

All parties are fully aware that sponsorship must be clearly acknowledged and apparent from the outset.

Code/s of practice that apply:

Signatories to the agreement:

Date of agreement:

ANNEX II Implementation and Procedure Rules

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) Code on Relationships between the Pharmaceutical Industry and Patient Organisations (the “**EFPIA Code**”), the processing of complaints and the initiation or administration of sanctions by member associations.

SECTION 1. Member Association Implementation.

Each member association is required to:

- (a) establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same including, at a minimum, a national body of the member association that is designated to handle complaints and consists of a non-industry chairman and, besides any industry members, membership from other stakeholders;
- (b) ensure that its national code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and
- (c) prepare, and provide to the EFPIA Code Committee (defined below), an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year.

SECTION 2. EFPIA Code of Practice Committee Implementation and Key Tasks.

- (a) The EFPIA Code of Practice Committee (the “EFPIA Code Committee”) shall assist member associations to comply with their obligations under Section 1 above.
- (b) The EFPIA Code Committee will be composed of all the national code secretaries, and chaired by the EFPIA Director General, assisted by one person from the EFPIA staff.
- (c) As a key part of its role of assisting member associations in their national code compliance activities, the EFPIA Code Committee shall monitor the adoption of compliant national codes. The EFPIA Code Committee will not participate in the adjudication of any individual complaint under any national code.
- (d) EFPIA Code Committee will, at least annually, invite member associations and representatives to participate in a meeting at which the participants will be encouraged to share their respective relevant experiences relating to the EFPIA Code. Any conclusions from the meeting shall be summarised in the annual code report (referred to under (e) of this Section 2 below) and, if appropriate, be presented to the EFPIA Board.

(e) The EFPIA Code Committee shall publish an annual code report, which summarizes the work and operations which have taken place in connection with the implementation, development and enforcement of the various national codes during the applicable year, based on the country reports provided by the member associations pursuant to Section 1(c) above.

(f) On an annual basis, the EFPIA Code Committee shall (i) advise the EFPIA Board of its work and operations and the work and operations of the member associations, as summarized in the member association annual reports and (ii) review with the EFPIA Board any additional recommendations to improve the EFPIA Code with a view towards increasing transparency and openness within the pharmaceutical industry and among member associations and companies.

SECTION 3. Reception of Complaints.

Complaints may be lodged either with a member association or with EFPIA. Adjudication of complaints shall be a matter solely for the national associations.

(a) Complaints received by EFPIA shall be processed as follows:

(i) EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).

(ii) EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.

(iii) In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

SECTION 4. Processing of Complaints and Sanctions by Member Associations.

(a) Member associations shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who has made the complaint.

(b) Complaints will be processed at the national level through the procedures and structures established by the member associations pursuant to Section 1(a) above. Each member association's national body shall take decisions and pronounce any sanctions on the basis of the national code in force in its country. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences.

(c) Where a complaint fails to establish a prima facie case for a violation of an Applicable Code, such complaint shall be dismissed with respect to that national

code. Member associations may also provide that any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.

(d) Each member association should establish effective procedures for appeals against the initial decisions made by its national body. Such procedures and appeals should also take place at the national level.

(e) National committees shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that is linked to the seriousness and/or persistence of the breach as follows:

(i) in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;

(ii) in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).

(f) National committees are encouraged to publish summaries in English of cases that have precedential value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest).