

Roundtable on Information to Patients – The Patient’s View European Parliament 16 April 2002

Background

On 16 April 2002, a number of European patient groups, amongst whom Alzheimer Europe, European AIDS Treatment Group, European Coalition of Positive People, European Patients’ Voice, GAMIAN Europe, International Diabetes Federation/Europe and the International Osteoporosis Foundation, held a roundtable in the European Parliament to brief MEPs on their perspective on the Commission proposal on information to patients. The roundtable was hosted by Mr Jules Maaten (MEP, ELDR, Neth.).

Roundtable speakers included representatives of the Global Alliance of Mental Illness Advocacy Networks/Europe, the European Aids Treatment Group and the Swedish Medical Association. Participants were representatives from the Commission (N. Behrndt and H. Kloppenburg), the European Parliament (P. Liese, M. Malliori, P. Whitehead and assistants of F. Grossetête, R. Oomen-Ruijten and of R. Müller), patients organisations (incl. Act-up Paris and Change), industry (EFPIA), Standing Committee of Doctors, International association for health insurers AIM, BEUC, Health Action International, European Public Health Alliance and the UK Consumers Association.

In his introduction, *Jules Maaten* underlined that the proposal of the Commission concerning information to patients lacks clarity. Input from patient groups and other stakeholders is necessary in order for the European Parliament to come up with a well-balanced approach and to ensure that MEPs can make sense of the proposal. He also remarked that he is not necessarily against DTCA if it is set within very strict limits.

Joint statement European patient groups on access to information

Twelve European patient groups have adopted a joint statement on the Commission proposal on information to patients (which was distributed at the meeting; see attachment) in which they, inter alia, state the following:

- All patients no matter their condition, background or nationality, have a fundamental and legitimate human right of access to all kinds of information about their health, medical conditions and the availability of treatment.
- EU patients/citizens need factually accurate, reliable, easily understandable information to be able to make informed decisions.
- Patients welcome information from different sources, incl. pharma industry, provided they meet the above-mentioned criteria, the ownership of the source is clearly identified and agreed safeguards are in place.
- Such information would enable patients/citizens all over Europe to:
 - make informed decisions;
 - optimise health outcomes through improved treatment compliance;
 - make more effective and rational use of therapies;
 - increase awareness of risks and benefits of medicines;
 - improve quality of life.
- Information should not be seen as a cost/control instrument for EU Member States.
- Patients do not want US style advertising.

Presentation ‘Legal aspects of information to patients’

Rodney Elgie (Global Alliance of Mental Illness Advocacy Networks GAMIAN/Europe) in his presentation, inter alia, discussed the following points:

- Already in 1984, the European Parliament in a resolution acknowledged the right of patients/citizens to information concerning diagnosis, therapy and prognosis.
- Because of censorship many EU citizens must rely on indirect and unofficial information sources. These sources are often unreliable and sometimes misleading.
- The Community should ensure that all EU citizens in every Member State should have access to the kind of information to which they are properly entitled – information that is clear, factual, accurate and balanced.
- Access to clear, accurate and reliable information is a basic right. Article 11 of the EU Charter of Fundamental Rights provides that every citizen has a right to receive and impart information...without interference by public authority and regardless of frontiers.
- In a leading case involving information about abortion and pregnancy, the European Court of Human Rights ruled that a Member State could not use censorship to deprive citizens of information they needed for their own health care.
- If denial of information were thought to promote lower health care costs, this could not justify censorship under the Charter and Convention on Human Rights. Cost savings, whether real or imagined, can never justify denials of fundamental rights. Access to reliable information would encourage better and more efficient health care.
- The availability of non-promotional information about prescription medicines would not compromise the roles of physicians or other health professionals in any way.
- As long as information is accurate and non-promotional, industry should be considered as one of the information sources, alongside others.

Presentation ‘The patient’s perspective’

Arjen Broekhuizen (European Aids Treatment Group) in his presentation, inter alia, discussed the following points:

- Good, reliable and understandable information is important to all patients in all disease areas.
- Health literacy helps to improve patients’ well being, it contributes to the prevention of illness and it supports patients’ understanding of their treatment.
- Informed patients tend to seek more appropriate medical treatment and seek it earlier. They are more likely to seek medical help for conditions that might otherwise go untreated, including asymptomatic diseases. Discussions with their doctors will be more constructive and result in a better understanding of the patient’s illness, and hence to better choice of treatment.
- Higher public awareness enables patients to take greater responsibility for their own health and medical treatment. Health care systems benefit, and so do budgets. Providing good information to patients will lead to more efficient use of health care resources.
- Prevention, early diagnosis and better-implemented therapies cut overall health care and social security costs. Patients recover faster, avoid hospitalisation, surgery, and other more expensive forms of care and, if in employment, often return to work earlier.
- Patients’ organisations fear that the Commission proposal will undermine information and education programmes of patients’ organisations.

Presentation: 'The GP's perspective'

Dr Anders Milton (Swedish Medical Association) in his presentation, inter alia, presented the following personal views:

- The public has a greater ability to find information. The relationship between doctor and patient is different now. The patient is not an object anymore. Patients have a right to information and a right to participate in the decision-making process. They also have the right to refrain from being treated. Patients nowadays also want comparative information on doctors and hospitals.
- He said it is inherently good if patients are better prepared when they come to their doctor. He referred to the Swedish medicines portal for patients on the Internet (FASS).
- According to him, it is not possible to keep patients away from information, because it is already available. Patients need all kind of information: on life-style changes, treatments, medicines, etc.
- Information must be truthful, should include information on other treatments, should not be exaggerated and side effects should not be downplayed.

Discussion

Margaret Ewen from Health Action International referred to the event that was co-organised by HAI and the European Public Health Alliance in January and at which an official from the Dutch Health Ministry commented on the issue of information to patients. She stressed that at this meeting the official argued that considering the current legal situation in EU Member States, the industry has the possibility of providing information, but can not advertise/promote its products to the public. She asked why DG Enterprise has come up with this proposal, despite this situation.

The assistant of Jules Maaten hinted at the promotional activities of pharmaceutical companies towards physicians and argued that industry "invests through the backdoor" in advertising its products. Wouldn't patient be more interested in receiving information from industry in a more direct manner rather than through their physicians.

Peter Liese (MEP, EPP, Germany) argued that the Internet offers both a challenge and an opportunity for informing patients. He, like many others, questioned the Commission over why it has changed the definition of advertising and why only three disease areas are listed in the proposal.

Lisette Tiddens-Engwirda (Secretary-General, Standing Committee of Doctors) pointed out that the doctor's association does not disagree with the proposal per se but that the proposals concerning information on demand should not in fact figure under the general heading 'advertising' as is currently the case. Instead there should be a new heading called, for example, 'information and advertising'. She stressed that one of the main points of contention concerning the proposal is the fact that it does not sufficiently clarify the difference between information and advertising, a point which was raised by other participants as well.

Some patient representatives also raised the issue of the proposed new definition of advertising and wondered to what extent this will hamper the activities of patient groups in providing useful and often crucial information on certain products to their members.

The Commission representative (*Nils Behrndt* - DG Enterprise, Unit of Philippe Brunet) did not respond directly to the questions about the changed definition of advertising and instead stressed that it is not the objective of the Commission to restrict the activities of patient groups. He further argued on the point raised by Margaret Ewen (HAI) that the legal situation at national level and the interpretation of the existing EU legal framework is in fact very different from country to country concerning what companies can and cannot do currently in the area of information provision: the proposals are not so much aimed at regulating advertising but more at regulating information.

Mr Behrndt distinguished two types of information. Firstly, there is information that is already approved by the authorities and which is reliable, such as summaries of product characteristics and package labeling. There is a second category that consists of information on products, disease area or other treatments. This second area is not defined yet and is open to further discussion.

He further argued that the reason the Commission is proposing the three disease areas is because it has looked at the sales volumes in these areas and has concluded that since in these three areas, patients are already taking medicines, this new proposal if implemented would not put an additional burden on national health budgets. In addition, there is clearly a need for medicines in these disease areas and hence for information.

Conclusions

Chairman *Jean Georges* (Alzheimer Europe) concluded that there was agreement on the following:

- Nobody at the meeting questioned that patients have information needs and that this is a human right.
- Patients need balanced, accurate, clear and non-promotional information.
- Informed patients are an asset to society.
- There is a need for a clear distinction between information and advertising.
- Patients' organisations should still be able to raise awareness on the availability of medicines amongst patients.

There was disagreement among the participants on the role industry should have and how information from industry had to be controlled, with organisations such as HAI, Act-up Paris and Change (AIDS coalition in Europe) being against information from industry.

Attachment: Joint statement European patient groups