

Position Paper on Patient Participation

EUROPEAN PUBLIC HEALTH ALLIANCE

1. Background

EPHA is developing this policy on patient participation in order to:

- focus on this important segment of EPHA membership and respond to EPHA's objective to *"Promote the rights of all citizens to participate in decisions concerning their own health and in particular to strengthen the position and the voice of patients and health care consumers in support of health-related rights in Europe"* (established in article 4, point 2 of EPHA's statutes)
- Contribute to current debates about European governance
- Address issues of balanced representation in relation to patient and citizen participation
- Examine issues of independence for patients' organisations and of appropriate relationships between patients' organisations and other health stakeholders
- Consider how best to support patients organisations to participate in decision making.
- Reflect on barriers to effective patient and citizen participation in decisions about health care which are occurring within the single market
- Clarify the role of patients and citizens in EU health policy

2. Patient participation and citizen participation

Patients and citizens

Patients are users of the health care system. Citizens are the population as a whole (sometimes referred to as 'the public' or 'the broader community').

Both patients and citizens have a role to play in health decision making. In this paper, health decision making includes decisions about health care systems and decisions which affect the health of the population, including issues of public health and the social determinants of health.

All patients have in common an interest in the ready availability of quality health care services and of appropriate information and support services to assist them to return to good health or to live well with their condition. Some patients have an interest in broad public health measures and the social determinants of health, but others do not. Patients are a diverse group and there are different interests between those with a chronic illness and those with acute conditions, and between wealthy patients and those who have low incomes, amongst others. On any given issue, there are likely to be a number of patient perspectives.

There are many ways to describe the citizen interest in the health system. One useful approach is stewardship: citizens are trustees of the national health. That trust is an intergenerational responsibility to use the available resources of the government and the community to improve the health of the community as a whole. The resources available to national governments include regulation and provision of health care services, as well as public health measures and social determinants of health. The scope of the European Community is more limited as there is currently no competence in relation to health care services, however there are a range of decisions made across the European Community competencies which impact on health of the population as a whole.

Rationale for citizen and patient participation in health decision making

Involving citizens in decision making about government policy is a basic democratic principle. There are arguments that formal processes for citizen involvement over and above the election process fill a 'democratic deficit' in the current political system.

Participation by citizens and patients in decision making is also about better decision making. It brings the knowledge of various sectors of the community to the decision making process. As patients have expertise in their condition and their treatment, they have important information to contribute to decision making in the health system.

Citizen and patient participation is also about educating the broader population about the many and complex issues which are considered in health decision making.

Citizen and patient participation is also about gaining broad public ownership of the decisions which are made. This is particularly important in the health sector as many of the decisions are controversial, such as those relating to rationing of health services, location of hospitals, regional allocations of funds, and access to and payment for pharmaceuticals.

Organised citizen and patient advocacy is important to ensure that the needs of patients and of the community as a whole are effectively balanced against the interests of business and the health professions. It is also important to ensure that health managers hear citizen and patient views.

Patients and consumers

Patients are sometimes referred to as consumers. Consumers are purchasers of good or services or are users of goods and services.

Consumer principles provide a valuable framework to guide improvements in health care services for patients and for the benefit of citizens generally. The European Consumers' Organisation (BEUC) has identified eight core consumer rights: safety, information, choice, representation, redress, education, satisfaction of basic needs, and a clean environment.

There are arguments that patients should participate in health decision making on grounds of consumer sovereignty, which is an approach drawing on classical market theory. There have also been suggestions that their role as consumers make patients the sole or primary partner in health decision making. The application of classical market theory to patients and health care systems is, however, problematic and a focus on broad patient and citizen participation is more appropriate.

One problem with applying classical market theory to the health care system is that improving the health of an individual is widely regarded as a common good, not merely an individual benefit. The interest in effective services is therefore not limited to the direct recipient of care. It is a broad citizen interest.

A second problem with applying classical market theory to the health care system is that the patient is commonly not the person paying for the services or not the only person paying for the services. In national health care systems, the payer is the state and the source of funds is tax revenue. This gives citizens an immediate financial interest in the transaction. In systems based on contributory insurance, the insurance companies and fellow contributors have a direct financial interest. In both cases, citizens have an interest in the overall cost of health care services to the community.

Participation processes and patients' rights.

Some member states have focussed efforts on documenting individual rights in the health care system. Patients' charters and legislation to protect patients' rights have an important role to play in describing what constitutes lawful (or prescribed) conduct, and in identifying and providing mechanisms for redress where these are breached.

Codification of individual rights is insufficient to incorporate the public interest into health decision making as the public interest is more than an aggregate of individual rights. Commonly, decisions about the rights of an individual are not processes in which wider issues of resource allocation and accountability can be effectively debated.

Examples of this are the recent decisions of the Court of Justice of the European Communities in the *Kohll* and *Decker* cases (1998). These cases overturned existing arrangements for coverage of health care abroad, but did not examine the wide-ranging implications for health care systems in Member States; such as capacity to contain rising health care costs and ensure adequate quality of care.

A focus on individual rights needs to co-exist with participatory processes which involve citizens and patients in decision making.

Involving patients and involving citizens

The citizens' perspective is that of the overall protection and promotion of health. Citizens therefore have an interest in decisions about health systems, public health and other issues which affect the health of the population as a whole.

Patients have an interest in decisions about health care systems and may have a broader interest in health matters. There are a number of conditions which are affected by issues which commonly fall into the scope of public health, such as diet (e.g. Coeliac Disease) and air quality (e.g. asthma). There are also some patients' organisations which have chosen to focus on broad strategies of prevention which are also public health measures.

Decisions about health care systems, public health and other issues affecting the health of the population as a whole are of concern to citizens and patients. **Thus, it is appropriate, and essential, for European Community policy makers to provide both the major citizens' organisations and patients' organisations with opportunities and financial support to take part in these debates.** Different organisations will have different levels of interest in specific issues, and it should be left to the individual organisation to determine whether or not it is a priority for participation.

3. Patients' organisations

Criteria for identifying patients' organisations

The criteria for identifying a patients' organisation is contentious, however there are growing needs to clearly identify patients' organisations and to distinguish them from other health stakeholders.

The need to identify patients' organisations flows from growing interest at national and European level in involving patients' organisations in health decision making. There is also growing interest at national level to funding patients' organisations to facilitate their participation, and the European Commission is also being approached to provide similar support.

The primary issue in distinguishing patients' organisations from other health stakeholders is the extent to which the organisation reflects the views of patients and their carers, rather than the views of health professionals (including researchers) or the pharmaceutical industry.

Patients' organisations can also be distinguished from citizens' organisations by their focus on the needs of health service users rather than on issues of concern to the community as a whole. In practice, the distinction between patients' organisations and citizens' organisations is not always clear.

In addition, there are other factors which need to be considered when determining whether or not an organisation should be recognised as a legitimate representative of patient interests. These include:

- Do they have a membership which is consistent with the organisation's title and the constituency it claims to represent?
- Do they have processes to involve their membership in developing the organisation's policy positions?
- Are they transparent about their structure and internal processes?
- Are they transparent about sources of funding and relationships to industry and other stakeholders?

In some parts of the patient movement, emphasis is placed upon the extent to which an organisation represents the views of patients over and above the views of their carers and family. This is particularly important in relation to conditions which have historically been viewed as reducing the capacity of the patient to identify and articulate their own interests, such as mental illness.

The European Commission should develop a public list of the patient groups with which they consult. This list should contain information on their membership, internal decision-making processes for consultation and representation, and its sources of funding.

Participation by under-represented groups

As with many membership organisations, patients' organisations commonly have very low rates of participation from people with lower socio-economic status, from indigenous communities and other ethnic minorities, and from other marginalised groups. While this does not undermine the value of participation by patients' organisations, it does mean that additional strategies are required to ensure effective representation of the interests of disadvantaged groups.

There is evidence that some patients' organisations have recognised this gap in their membership and have implemented strategies to identify the needs of disadvantaged groups and to incorporate this information into their advocacy work.

As heavy users of the health care system have a greater motivation to pursue improvements in care, the majority of patients' organisations relate to chronic conditions. Patients with acute conditions do not commonly organise as patients' organisations and alternative processes to identify their needs and advocate their interests are required.

In creating any consultation structure with patients' groups, the European Community should ensure that the interests of under-represented groups are included.

Ensuring the independence of patients' organisations

The value placed upon the participation of patients' organisations flows from their ability to reflect, accurately and fairly, the views of the patients they represent. In order to do this, they need to be independent from other health stakeholders.

One area of particular concern is the relationship between patients' organisations and the pharmaceutical industry.

While the views of patients and pharmaceutical companies can overlap on different issues, they are not identical. While it is important that these commonalities are pursued when they exist, it is also important that patients' organisations maintain the capacity and independence to express views which are different from industry and which may be critical of industry.

Some patients' organisations refuse to accept funding from pharmaceutical companies on the grounds that this is a conflict of interest. Many patients' organisations do accept funding from pharmaceutical companies.

Approaches to minimising conflict of interest for patients' organisations which receive pharmaceutical funding include:

- establishing limits on industry sponsorship as a proportion of total income; and
- clearly articulating the role of the sponsoring body in relation to sponsored projects and the organisation generally in policy documents.

Funding from pharmaceutical companies is not limited to direct sponsorship. In some cases, a formally constituted not-for-profit agency acts as a conduit between the pharmaceutical company and patients' organisations.

In the development of any funded Community Patient Forum, clear and transparent guidelines should be agreed in advance with interested patient groups to respond to the issues raised in commercial sponsorship.

4. Infrastructure to support participation

Infrastructure

Infrastructure refers to structures which support NGOs to operate more effectively.

In the context of promoting patient and citizen participation in decision making about health, this would include structures to support networking, debate and, where appropriate, the development of common positions. These structures include such things as umbrella organisations (such as EPHA); informal networks; forums and conferences; and newsletters and email lists.

Infrastructure in Member States

Infrastructure in Member States varies greatly. Examples include:

- umbrella body for a specific condition
- umbrella body for a collection of similar conditions (such as neurological conditions)
- umbrella body for all patients or for patients and citizens
- a statutory body to pursue the interests of all patients or of patients and citizens
- informal networks relating to a specific issue

These bodies and networks may be funded by membership fees, public donations, government grants and contracts, grants from charitable foundations, or funding from pharmaceutical companies and other parts of the health industry.

There are a number of Member States which have decided to provide public funding for infrastructure bodies. This reflects a commitment to promoting civil society and also reflects a recognition amongst policy makers of the practical assistance of such infrastructure to the process of involving civil society. This practical assistance can include:

- Facilitating wider consultation with patients' and citizens' organisations. Infrastructure bodies can provide advice on strategies for effective consultation and on the constituency which various respondent organisations represent. They can also undertake part or all of a consultation process.
- Identifying a suitable representative. Infrastructure bodies can recommend individuals with the appropriate expertise to contribute a patient or citizen perspective to committees working on specific policy issues. They can also develop processes to facilitate exchange of information between these representatives and others with an interest in the specific issue.
- Providing a primary point for negotiation during policy development. This allows the development of compromise positions which have broad acceptance amongst civil society organisations and the broader community.

Another reason for public funding of this infrastructure is the recognition by governments that corporate funding has the potential to undermine the independence of the advice and input provided by the organisation. Infrastructure organisations commonly face particular difficulties in raising sufficient public donations to support their work.

Europe-wide infrastructure

Infrastructure for NGOs working for health at European level consists of:

- Umbrella NGOs funded by the European Commission to promote the involvement of civil society. EPHA is an example.
- European NGOs working on specific conditions or on related conditions. Some of these have a membership of national organisations from across Europe and clear processes for developing the policy positions which are advocated at European level. Many do not. Some are self-funding and some rely heavily on funding from pharmaceutical companies.
- Structures which are attached to the pharmaceutical industry or which are in close partnership with industry. These include the EFPIA Patients' Platform, a number of conferences, and some umbrella patients' organisations.

There is significant scope for development of infrastructure on health decision making at European level. Trends which support development of this infrastructure include:

- Policy makers seeking civil society input which relates to a broad set of conditions (or all conditions) rather than to a specific illness. Achieving representation of a broad collection of interests requires investment in umbrella organisations, forums and networks that can negotiate common positions and seek broad input on policy questions.
- The need for civil society input into increasingly complex decisions about health. There are decisions about health which are occurring under the trade competence. Effective civil society input on these matters requires sophisticated analysis. Developing the capacity for sophisticated analysis of the intersection of trade, social protection measures and health is an issue of resources.
- Public concern about the role of the pharmaceutical industry in sponsoring patient and citizen debate on issues in which they have a direct economic interest.
- The need to ensure that the interests of disadvantaged patients and citizens are represented in debates about health services. This is particularly important to prevent entrenching health inequalities.

The European Commission has launched the first developments of an EU Health Forum in 2001, which aims to provide the health community, both profit and not-for-profit stakeholders, a forum for dialogue and policy exchange. It includes a Health Policy Forum, an Open Forum and a Virtual Forum. More information can be found on: <http://forum.europa.eu.int/Public/irc/sanco/ehf/home>

To promote the transparency on its consultation with civil society, the European Commission, together with the health community, should develop criteria for representativeness of European health NGOs.

In order to exploit the potential of civil society's participation in health decision making, **the European Commission should ensure core funding for representative European health NGOs and patient groups along the lines of those used for environmental or consumer groups for such purposes.**

It is however important to ensure that all NGO networks have equal access to the EU institutions, independently of being funded or not by the European Commission.

5. European Community competence for health

Health care services formally remain an exclusive competence of Member States. The internal market, in so far as it affects the free movement of goods and services (health care), the free movement of professionals and other workers (health care), and the free movement of citizens (patients), already means that major decisions concerning health care rest with the European Community.

The limited EU competence in health, established in article 152 of the Amsterdam Treaty, does not allow the EU to legislate with the sole purpose of protecting health (except in the area of blood and organ products, veterinary and phytosanitary matters). The European Commission's formal commitment to health resides in Directorate SANCO.

Adhering to the formal competence in the structure of decision making in the European Commission means that the development of policies on health care services is being driven by principles appropriate to private economic transactions in the single market rather than health and social protection mechanisms.

An approach to health care services, which is based on trade principles rather than health and social protection, poses considerable dangers to patients and citizens. It threatens to exacerbate inequities in access to health care service, to undermine strategies of cost-containment and threaten strategies to ensure quality of health care services. It also has the potential to further focus Member State resources on health services rather than on a balanced investment in health services and public health measures.

The structure of the European Commission also provides no site within the Commission services for citizens' and patients' organisations to contribute to debate about the development of European Community policies on health care.

The EU competence for health, established in article 152 of the Amsterdam Treaty, should be extended in order to avoid that major decisions concerning health care are taken on the basis of internal market rather than health promotion principles.

6. Conclusions

Both patients and citizens are two distinct interests and both have a role to play in health decision making. Patients are users of the health care system and citizens are trustees of the national health. Both patients and citizens and their respective organisations should have the opportunity to participate in health decision making.

While calling for transparency in European Community decision making, NGOs have a responsibility to be transparent about their own structures and activities. Patients' organisations and citizen's organisations need to provide clear information about their membership, processes for involving members in policy development, structure and internal processes, and sources of funding and relationships with industry and other stakeholders, amongst other issues.

Patients' organisations are well developed in the areas of chronic illness, but there are gaps in representation in relation to acute conditions and disadvantaged communities. Additional strategies are required to ensure effective representation of the interests of these groups.

There is very limited infrastructure in place to support patients' organisations and citizen's organisations to effectively participate in health decision making at European level. There are a number of trends which support further development of this infrastructure, including policymakers' desire for input relating to a broad set of conditions rather than specific conditions; the need for civil society input into increasingly more complex decisions about health, public concerns about the role of the pharmaceutical industry in sponsoring debate on issues in which they have an economic interest, and the need to represent the interests of disadvantaged patients and citizens in debates about health care services.

Adhering to the European Commission's formal competence in the structure of decision making in the European Commission means that the development of policies on health care services is being driven by principles appropriate to private economic transactions in the single market rather than health and social protection mechanisms. It also provides no structure to facilitate the involvement of civil society in European Community decisions about health care.

Recommendations to the EU Institutions

1. *Involving patients and involving citizens*

It is appropriate, and essential, for European Community policy makers to provide both the major citizens' organisations and patients' organisations with opportunities and financial support to take part in Community health debates

2. *Patients' organisations*

It would be useful for the European Commission to develop a public list of patient groups operating at a European level which contains information on their membership, internal decision-making processes for consultation and representation and its sources of funding.

Some criteria which may be useful for identifying and comparing patients' organisations include:

- Do they have a membership which is consistent with the organisation's title and the constituency it claims to represent?
- Do they have processes to involve their membership in developing the organisation's policy positions?
- Are they transparent about their structure and internal processes?
- Are they transparent about sources of funding and relationships to industry and other stakeholders?

3. *Participation by under-represented groups*

In creating any structure for a European Patients Platform, the European Community should ensure that the interests of under-represented groups are included.

4. *Ensuring the independence of patients' organisations*

In the development of any funded Community Patient Forum, clear and transparent guidelines should be agreed in advance with interested patient groups to respond to the issues raised in commercial sponsorship.

5. *Infrastructure to support participation*

The European Commission, together with the health community, should develop criteria for representativeness of European health NGOs.

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