

The patients' involvement in health policies in Europe

INDEX

INTRODUCTION	Pag. 3
1. OVERALL VIEW	Pag. 5
1.1 An intense, diverse and complex system	Pag. 5
1.2 Consultation forms	Pag. 6
1.2.1 Forms	
1.2.2. Subjects	
1.2.2. Critical Areas	
1.3 Empowerment	Pag. 10
1.3.1 Areas	
1.3.2 Instruments	
1.3.3 Prospects	
1.4 Civic Activism	Pag. 12
1.4.1 Forms	
1.4.2 Technologies	
1.5 The representation of patients' experiences	Pag. 16
2. THE 'CIVIL DIALOGUE' IN HEALTH POLICY	Pag. 18
2.1 A European feature	Pag. 18
2.2 DG Health and Consumers and Brussels "civil society"	Pag. 19
2.3 EU Health Forum	Pag. 20
2.3.1 EU Health Policy Forum	
2.3.2 Open Forum	
2.3.3 The 2009 renewed mandate	
2.3.4 Criteria for membership's selection	Pag. 22
2.4 The European Medicine Agency	
2.4.1 Forms of involvement	
2.4.2 The European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organizations (PCWP)	
2.4.3 Criteria for the selection of the organizations	
3. THE HEALTH TECHNOLOGY ASSESSMENT APPROACH	Pag. 25
3.1 A "bridge" between science and decision	Pag. 25
3.2 Citizens involvement	Pag. 26
3.2.1 Where, how and when	
3.2.2 Representation issues	
3.2.3 Patients' evidence	
3.3 Some international experiences	Pag. 30
3.3.1 Australia	
3.3.2 Scotland	
3.3.3 United Kingdom	
3.3.4 Canada	
3.3.5 Brief note on the impact of citizens' presence	
3.4. The European Coordination (EUnetHTA)	Pag. 37
3.4.1. Stakeholder definition	
3.4.2 Different forms of stakeholder involvement	

3.5	Towards an equal dignity?	Pag. 40
3.	PARTICIPATION IN MEMBER STATES	Pag. 41
4.1	Introductory note	Pag. 41
4.2	Belgium	Pag. 42
4.3	Bulgaria	Pag. 43
4.4	Cyprus	Pag. 44
4.5	Denmark	Pag. 45
4.6	England	Pag. 47
4.7	France	Pag. 48
4.8	Hungary	Pag. 49
4.9	Italy	Pag. 50
4.10	Latvia	Pag. 52
4.11	Netherlands	Pag. 53
4.12	Northern Ireland	Pag. 54
4.13	Poland	Pag. 55
4.14	Portugal	Pag. 56
4.15	Scotland	Pag. 57
4.16	Slovakia	Pag. 59
4.17	Spain	Pag. 60
4.18	Sweden	Pag. 62
4.	FOCUS: THE PLANET OF ONCOLOGY	Pag. 63
5-1.	Introduction	Pag. 63
5.2	Presence in the European area	Pag. 64
5.2.1	European Cancer Patient Coalition	
5.2.2	Europa Donna	
5.2.3	Myeloma Patient Europe	
5.2.4	Sarcoma Patients euronet (SPAEN)	
5.3	Empowerment and the patient-centered care	Pag. 69
5.3.1.	Personalized Medicine in cancer treatment – Hype or Hope	
5.4	Patient organizations' involvement in research	Pag. 72
5.4.1	Involvement of Men Against Cancer (MAC) in research projects	
5.5	Patients' organizations and empowerment services	Pag. 74
5.5.1	General and medical information	
5.5.2	Advocacy and advice	
5.5.3	Support for individuals and families	
5.5.4	Socialization and entertainment	
5.6	Participation 2.0, a trial	Pag. 76
5.7	A small final note	Pag. 78
5.	CONCLUSIONS	Pag. 79
6.1	A major concern	Pag. 79
6.2	Recognizing and promoting areas of active citizenship	Pag. 81
6.3	Final recommendations	Pag. 85
7.	BIBLIOGRAFY	Pag. 88
	THANKS TO	Pag. 92

INTRODUCTION

Despite the rise of health consumer and patients' organizations (HCPOs) in modern healthcare systems, studies are few and far between. In particular there is a lack of comparative research across Europe and at the pan-European level. In an effort to address this gap, an experts workshop funded by the European Science Foundation has been held in Vienna in February 2006 and has seen the participation of 22 delegates from 10 European countries (Baggott, Forster, 2008).

A number of studies on the involvement of citizens/patients/consumers has been carried out in the following years, as a consultation of the reviewed publications on PubMed¹ and the Cochrane Data Base² clearly shows. However, comparative researches are still rare or otherwise limited to a few countries, and they often cover only specific diseases.

Therefore, there is a significant gap between the reality of citizens' involvement and the set of knowledge and concepts used to interpret it. The problem is recurring and affects all processes that involve active citizenship. Particularly, it can be found that, in health policies:

“The more the scientific community and policymakers attach importance to the existence and action of citizens' organizations for the fortune of the European Union, the less these are known and clearly defined” (Moro, 2009, p. 19).

The literature reviews also highlight the methodological variability used in projects and studies, made easier by the fact that, in the health sector there is a large variety of different situations in which citizens are involved (CEREF, 2010; Tempfer, Nowak 2011).

What is still specifically missing, from our point of view, is an approach that admits the variety and diversity of citizens' presence in health systems. The issue is particularly relevant to civic organizations as it is linked to the crisis of the “European social model”, started by a few years (ACN 2008, ACN 2011 a) and definitely worsened - especially in some countries - by the ongoing financial crisis.

The following report is our modest contribution to the work needed to bridge this gap. We intend to place a set of useful knowledge for the definition of policies of engagement at the European and National Institutions' disposal for, as we hope becomes evident, they are an essential component to the protection and development of the European social model .

In the **first chapter** we propose a description of the **“vast reality” that the involvement of citizens/consumers/users/patients.** Is a necessarily incomplete description, due to this vastness, but hopefully a meaningful one.

In the **second chapter** we describe **the methods of involvement used by the European Institutions and health organizations** (DG Sanco, Health Policy Forum, European Medicine Agency).

¹ <http://www.ncbi.nlm.nih.gov/pubmed>

² <http://www.cochrane.org/>

The **third chapter** covers **the approach of the Health Technology Assessment (HTA)** as a useful – although not exhaustive – paradigm for the definition of involvement policies, even in the lights of consultations carried out in 2012 by the European Network for Health Technology Assessment (EUnetHTA).

The **fourth chapter** is a **first attempt at describing the current situation of the citizens/consumers/users/patients' involvement in national health policies.**

The **fifth chapter** focuses **the patients' involvement in cancer care policies** and in particular in research and in the promotion of personalized treatments.

The **conclusions** are, as usual, directed towards the formulation of **recommendations** for Institutions and civic organizations.

1. OVERALL VIEW

1.1 An intense, diverse and complex system

The uncertainties reported in the introduction arise from a necessarily high level of intensity, diversity and complexity that characterises the relations between citizens and the healthcare systems. The **intensity** is due to the fact that the stakes are, exactly, health. A simple but fundamental consideration, to whom we should add the fact that the increasing levels of education and information have transformed the citizen into a subject less and less willing to completely delegate decisions to professionals, as it was the case in traditional paternalistic relationships. He/she, instead, wants now to intervene actively in the definition and implementation of treatments. Also the concept and development of patient-centered care originate from such a will to consider this new attitude a useful resource to improve treatments' suitability and efficacy.

The **diversity** comes from the fact that the relationship with the healthcare services is not limited solely to treatment but, more generally, the rights of citizenship. The citizen is not just a patient/user, but as well a voter belonging to a specific community, a taxpayer and a consumer; and in each of this capacity, he/she may establish specific relationships with the healthcare institutions. They can relate to the legitimacy of local and national policies, resources' allocation, the exercise of advocacy and more (Tritter, McCallum; 2006). In this regard, there are strong asymmetries of power and information between administrations, professionals and users. It is not surprising that, in order to reduce this gap, health policies have therefore become a privileged field to exercise active citizenship and that this could lead, with a certain frequency, to conflicting situations.

The **complexity** is an intrinsic feature of the healthcare systems and determines, by necessity, an equal or at least similar complexity in the relations with citizens. The literature reviews show that the involvement of patients and the community can take place at different levels and cover very different subjects, such as:

- The health of individual patients and therapeutic choices;
- The presence and quality of health services:
 - Access to hospitals and clinics;
 - Availability of treatments;
 - Waiting lists' cut;
 - Improvements of services available inside and outside hospitals;
- A contribution to clinical research and drug testing;
- An involvement of the general public and patients in choosing and planning priorities (ISS, 2008, p. 12).

In addition, to better manage the major chronic or long-lasting diseases, more and more services and dedicated paths are been developed both in hospitals and on territories. This suggests even more that the relationships established between service providers, professionals and citizens are necessarily diverse and can generate an extremely varied set of means and solutions. To give some examples, we could think of the use of satisfaction surveys - that however relegate users to a fundamentally passive position - periodic consultations up to autonomous forms of audit and evaluation.

The foregoing considerations should be sufficient to demonstrate that the issue of the involvement of citizens/consumers/users/patients in health policies cannot be confined in rigid patterns nor treated with unilateral approaches. It is however helpful to focus on approaches that are to be found more frequently in the literature: **consultation**, **empowerment** and **civic activism** (Terzi, 2012). A further one, stressed in particular - but not only - by the spread of **HTA**, should be added to the list: namely, an approach determined by the realization that, in order to achieve robust findings and effective decisions, it is necessary to integrate traditional scientific knowledge with the experience of citizens (Facey et al, 2010; Akrich, Rabeharisoa, 2012).

1.2 Consultation forms.

As a tribute to the principle that citizens/consumers/users/patients' involvement should be an essential components of health policies, public institutions have often equipped themselves with consultation tools at different stages of policy making: planning, decision-making, implementation and evaluation. The spread, shapes, quality and effectiveness of this activity vary considerably from country to country, as will be seen in the fourth chapter.

In some cases citizens are virtually ignored. Consultations assume often a ritual and formal character and do not substantially alter any policy. In the best cases, they lead instead to essential contributions to the governance of healthcare systems.

To try and describe in an orderly and not-too-summary way the rather heterogeneous whole that is the consultation experience, we will make use of a study carried out by the Italian National Institute of Health (ISS, 2008).

1.2.1 Forms

In principle, citizens' involvement in consultations takes place in three ways: participation in permanent bodies, the use of decision-making techniques of deliberative democracy, the collection of information and opinions with non-decision-making tools.

Permanent bodies can be of different kinds:

- Committees or groups used by the authorities/agencies/administrations as advisory bodies to collaborate in the establishment of laws, programs and projects. They see the involvement of citizens' representatives, whose choice is, in most cases, exclusive competence of the authority/agency/administration.
- Forums/Advice boards/Representative bodies, coordinated and entitled to deliver either mandatory or optional opinions, depending on the case. These bodies are selected with criteria varying from case to case, leaving plenty of room for discretion.
- Mixed committees that formulate mandatory or optional opinions, in which both members designated by the authorities/agencies/administrations and those recommended by the Representatives' associations are involved.

Large variations on the theme are possible in each of the above cases, but in our opinion they do not essentially differ from the described solutions.

The use of **techniques of deliberative democracy** takes usually place in well determined occasions. It's fairly frequent when the authority/agency/administration is called upon to deal with issues of great public and social relevance (from the assistance to people with disabilities to resource allocation) or to perform acts that are significant to the structure of the health services (e.g., budgets or plans for the rearrangement of services). The repertoire of techniques is quite large (ISS, pp. 38-40) and ranges from citizen jury to deliberative polling. With the exception of open public meetings, the inclusion of citizens in the bodies called to deliberate is predominantly operated by the authority/agency/administration.

Even the **non-decision-making techniques'** repertoire is quite wide (focus groups, public hearings, community meetings, surveys etc.). Consultations can be open (e.g. Public hearings) or closed (e.g. Focus groups). Recourse to targeted investigations is frequent and aims at providing decision-makers with verified information on citizens and users' opinions on the problems under scrutiny. The technical quality of the tools used and the statistical representativeness of the people involved are two very relevant features (ISS; p. 40).

1.2.2 Subjects

The topics on which to work out the interactions between authorities/agencies/administrations and citizens/consumers/users/patients are numerous and not always easy to classify. For the sake of clarity and synthesis it is possible to focus on four aspects: policies, guidelines, assessment of services for chronic diseases.

With regards to the **policies**, "The 'political dimension' of participation takes place when citizens are directly involved in the choices; when they discuss standards, seek to influence decisions about resource allocation, express their views on priorities; when they propose new services or the improvement of the ones existing; when they attempt to practice forms of control, claim or negotiation" (Altieri, 2002).

In reality, all this happens quite rarely, especially at the national and regional levels. Instead, interesting experiments seem to take place at local levels (ACN, ACN 2011b, 2012), but they also seem to meet with a certain difficulty in organizing themselves as a whole. In particular "the sphere of the definition of priorities falls little within citizens' availability. Economical and political reasons enter powerfully to influence decisions regarding resource allocation and the definition of the general goals of health policy" (ISS; p. 30).

Generally, the authorities/agencies/administrations' resistance to involve citizens remains high at this level, even in countries with strong traditions in this regard as Canada (Couet et al. 2013).

The **guidelines** for the management of specific diseases or particular aspects of healthcare (e.g., Patient safety and Pain-relief medicine) seem to be a privileged field for the involvement of citizens. The absence of sufficiently large and well-documented studies on the actual impact of these guidelines on organizations and health activities should be however pointed out.

Involvement is particularly taken care of in countries such as Australia and Canada. Even in the UK, in the Scandinavian countries, the Netherlands, and sometimes in Italy,

representatives of active citizenship are expected to be included in groups responsible for drawing up guidelines. It is likely to happen in other countries too, but there's a lack of information in this regard. As we see in the next chapter, the European Union plays a significant role in this regard.

There is a general consensus that **the evaluation of the quality and services** should be a constant activity of authorities/agencies/administrations and that it must include the views of citizens.

Instead, it is actually not always well developed and is frequently carried out through customer satisfaction techniques that relegate the citizen to a passive role. With commendable exceptions (e.g. the Picker Institute) the citizen is treated as a mere carrier of opinions and not as a holder of essential information on the running of services. The experience of the Italian Civic Audit works as an exception: a project that has been running since ten years and promoted by Cittadinanzattiva with the support of the Ministry of Health and ten regions, it basically collects data on the technical quality of the services directly from citizens, who then provide to draw up the evaluation report themselves (Terzi, Tanese, Lamanna 2010).

Over the last decade, a crucial topic in the relationships between citizens and institutions is the one concerning intervention strategies on **chronic or long-lasting diseases** (such as cancer or long-term treatments) and mental health.

It is common belief that it is difficult, if not impossible, to achieve satisfactory results in this sphere without the active involvement of patients, users and members of the family. However, several situations remain underdeveloped, with significant differences between countries and, within them, between local realities.

It is all the same a privileged field of empowerment actions (see below) and dialogue in the planning of services organization. Numerous are also the studies that agree on the fact that mutual understanding between users, professionals and administrators generates significant improvements in the setting, use and performance of services (ISS, pp. 33 – 37).

1.2.3 Critical areas.

The literature reviews report a number of critical areas:

“The analysis of the literature on the involvement of citizens in decision-making often reports disappointing results: in fact, taking part in a group is not always a guarantee of effective participation in decision-making by the patient/citizen. The intention to consult the community can often hide processes that inhibit and affect the ability to speak freely or the decision that has been taken. The conflict of interest that characterizes the sphere of health services also plays its role here. The work of doctors, patient groups, and health authorities can sometimes be heavily influenced by strong economic interests, and particular situations may then arise:

- consultations turn into an exercise in public relations on the part of policy-makers and service providers that have already taken the decisions under scrutiny;
- methods are too tied to the preferences of health professionals and administrators;

- there isn't a real will to turn citizens' ideas into concrete acts;
- the information asymmetry affects the process of citizen's involvement ;
- public consultation results in a decision-time delay;
- the findings do not meet with the approval of those who have commissioned the research and are therefore ignored" (ISS, pp. 39-40)

"The effects of patients' involvement are, on the other hand, difficult to assess, as their voice is always less effective than that of health care professionals and administrators. In fact, it occurs sometimes that patients ' expectations are not realistic and feasible, and administrators and health professionals show a defensive attitude towards their powers and interests" (ISS, p. 40).

Very often, administrations adopt formal and bureaucratic consultation schemes or, even worse, made-up procedures based on the 'common sense' of politicians and officials rather than on relevant studies. Even the economic aspect of involvement programs come to be often underestimated (ISS, p. 41). The surveys carried out by ACN in 2004 (ACN 2004a, ACN 2004b) on the general issue of the relations between citizens and institutions, provide **two useful contributions to the understanding of the problem.**

The first contribution highlights the big gap of knowledge existing on the nature, the business and the reality of civic organizations. The fact that organizations are brought by their nature - and rightly so - to focus on outcomes and political objectives rather than formal aspects of governance, is particularly underestimated. As a result, the initial goals of dialogue frequently do not match (ACN 2004a, pp. 65 – 66). A specific work should be carried out on these aspects, as even a study of the EU Civil Society Contact Group reports (Fazi, Smith, 2006, p. 41).

The second contribution refers to the uncertainty that characterizes the identification criteria of the organizations to involve. This is an obviously crucial issue to the successful outcome of the consultation processes. The attitude of the institution in this regard is, primarily, a source of uncertainty itself. Often, the representativeness of organizations is assessed through criteria that are specific to political parties and trade unions and that are obviously not appropriate in this context. Equally often the local authorities retain large amount of freedom and discretion in identifying their own target audiences, by using criteria not publicly stated. Almost always, the consultation is not considered a right of citizenship but a government prerogative (ACN, 2004b). We find ourselves sharing, once again, a substantial identity of views with the EU Civil Society Contact Group, when it states:

- representativeness is not a matter of numbers, but rather a mix of skills built on the field and the ability to enhance the voices of the members of organizations;
- representation on specific issues should not be a monopoly of the European network [...] valuable inputs can be collected by NGOs working on specific issues that never existed on a European basis;

- representativeness should therefore be measured on a qualitative approach based on the relevance to specific processes and issues (Fazi, Smith, p. 46).

The application of the European Charter of Active Citizenship (ACN, 2006) could be a useful guide to give this kind of problems less approximate answers.

1.3 Empowerment

Using the fundamental texts by Rappaport and Zimmerman as a starting point, the Italian National Health Agency conducted in 2010 a major study on empowerment, supported by a thorough review of the international literature on the subject (Agenas, 2010). The study highlights the nature of a phenomenon that surely cannot be confined - as sometimes happens - in reductive interpretation schemes:

“Empowerment is a process of social action through which individuals, organisations and communities **acquire jurisdiction over their own lives**, in order to change their social and political environment with the goal to improve the fairness and quality of life” (Caracci Carzaniga, p. 11).

Three are the key components: monitoring, critical awareness and participation.

“The ‘**monitoring**’ refers to the perceived or actual ability to influence the decisions that affect your own existence. The ‘**critical awareness**’ is the understanding of the functioning of power structures and decision-making processes; the understanding of how factors come into play and are influenced, and how resources are mobilized. The ‘**participation**’ relates to working with others to achieve desired and shared results” (Caracci Carzaniga, p. 12).

It is clear that: a) in empowerment processes research and action are both essential and cannot be separated from one another; b) a process of empowerment cannot be granted from the authority but originates and takes form from the subjects that animates it and the context in which it occurs.

1.3.1 Areas

The study conducted by Agenas identifies three areas of development of the empowerment processes. The first area concerns the **individual empowerment** of people involved in healthcare treatments who can, for example:

1. “adopt healthier lifestyles and behaviours: e.g., taking part in movements/information campaigns for the prevention/education to healthy lifestyles;
2. manage and make themselves responsible for their own chronic disease: e.g., self-help groups in welfare and healthcare systems;
3. access to the services’ organization: e.g., facilities such as the Public Relations Office, Complaints Department, Toll-free number, Customer Service.
4. access to the decision-making process of treatment: e.g., informed consent, integrated medical records” (Caracci, Carzaniga, p. 16).

Actions to build the ability of citizens/patients to better manage their health conditions are a privileged framework of empowerment policies. In fact, over 71 experiences taken into account in the Agenas' study, as many as 40 were part of this area. The PubMed query leads to similar results: from a total of 415 bibliographic records, more than half (232) is related to the care of patients suffering from chronic or long-lasting diseases³.

The second area concerns the **organizational empowerment**, which includes actions such as:

1. "sharing the treatment's decision-making process: e.g., conflict and cultural mediation in the doctor-patient relationship;
2. sharing the services' planning: projects and/or contexts such as the Civic Audit and the National Laboratories, where citizens are involved in the analysis, design and needs assessment;
3. sharing the services' management: e.g., the inclusion of volunteers and caregivers in the management of certain areas of the organisation, like reception and guiding" (Caracci, Carzaniga, p. 16).

The experiences surveyed by Agenas in this area are little more than a third of the total, while the articles found in PubMed are 164 on 415, or about 40%. Interesting to note, in both cases, a strong presence of patients' involvement in the assessment and evaluation phases (about 50% in Italy, more than 80% in PubMed).

The third set includes the experiences of **community empowerment** such as:

1. "Voice your opinion: e.g., patient's rights defence movements, lobbies, networks of hospitals working together on measures to humanize treatments;
2. contributing to the local community management: measures and instruments of local government – such as Citizen Forums, Solidarity Pacts, strategic planning tools - aimed at involving citizens and organizations in the choices regarding problems, needs, issues to work on" (Caracci, Carzaniga, p. 16).

Compared to previous areas, the number of experiences surveyed by Agenas (10 on a total of 71), as well as that reported in PubMed (48 on a total of 415)⁴ is smaller but shows often a very high relevance, as the interventions included can have a significant impact on the organization and functioning of services.

1.3.2 Instruments

A careful examination of the literature reveals that the tools used to develop empowerment are, strictly speaking, very similar to those studied for consultations (see paragraph 2). The relationships established among citizens, professionals and administrations are, however, more substantial and tend to be built on equal terms.

1.3.3 Prospects

3. The distribution by sector of intervention is as follows: 49 cancer; mental health 40; diabetes 25; Geriatric and senior citizens 21; HIV/Aids 16; young people 15; palliative treatments 13; other chronic diseases 12; intensive care 8; other 33

4. In some cases the studies relate to more arguments; therefore, the sum of the three areas is slightly higher than the number of studies found.

There is a widespread consensus that citizens' empowerment is of strategic importance to the development of health policies that could combine quality, appropriateness and sustainability. To give this consideration a more precise meaning, we might make mention, albeit summarily, of three particularly significant perspectives related to the examined areas.

The first perspective concerns the overcoming of the paternalistic model through the **patient centred care**, which allows the subject to become a resource more than a mere object of treatment. This even seems to make possible a major costs saving, to the point that some critics fear it might lead to a certain relieve of responsibilities on the side of governments (Lancet, 2012).

The second perspective concerns the possibility to improve the liability and transparency of Governments through the development of advanced forms of **accountability**. Citizens can either act with autonomous assessments (as in the case of the Civic Audit in Italy), or check and discuss in public hearings the data provided by the administrations. The results of the talks, as already happened, may affect the evaluation of managers or the planning of services.

Finally, empowerment processes can further **develop the ability of local communities to be agents of development** - and not, as is the case in traditional approaches, mere catchment areas. A confirmation comes from the repertories of Best Practices, published in 2012 by several sources during the European Year for Active Ageing⁵. Certain successful experiences in major fields, such as the construction of networks of local agents - greatly enhancing the spread of information and access to benefits - or the protection of frail subjects through reception and socialization centres, might be mentioned. (ACN, 2012).

1.4 Civic activism

Most of the experiences so far mentioned would probably not exist where the autonomous mobilization of citizens had not forced - or at least solicited - institutions and professionals to accept and develop new forms of dialogue.

“For at least 30 years people get directly involved in public life, i.e. without the mediation of political parties, trade unions and the general bodies of representative democracy ... in very different forms (from local committees to international NGOs, from single-issue groups to movements active in broad sectors of public life) and in very extensive and detailed spheres of action” (Moro, 2005).

The processes of citizens' activation are very complex and diverse. To give a brief idea of the phenomenon, the variety of organizational structures and operating technologies could be taken into account.

1.4.1 Forms

The number of civic commitment organizations operating in the health field is truly broad. In Denmark alone, it is estimated that, out of a population of less than 6,000,000 inhabitants,

⁵ http://www.activecitizenship.net/files/take_action/active_ageing_eu_policy.pdf

patient organisations are between 200 and 300 (HIT, Denmark, 2012), and it is reasonable to assume that this ratio does not vary too much from one country to another. Giving the report itself a prudential value , it can be assumed that in the EU there are no less than 15,000 civic organizations active in health policies - but the number could also be twice as much.

It's an extremely diverse universe, ranging from local groups and committees up to large umbrella organisations operating in Brussels, from associations with a few members to others that exceed one million subscribers. Their forms of organization are highly variable, depending on size, purpose and the interests at stake. Giovanni Moro, for example, has identified at least 12 recurring types:

1. Voluntary organizations;
2. Representative movements;
3. Consulting and advisory centres;
4. Self-help groups;
5. Social enterprises;
6. Social promotion associations;
7. International cooperation organizations;
8. Local groups and committees;
9. Host centres and communities for rehabilitation;
10. Reform workgroups;
11. Collective action movements;
12. Second level structures.

(Moro, 2005, p. 86).

If one considers the members' origin, the **associations of chronically ill** is, in all likelihood, the quantitatively prevalent type in the health field – in fact, we see them frequently appearing in this report. Also significant is the presence of **voluntary organizations** providing services of various kind. Health policies are a privileged field of action for **active citizenship movements** – just remember the promotion of National and European Patients' Rights – and, as we have just mentioned, for the ageing organisations. An important role is also often played, then, by **consumer and users organizations**.

1.4.2 Technologies

Civic organizations are involved at all levels of public life:

- At a local and regional level, where communities measure themselves with the tangible reality of benefits and services;
- At a National level, with lobbying but also by participating in the development of guidelines and policies;
- At a supranational level, giving an important contribution to the European Union's intervention in health policy, previously reserved to the sole competence of the Member States;
- At a global level, through relations with the WHO and the scientific community.

The forms of intervention are likewise diverse: we can define them as real technologies - namely “operational rules systems based on a specific set of knowledge [...] (gained through) [...] the practical experience of active citizenship, the research and deliberation upon it, and its transmission over time” (Moro, 2006, p. 147). They can be grouped into five families (ibid., pp. 148 – 160).

The **first family** consists of direct action technologies: namely “those that organized citizens can practice on their own without any need of consent or involvement of other parties”. They are no less significant, as shown by the following examples:

<p>Direct action technologies (ibid., pp. 149 - 151)</p> <ul style="list-style-type: none"> • The declaration and spread of Charters of Rights, where rights are identified through a collection of information on critical situations in which citizens are involved; • The creation and management of consultancy, advice and assistance facilities; • Monitoring and production of data and information on the operation of the services and/or on environmental and local critical situations; • The running of symbolic actions to attract the public's attention and put pressure on those responsible for; • The implementation of awareness-raising information and actions; • The proximity information, created by citizens considered trustworthy, ensuring the reliability of information that may not be trusted where and when collected from other sources; <p>Conflict management aimed at preventing the deterioration of tense situations between individuals or groups.</p>

A **second family** is that of technologies for the mobilization of human, financial and technical resources necessary for the mission of the organization. Fall into this category both the actions to give stability and continuity to the organization itself, and high public relevance actions that often contribute to determine or influence the institutional agendas.

<p>Technologies for the mobilization of resources (ibid., pp. 151 -154)</p> <ul style="list-style-type: none"> • Recruitment of people on specific or permanent projects; • Fundraising; • Mobilization of the necessary technical resources (computers, mobile phones, etc.) through direct acquisition or the involvement of members; • Signatures and memberships' collection in support of campaigns or initiatives; • Boycotting individuals responsible for prejudicial conducts towards citizens ' rights; • Collection and spread of good practice, including the delivery of awards, prizes and certifications; • Education and training to improve members' skills and the quality of the action; • Creation of networks and associations; • Public use of Information Technologies - websites, interactive forums, social network; • Public use of media in support of the action - press conferences, dossiers and reports, relationships with editors.
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A **third group** is given by technology of interlocution with institutions, trade unions, businesses, etc. They are aimed at putting active citizenship on an equal footing with institutions, with the intention to provide innovative, and otherwise unfeasible, solutions to emerging issues. The action is mostly cooperative, but it can also take conflicting connotations.

Technologies of interlocution (ibid., pp. 154-156)
<ul style="list-style-type: none"> • The promotion of negotiating tables; • The definition - even just on a formal level – of co-operation agreements with partners, both in general and on specific activities; • Participatory planning of actions, promoted both by the citizens and the authorities, to address needs identified by the civic action; • Building partnerships with different parties (other organizations, institutions, professionals, businesses, etc.)

The **fourth family** covers the Institutions’ enabling technologies, used “to bind administrations and authorities to implement laws and regulations containing principles, institutions and procedures aimed at the protection of rights and the care of the common good”. Without the public intervention, very often “the institutions act in a dull, self-referential way, following bureaucratic logics to interpreter norms that remain therefore a dead letter”.

Institutions’ enabling technologies (ibid., pp, 156 – 157)
<ul style="list-style-type: none"> • Production of reports and complaints; • Implementation of the institutions and procedures laid down by laws, regulations, municipal and provincial statutes relating to the protection of rights and the opportunities for citizens to participate in policy making;; • Lobbying – putting pressure on political authorities and public institutions in order to obtain regulatory changes, allocation of funds and resources in favour of causes of common interest; • Lawsuits to protect individuals from violations of their rights and to pledge the judicial system to fill gaps and clarify the eventual ambiguity of laws.

The **fifth and last group** consists of technologies for the management of services promoted and implemented directly by civic organizations to support the practical realization of the rights and the care of the common good. They actually come to be part of the “common heritage”, as it happened with experiences like the rescue by ambulance or psychological support to abused women.

Technologies for the management of services (ibid., pp. 157 – 160)
<ul style="list-style-type: none"> • Counselling centers; • Reception centers for people in need; • Collaboration with services supporting the customizing of treatments and the integration between users and the services themselves; • The proximity information - previously mentioned, it may become a permanent or systematic service; • Public action to enhance the community spirit and mobilize the organization’s resources, ensuring more effective interventions.

The existence of a good correlation between civic participation, sustainability and quality of health services seems to have been proved (EHCI, 2012). This survey on technologies of active citizenship helps to understand the nature of the additional resources that come into play.

1.5 The representation of patients’ experiences

The second half of the last century has seen an increasing awareness of the fact **that patients’ experience is not only a psychological problem that must always be taken into account, but also a valuable source of essential knowledge necessary for a good governance of healthcare**

systems, the development and implementation of treatments, and the scientific research (Akrich, Rabeharisoa, 2007, p.70). At a first stage, this has led to the development of methods and instruments to collect information from patients, that relegated them, however, to an essentially passive role (Altieri, 2002). Since the early 80 's, the development of civic activism, in particular in the field of chronic diseases, has countered this unilateral approach with increasing success. A major turning point comes with the fight against HIV.

“ The notion of **"expert patient"** as known today appears, although very controversial in these terms; and it can take many other names: "patient trainers", "expert users ", " patient educators ", expert by expertise, « expert of the living »... These new figures seem to be needed due to the profitability of their involvement in the healthcare systems, ,but in reality is the reaction of patients facing the management of AIDS that allows health democracy to become established and to articulate expertise of the patients and public health policies” (Jouet, Flora, Las Vergnas, 2007)

The introduction of a concept such as 'health democracy' confirms that the issue is not just a “technical” improvement of the available knowledge, but also the legal ownership of citizens to become active participants in governance. It is interesting to point out, in this regard, that legitimacy does not come from the application of formal criteria of representativeness, but by the ability to practice a set of pertinent and relevant actions that go under the name of Evidence Based Activism (Akrich, Rabeharisoa, 2007, p.74).

The fields in which the collection and representation of patients' experiences have taken a more relevant meaning are the development of **patient centered care**, scientific research and Health technology assessment. Regarding the first field, we have already seen how it is closely linked to the practice of promoting empowerment of individuals.

In the case of **scientific research**, the involvement of patients' associations is an increasingly spreading reality and it's taking forms that are very different to one another: from the definition of protocols to the recruitment of people, from the presence in executive committees to real forms of partnership (Akrich, Rabeharisoa, 2007, p.74).

Patient involvement is an integral part of the **Health Technology Assessment** approach and has been the subject of a specific disciplinary proceeding. The topics examined in this regard have been-

- Information production about citizens ' point of view;
- Consultation, meant as participation in public meetings and/or organized collection of patients' evidences and/or their level of satisfaction;
- Dialogue, interaction and participation in ongoing discussions, in organized and/or in-focus groups;
- Official and on equal terms participation as members of the assessment committees;
- Independent intervention on agencies and processes. (Facey et al., 2010).

These procedures have seen a major development particularly in countries like Australia, Canada and the UK, where the National Institute for Clinical Excellence has set up a specific program: the Patient and Public Involvement Program (NICE, 2013).

Health Equality Europe - an informal coalition of people from a number of countries with a range of expertise who wish to see the patient voice placed firmly at the heart of health-care decisions within Europe – has published a guide for citizens that provides detailed, complete information on the technical and political intervention in the evaluation processes (HEE; 2007).

2. THE 'CIVIL DIALOGUE' IN HEALTH POLICY

2.1 A European feature

The so-called 'democratic deficit' has been an issue for the European institutions since their very birth. A number of corrective actions of great significance has been proposed over the decades, both in the constitutional architecture (e.g., the direct election of the European Parliament by the citizens) and in the construction of policies aimed at establishing 'direct' relationships between the European institutions and its citizens. Although there is no coordinated strategy in this regard

“There is, however, a convergence between the EU institutions when considering civil dialogue as an integral part of the process of 'consultation' in their system, as deemed necessary to meet the principles of good governance, especially *transparency* and *participation*. It represents the interactive dynamic which finds expression in the extensive, complex network of access' channels the EU institutional seats are gradually making available to public organizations” (Mascia, 2010).

“Civil Dialogue' is, along with 'civil society', one of those expressions increasingly used in the language of political circles, particularly those of the European Union. Refined political experts and philosophers like Philippe Schmitter and Jürgen Habermas, just to name a few, rightly see in this expression a sort of last resort for the recovery and development of democracy and good governance. The topic is certainly related to the more challenging and demanding democratization of international institutions and their decision-making processes. In this context, civil dialogue would mean and indicate the 'popular and participatory' dimension of the international democracy” (Mascia, 2007).

The development of civil dialogue has been supported in particular by the European Economic and Social Committee - which also sees the involvement of public representatives - and by the Parliament. The opinions issued by these two institutions have played a significant role, for example, in the recognition of the European Charter of Patients Rights.

As already noted in the previous chapter, a basic problem in the conduct of civil dialogue is for the European institutions to declare their interlocutors to have certain 'representativeness requirements'. **Those requirements are not precisely defined, leaving therefore the institutions with the power to designate these public representatives themselves.** “A particularly practical implication of this attitude is 'the EU giving a preferential financial support - not just on projects' implementation but even for ordinary operations - to organisations considered 'European', that can therefore be based and have operating staff in Brussels. As a matter of facts, this is just another way to select privileged partners” (Moro 2009, p. 114).

As for health policies, civil dialogue is still intense and takes place in different forums: DG Health and Consumer (DG SANCO), the EU Health Forum, the European Medicine Agency (EMA) and the European Network for Health Technology Assessment (which will be covered in the next chapter).

2.2 DG Health and Consumers and Brussels “civil society”

As with all the decisions of the European Commission, all EU citizens can consult the texts of the measures under scrutiny and submit their opinion within the agreed deadlines. Due to its special nature, the direction is particularly 'exposed' to the confrontation with stakeholders and has developed, in this regard, a particular assets and 'Code of Good Practice for Consultation of Stakeholders' (DG SANCO; 2011).

The guiding principles are: effectiveness, transparency, proportionality, inclusivity, accountability and coherence. On this basis, the code defines the general operating modes (deadlines, document features, feedback, etc.) and the criteria for the selection of stakeholders, who are required:

“..one or several of the essential characteristics below:

- a. One who is affected by or affects a particular problem or issue, and/or;
- b. Is responsible for problems or issues, and/or;
- c. Has perspectives or knowledge needed to develop good solutions or strategies, and/or
- d. Has the power and resources to block or implement solutions” (ibid., p. 10)

The evaluation of these features remains firmly in the hands of DG. An area of privileged interlocutors has been created this way. They can exercise relevant functions, for example in comitology – namely, the establishment of groups and committees which assist the DG in designing its measures. More generally:

“consultation is part of a wider process of stakeholder engagement. Stakeholder engagement is a means of describing a broader, more inclusive, and continuous process between DG Health and Consumers and stakeholders. While consultations are often one-off exercises, stakeholder engagement encompasses a range of activities and approaches, and spans the long-term rather than the short-term” (ibid.).

Actually these functions are carried out mainly by the so-called 'civil society in Brussels', made of officials and managers of 'umbrella organizations' with permanent headquarters in Brussels, and professionals working as experts in their field (Zimmer, 2004).

Umbrella organizations are, mainly, confederations of national associations operating in member countries. However, there are also, so to speak, second level confederations, whose members are, in turn, umbrella organizations. This is the case, for example, of the European Patient Forum that counts, as permanent members, over 50 European coordination of associations of chronically ill.

In various documents - and still often in practice - representatives of this 'organised civil society' were considered to be the vanguard of public opinion, at the forefront of a European public space. This approach has been the subject of numerous criticisms, pointing out particularly the fact that these organizations tend to be, basically, self-referential, distant from their 'grassroots constituencies' and often opaque (Kroger, 2008).

The issue is of great importance and should be treated, both by scholars and institutions, with an attention greater than the current one. It is fair, however, to remember that some umbrella organizations have played an important, positive role, promoting the inclusion of the patient's perspective in the health policies of the EU, WHO and international research centres.

2.3 EU Health Forum

“The European Union Health Forum originated in 2001 with the aim of bringing together umbrella organizations in the health sector in order to ensure that the European Commission's health policy is transparent and responsive to public concerns” (EUHF, 2009, p. 1).

The work of the EU Health Forum takes two main forms, the EU Health Policy Forum and the Open Health Forum⁶.

2.3.1 EU Health Policy Forum

The EU Health Policy Forum brings together 52 umbrella organizations representing European stakeholders in the fields of public health and healthcare.

The forum meets regularly in Brussels and performs the following tasks:

- Reviews the EU's work in various areas of public health and adopts recommendations;
- Responds to Commission consultations and assists in organizing consultations;
- Enables exchange of views and experience on a wide range of topics;
- Assists in implementation and follow-up of specific initiatives.

The Forum seeks to ensure 4 groups of organizations are represented:

- public-health non-governmental organizations and patients' organizations (NGOs should cover a broad range of issues and have member organizations in all or most EU countries);
- organizations representing health professionals and trade unions;
- health service providers and health insurance bodies;
- businesses with an interest in and commitment to health promotion, protection and improvement.

Over the years the Forum has approved six recommendations on particularly relevant subjects: qualifying Health and enlargement (2002); Health and EU Social Policy (2003), Mobility of Health professional (2003); Health services and Internal market (2005); Health information (2005) and Chronic disease (2012). Starting in 2009 and accomplishing a new mandate, it has produced eight papers on European strategies in the new crisis' context.

⁶ The information displayed below are dealt with directly from the website http://ec.europa.eu/health/interest_groups/eu_health_forum/policy_forum/index_en.htm

2.3.2 Open Forum

The Open Forum extends the work of the EU Health Policy Forum to a broader set of stakeholders in an annual flagship event. The idea is to provide a platform for networking and exchanging ideas, particularly for groups and organizations which are not normally part of the 'EU circuit'.

In principle, the Open forum should meet once a year. Actually, it has so far held four sessions. The latest, in 2010, was devoted to the theme ' Together for Health: a Strategy for the EU 2020 '. The conference, as well as the accompanying exhibition, attracted over 550 participants from a huge range of stakeholder representations at EU, national and regional level.

2.3.3 The 2009 renewed mandate

In October 2007 the European Commission adopted the White Paper "Together for Health: A Strategic Approach for the EU 2008-2013". On this basis, in 2009, the mandate of the Health Forum was also redefined (EUHF, 2009).

"The overarching goal of the EU Health Forum is to contribute to the development and implementation of actions to protect and improve the health of European citizens. In particular, the objectives of the Forum are:

- To provide a communication channel between policy makers and stakeholders on EU health policy issues. The information in this channel should flow in both directions and should also facilitate communication among stakeholders. This requires a strong commitment of Forum members both to ensure dissemination within their networks but also to reach beyond their members in an open and inclusive manner.
- To enable stakeholders to contribute to EU health policies by identifying emerging health issues, proposing policy options or shaping and giving feedback on policy proposals and implementing measures;
- To support delivery of the EU Health Strategy by health advocacy and other appropriate means and tools at EU, national, regional and local levels.
- To enable health actors at national and local level to define EU level work that will support their agenda.
- To define European work packages that are relevant to the broader range of health actors, e.g. youth, lifestyles, workplace, health promotion or HIAP"
(EUHF, 2009, p. 2).

2.3.4 Criteria for membership's selection

The decision to give preference to umbrella organizations is openly stated and has always been consistently practiced

"The membership of the EU Health Forum should concentrate on associations with a pan-European coverage, rather than on national or regional organizations. In general preference is given to umbrella organizations covering several topics or mandated by other organizations to

represent them in the Forum. For practical reasons the Commission will generally seek to keep membership limited to around 50 organizations” (EUHF, 2009, p. 3)

The criteria were updated in 2009 on the occasion of the renewal of the mandate and are aimed at ensuring the ability of organizations to participate effectively in the work of the Health Policy Forum:

“Broad coverage of issues:

Organizations should cover broad, horizontal issues which are of relevance to developing the Community’s health agenda and with an interest in overall public health policy development.

Representativeness:

Organizations should be recognized as being able to speak for their sector. Their membership should cover (operations) in at least half, (currently 14) and, ideally, all (currently 27) Member States. Organizations should be committed to extending their membership.

Active involvement

Each participating organization should contribute actively to the work of the EU Health Policy Forum. Failure to do so will lead to discontinuation of membership.

Transparency

Organizations should apply the principles of transparency agreed by the members of the EU HPF in the past as set out in the EUHPF guiding principles with regard to transparency published on the forum's website, as well as the European Transparency Initiative”.
(EUHF, 2009, p. 3)

Admission to the Forum and periodical checking of the permanence of requirements are the sole responsibility of the European Commission.

2.4 The European Medicine Agency

The European Medicines Agency (EMA) is a decentralized agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union and, in particular, for licensing laws to market new drugs.

The opening of EMA to consumer and user organizations is relatively recent and has experienced **a significant quantitative and qualitative development**. It has moved from 78 individuals involved in 2007, to 432 in 2011 (EMA; 2011). After careful assessment, the Agency has in fact considered the experience positive, and expects further forms of involvement:

“The added value of patients and consumers in the scientific process of benefit/risk evaluation is confirmed, as they enrich regulatory outcomes by complementing them with the views of those directly affected by regulatory decisions. This is illustrated by various examples taken from existing experience at the Agency. A procedure to systematically assess the need to involve patients at different levels of the CHMP is proposed” (EMA; 2009, p. 4).

2.4.1 Forms of involvement

The opportunities for the involvement of consumers and patients' representatives offered by EMA are multiple.

The most traditional one is the presence in the Management Board with a number of three members appointed by the Commission. It also appoints consumers and patients' representatives in four scientific committees:

- Pharmacovigilance Risk Assessment Committee (one member);
- Committee for Orphan Medicinal Products (three members);
- Committee for Advanced Therapies (two members);
- Pediatric committee (three members).

A quantitatively significant involvement is the participation of experts, designated by the organizations, in the consultations organized by committees or in thematic working groups (e.g., on the package leaflet). People currently mobilized this way are 200. EMEA also organizes workshops, group meetings and other activities that involved, in 2011, a good 176 organizations' representatives. Surprisingly though is, in the report on activities, the lacking of patient experiences (EMEA; 2011, pp. 22- 23).

Participation in the proceedings is often expensive and requires large amounts of time - especially in committees. In such cases, the Agency provides a proportionate financial support.

2.4.2 The European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organizations (PCWP)

"The EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organizations (PCWP) is established to provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients in relation to medicinal products" (EMEA, 2010, p. 2).

This mandate is broadly interpreted by the Agency and the range of possible interventions appears to be quite extensive and detailed.

The PCWP is composed of representatives of the organizations that match the requirements established by the Management Board, the EMA Human Scientific Committees and the Secretariat of the Agency. It meets four times a year to carry out institutional activities and to monitor the activities of the Agency in its relations with consumers and users' organisations.

2.4.3 Criteria for the selection of the organizations

Even in this area the preferred choice for umbrella organizations is openly stated and consistently practised. The Agency defines the requirements - which are substantially the same as those already examined in the previous paragraphs - and maintains a total control over the selection of partners. The eligible patients and consumers' organizations working with the EMA are 34.

The role played by EMA in the selection of its interlocutors is particularly evident in the case of PCWP.

“ The EMA will decide on the organizations that will be represented in the group on the basis of their appropriateness to the subjects covered within the scope of the working party’s mandate. The following areas will be covered: general consumers’ organizations, general patients’ organizations, organizations with specific interest in the mandatory scope of the centralized procedure (orphan drug HIV/Aids, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions).

Upon request from the EMA, patients’ and consumers’ organizations, which fulfill the criteria, will nominate one representative. It would be preferred that the patients’ organizations nominate a patient or career as representative, whenever possible.

The final composition of the group will be of a maximum of 21 core representatives. If several organizations in the same area are eligible, EMA may select only one/some of them, as appropriate” (EMA; 2010, p. 2-3).

Such a form of control reveals a willingness to significantly mark out the scope of the interlocutors, proportioning it to the organization's internal needs. This leads to the exclusion of smaller reality, which are instead very close to the experience of patients and could give valuable contributions. It is no coincidence, perhaps, that the report on activities is lacking, as already pointed out, news on the collection and evidences of the ill.

3. THE HEALTH TECHNOLOGY ASSESSMENT APPROACH

3.1 A “bridge” between science and decision

Developed in the 80s, the Health Technology Assessment intends to provide decision-makers with scientifically verified information to be used in health policy choices. The HTA aims to act as a 'bridge' between science and the decisions taken:

- a) at a macrolevel, with regard to the definition of the levels of assistance, authorization and refundability of technologies;
- b) at a mesolevel, in hospitals and nursing homes for the adoption and purchase of the technologies themselves;
- c) at a microlevel, in clinical practice. (Battista et al. 1989).

In order to achieve this goal, a multidisciplinary approach involving professionals and experts from the medical, humanistic, economic, managerial, engineering and statistic fields has been developed.

“HTA, though, is not simply a set of disciplines and methods to assess technologies. It represents instead a real philosophy of management for a healthcare system that intends to tie the decisions systematically taken to the available scientific evidence or, otherwise, to 'transparent' mechanisms in which all stakeholders can participate by bringing their own perspective ' (Cicchetti, Marchetti, 2010).

This philosophy has allowed the widening of the connections existing between assessment and decision-making processes, and the identification of distinct phases which promote, among other things, a more timely involvement of stakeholders and citizens. In principle, three main stages can be recognized:

- **Horizon Scanning:** detecting and identifying health technologies under development and assessing - often on a forward-looking perspective - their potential clinical and managerial impact on health services;
- The actual **Evaluation Process**, divided in turn into several steps;
- **Post-marketing:** monitoring the actual impact of the decision under various aspects (clinical and economic effects, life quality of stakeholders, etc.) and supervising the stakeholders' behaviours. Information collected at this stage may involve a review of decisions.

The **steps of the assessment process** are the following:

- **Priority setting:** the establishment of scale of priorities on the basis of the gained and shared experience, the of setting priorities for HTAS should be to identify those assessments that offer the greatest benefits in relation to their cost, and thus to maximize the benefit derived from investments in HTA;
- **Assessment:** the most complex phase of the whole process, as it involves the collection and evaluation of all available information (costs, efficacy, social impact, ethical issues,

etc.) and various forms of dialogue with stakeholders. It ends with a reasoned report that can be used by decision-makers.

- **Appraisal:** the in-depth evaluation of the key properties of new technologies, including recommendations for reimbursement.
- **Informing** the stakeholders and **providing** them with the results of the assessment processes.

At every stage of this process, high standards of transparency, accountability, independence and adequate levels of dialogue with all stakeholders should be guaranteed.

HTA's philosophy and approach have been accepted so far by a limited number of decision-makers⁷, and the situations in which they are applied in a consistent and systematic manner are still a few. The political and scientific contributions accrued in these experiences are still highly significant, and could have a general paradigmatic value for the organization of the dialogue between healthcare institutions and citizens.

3.2 Citizens involvement

The involvement of stakeholders is a constituent part of Health Technology Assessment approach. It believes impossible to build a complete and reliable information without a careful comparison with the viewpoints (standpoint) of all stakeholders.

Among stakeholders, of course, the citizens! This is no little a detail as, unlike what usually happens, the fact they are involved in health policies not as an undifferentiated subject but like one exerting instead different, tangible roles (patients, caregivers, members of a local community, public, consumers) has relevant consequences. Such an aspect, correlated with the intrinsic diversity of the assessment processes (see above), has led to the development of innovative and interesting methodologies. Not surprisingly, the international scientific society has set up a special 'Interest Sub-Group on Patient and Citizen Involvement in HTA' (PCISG - <http://www.htai.org/index.php?id=545>).

The growing interest towards the active involvement of citizens is due to technical and political reasons. Regarding the **political** aspect, all health systems are exposed to a crisis of sustainability determined by their own successes - the increase in life expectancy, taking charge of chronic and long-term diseases, etc.- and made more acute, particularly in some countries, by the current economic conjuncture. This calls for innovative choices, often of great social impact. The responsible involvement of all stakeholders – particularly the citizens - in decision-making processes seems to be a prerequisite for the identification and implementation of appropriate and shared actions.

As for the more **technical and scientific aspects**, there is a broad consensus that patients experience allows you to see what clinicians and technicians do not see. Such involvement may improve the basic information on the efficacy of new technologies and their effects on quality of life; it may also allow a more accurate assessment of the actual economic impact of

⁷ For example, only 18 decision-makers (national government, regional governments and insurance funds) from 10 European countries responded to the survey conducted in 2011 by the European Patient Forum (EPF,2001a).

decisions (not just with a mere quantitative approach, but 'a wider scope' which includes the views of final users); last but not least, it takes into account information and views that allow an ex ante evaluation of the impact of decisions on recipients (Deloitte, 2009).

3.2.1 Where, how and when

As mentioned above, the involvement of citizens, in their different roles, covers virtually all phases of the assessment process and can be achieved:

- 'by implementing mechanisms to report the relevant issues for the patient, taking his views and perspective into account. 'Phase of **identification of the technologies** to be assessed ';
- providing the opportunity for the patient to help – alongside healthcare and industry professionals – in the collection of evidence to inform decisions: '**Assessment phase**';
- creating forms of patient participation in the decision-making process itself: '**Decision phase**';
- involving patients in the circulation of the recommendations made on the basis of the assessment process '**Communication phase**'.

A survey conducted in 2004 by the CAHTA⁸ (Gagnon, 2004) found that a growing number of agencies engaged in promoting the involvement of patients and citizens in decision-making processes. In particular it was found that patients may be involved:

- within audit groups (in the phase of reporting and prioritisation of the technologies to be assessed);
- through patient/consumer representatives in committees or committees of patients/consumers (Assessment phase of decision-making);
- as recipients of publications or consumers patient-oriented means of communication (Information and communication phase of assessment results). (Cicchetti, Marchetti, 2010, pp. 21-22).

Actually there is still a considerable gap in the attention paid to the dialogue with citizens. A survey conducted by INAHTA⁹ in 2010 among agencies that engage in the HTA found that only 52% of the respondents had practiced some form of involvement and that 19% did not even envisage activities in this regard for the future. Furthermore, only 60% of the agencies reporting to involve citizens acknowledge them an active role, although a mere advisory one; 40% considers them, however, an important source of information but prefer to acquire their views through investigations or surveys that, basically, relegate them to a passive role. Finally, only 20% invests in training patients to the Health Technology Assessment, while only 19% evaluates the impact of this involvement on the quality of final decisions. On the one hand, these data confirm the existence of an important commitment of the part of the agencies. On the other hand, however, they show a lot more needs to be done.

⁸ Catalan Agency for Health Information, Assessment and Quality (www.cahta.com)

⁹ International Network of Agencies for Health Technology Assessment (www.inahta.org)

As for the phases of the assessment process in which citizens are involved, one can refer to a comparative study by Deloitte that distinguishes consumer prospects from those of the communities.

“Essentially, there are two narratives from the public that are becoming major components of HTA processes:

- *The consumer perspective* — to account for important variation in health outcomes an/or preferences across patients and to provide evidence in relation to benefits not captured by QALY assessments
- *The community perspective* — a broad societal perspective on value facilitates informed discussion and decisions about access, use and affordability of new health technologies” (Deloitte, 2009, p. 27).

The comparison reveals a fair variability in the way agencies act, characterized by a common lacking of initiatives only in the horizon scanning, monitoring and review phases. It is a critical matter that needs to be addressed.

Tab. 1: Overview of patient and public involvement in HTA by market. (Deloitte, 2009, p. 8)

<i>Hta phase</i>	<i>Perspective</i>	<i>Rationale for consumer involvement</i>	<i>Australia</i>	<i>England</i>	<i>Scotland</i>	<i>Canada</i>	<i>France</i>	<i>Germany</i>
<i>Policy development</i>	<i>Community</i>	<i>Priority/moral/ethical aspects</i>	X	√√	X	√	X	X
	<i>Consumer</i>	<i>Areas of need</i>	X	√	X	X	X	X
<i>Horizon Scanning</i>	<i>Community</i>	<i>Priority/moral/ethical aspects</i>	X	X	X	X	X	X
	<i>Consumer</i>	<i>Areas of need</i>	X	X	X	X	X	X
<i>Product appraisal and reimbursement</i>	<i>Community</i>	<i>Value Judgment pertaining to rationing/affordability</i>	√	√√	√	√√	X	√
	<i>Consumer</i>	<i>Not all benefits captured by QALYs</i>	√	√√	√√	√	X	X
<i>Monitoring and review</i>	<i>Community</i>	<i>Measures of value, are value/norms changed</i>	X	X	X	X	X	X
	<i>Consumer</i>	<i>Effectiveness assessment (i.e. to safety evaluation)</i>	X	X	X	X	X	X

3.2.2 Representation issues

The choice of criteria for the identification and selection of citizens and patients' 'representatives' remains an open question even in Health Technology Assessment. The aforementioned INAHTA survey highlights, once again, a preference for large organizations.

They turn out being, in fact, the target of a good 91% of the agencies. The particular nature of the approach, however, favours the search for more open and more inclusive solutions.

The need to produce robust evidence, for example, brings a good 86% of the agencies to enable forms of collection of information on patients' experience, and 45% of them to even include individuals in the conduct of the trial. Quite frequent the recourse to direct consultations, both open and online. There are actually many openings for independent intervention of civic organizations and 58% of the agencies accept their proposals.

Belonging to major organizations remains a preferential requirement to be involved in working groups and, particularly, committees with decision-making powers. Agencies, however, reserve special attention to potential conflicts of interest that may arise also in the context of civic organizations. It often happens, in fact, that larger associations can support their business thanks to funding received from industry. In this case, the representatives of the associations are required to declare them scrupulously (Facey et al., 2010).

3.2.3 Patients' evidence

Citizens and, above all, organizations can participate in the production of evidence – namely, conclusions supported by rigorous evidence. They can do so either by presenting their own reports on the subjects under assessment, or by sending notes and comments on intermediate documents and final recommendations of agencies.

Tab. 2: The information which consumers and community member can provide at each stage of HTA. (Deloitte, 2009, p. 44)

<i>Hta phase</i>	Experience with relevant disease	General experience with healthcare	Personal values and beliefs	Understanding of societal value	Direct impact of HTA outcome	Indirect impact of HTA outcome	Consumer Community input
<i>Policy development/ priority setting</i>	x	√	x	√	x	x	Community
<i>Horizon Scanning</i>	x	x	x	√	x	x	-
<i>Product appraisal and reimbursement</i>	√	√	x	√	√	√	Consumer Community
<i>Monitoring and review</i>	√	x	x	x	√	x	Community

Organizations' activities, in general, are not very visible. It is rare indeed to find news about them through literature reviews. Another important limitation is that agencies tend to involve citizens and their organizations at already advanced stages of the process, when the possibility to concretely affect the activities are smaller. Last but not least, the content and form of patients' information are rarely supported with the necessary conceptual and technical tools.

Citizens' contributions, then, are likely to be of poor quality and it can become difficult to enter the patients' evidence in the assessment, as instead pressed for by the general methodology.

Nevertheless, a few agencies invest, as we have seen, on the training of patients and the public. To help overcome this gap, Health Equality Europe¹⁰ has produced a guide that describes how patients and the public can get involved, and that contains, among other things, detailed instructions on how to compile patients' evidence on the following subjects:

- Nature of illness (chronic, common, rare, life threatening, etc)
- Limitations illness imposes on daily life (home, work, social activities...)
- The most difficult aspects of the illness
- Psychological and social issues (stigma, exclusion, mental wellbeing, benefits/unwanted effects compared with existing treatments)
- How easily technology fits into daily life (including adherence)
- Financial impact of technology (cost of travel, loss of earnings, cost of paying carer)
- Outcomes from a treatment that would be most valued by patients (and carers). (HEE, 2008, appendix 5).

The European Federation of Neurological Associations (EFNA) in partnership with the London School of Economics has given birth to the HTA Patient Academy, which organizes an annual **Summer School for leaders of civic organizations**. A similar initiative was taken in Italy by Cittadinanzattiva in collaboration with Agenas and the Italian Society for Health Technology Assessment (SiHTA).

3.3 Some international experiences

The already mentioned study by Deloitte has analysed the policies of patients' involvement in six countries (Australia, UK, Scotland, Canada, France and Germany). The first four are particularly significant and help to understand how the general principles actually develop, as well as to assess the actual impact of public intervention.

3.3.1 Australia

“Australia operates a national Pharmaceutical Benefits Scheme (PBS) to provide ‘timely, reliable and affordable access for the community to necessary and cost effective pharmaceuticals. Under the PBS the Australian Government subsidizes medicine costs to help people pay for prescription medicines for most medical conditions. Members of the public are integrated into the PBS process in three ways:

¹⁰ Health Equality Europe (HEE) is an informal coalition of people who wish to see the patient voice placed firmly at the heart of healthcare decisions within Europe. HEE brings together people from a number of countries with a range of expertise united by a commitment to making the patient voice heard.

- *Committee member (community involvement as healthcare consumers)*: a Consumer Representative sits on the Pharmaceutical Benefits Advisory Committee
 - *Patient Group Submissions (consumer)*: a version of the PBAC agenda is made publicly available within 4-6 weeks before a meeting. Consumers have the opportunity to provide comments on new drug submissions, changes to listings and re-submissions. In many circumstances, consumers are able to comment on items in other sections of the agenda. There is no provision for consumer comments to the PBAC in relation to pricing matters.
 - *Consumer Impact Statements*: [...]have recently trialled (three trials) to produce information about the nature of a condition, separate to the consideration of any drug in particular. The Statements are requested by and provided to PBAC, and allow patients to present, in their own words, details about how a condition affects their daily life as well as the impact on carers.”
- (Deloitte, 2009, pp. 30-31)

“Key insights gained and perspectives offered in consultations with Australian consumers and regulators were:

- *Transparency is essential — consumers must have a clear idea about how their information will be integrated into the process.* Consultations revealed that there was limited information set available to consumer groups about how and to what extent their input will be integrated into the PBAC process of deliberation[...].
 - *Submission processes should be more accessible.* Interviewees pointed to difficulties they had with understanding the submission processes, beginning with difficulties in navigating to the appropriate websites. There was a concern that this in itself may act as a barrier to the involvement of smaller, poorly resourced patient interest groups.
 - *Patient group involvement varied by patient group.* It was pointed out that some treatments receive a significantly larger response than others. Tied into the issues mentioned in the above point regarding accessibility, it is possible that some patient interest groups were potentially geared better to providing meaningful and multiple angles of submissions. Other groups were not well coordinated or adequately resourced and were notably under represented in the processes.
 - *There is value in considering complementary medical technologies together.* It was raised by some interviewees that the separation of assessment processes for drugs and complementary devices meant that they were required to invest extra resources into their submission processes, sometimes frustratingly ending with the conclusion of one technology being approved and not the other.”
- (ibid., pp. 31 – 32).

3.3.2 Scotland

“To ensure that medicines are equally available to all people in Scotland [...] the Scottish Medicines Consortium (SMC) was established in 2001 to assess all new medicines as to whether they were cost effective for use in Scotland. Members of the public are integrated into the Scottish Medical Consortium (SMC) process in two ways:

- *Committee members (Community involvement)* — SMC has three lay members who offer a lay perspective within the assessment process. The lay members are recruited

by a process of open advertising, resume scanning and interviewing. Successful candidates must not be health care professionals but at the same time must have some background experience in healthcare and an interest in being involved.

- *Patient group submissions (Consumer involvement)* — Patient interest group submissions are also considered by the SMC. In order to submit information, the Patient Interest Group must understand the medicine under review. Typically, the SMC secretariat will be able to provide company prepared documentation entitled 'Summary of Information for Patients'. Submissions are encouraged to include information about:
 - What it is like to suffer from the condition
 - The perceived advantages and disadvantages of existing medicines
 - The potential benefits and impact of the new medicine upon the lives of people with the condition.

The Public and Patient Involvement Group, a sub-committee of the SMC, present a summary of the Patient Interest Group submissions to SMC meetings. They also have a role in promoting public awareness of the SMC, ensuring patient/carer perspective is prominent in all SMC assessments and making recommendations to the SMC on the development about public involvement opportunities.” (ibid., p. 32)

“Key insights gained and perspectives offered in consultations were:

- *Patient involvement was variable.* Some patient interest groups were perceived to be well resourced and have greater ability to be both actively and meaningfully involved in the SMC processes. Other groups were noted not to be as well coordinated or adequately resourced and had been perceived to be comparatively under-represented in SMC processes.
- *Education and outreach are important to overcome informational and community awareness barriers about the SMC process.* The SMC provides training and presentations to consumer groups to educate them about the process, reduce information barriers to participation and encouraging awareness of the process. The SMC has sought to increase their accessibility through the development of a website..
- *Evaluation and monitoring of performance was seen as important.* The SMC [...] continues to learn about and develop mechanisms for public involvement in their processes [...] (and) [...] to encourage and facilitate participation from all potentially interested patient interest groups..
- *There is a need take into consideration any conflicts of interest which may impact on patient group submissions.* Patient groups require financial resources to function. At times, these are funded by sponsor companies, potentially compromising the ability of these groups to provide independent and objective information in their submissions. The SMC considered a solution to be for a body such as the SMC to provide financial assistance to the groups to facilitate the preparation of submissions. However, in light of limited resources, the SMC addresses this matter by requiring each submission to include a declaration of any conflicts of interest [...].
- *Lay members who sit on the committee should not be treated as 'representatives'.*
- *The timing of presentation for consumer input is important* It was raised in consultations that the time at which consumer input is presented to the committee has the potential to determine the weight it is given. In the SMC, Patient submissions were originally considered after the presentation of the New Drug Committee and the accompanying response from the sponsor. Following a review of the effectiveness of

consumer involvement, the SMC considered that this was ‘too late’ in the process, such that consumer input was being discounted relative to other evidence. Patient submissions are now considered alongside evidence provided by the New Drug Committee.” (ibid., p. 33-34).

3.3.3 United Kingdom

In the UK, the assessment process is managed by NICE (National Institute for Health and Clinical Excellence), an independent organization responsible for providing national guidance on the promotion of good health and the prevention and treatment of illness.

“NICE has formed a Patient Involvement Unit aiming to involve patients and carers in the development of individual clinical guidelines. NICE involves consumers and community members in several ways, at different stages of HTA [...].

- *Citizens Councils (community involvement)* — The objective of Citizens Councils is to bring the views of the public to NICE decision-making about guidance on the promotion of good health and the prevention and treatment of ill health. Citizens Councils are formed from a varied group of 30 people and address challenging questions about values, such as fairness of resource allocation and priorities of need. A summary sheet of the values they decide upon is made available for all NICE committee members at meetings.
- *Suggest a topic (community involvement)* — the topics NICE develops guidance on are derived from a number of sources, including the Department of Health, healthcare and public health professionals, consumers and the community.
- *Committee members (community involvement as healthcare consumers)* — All NICE committees and working groups include at least two community members with personal experiences in the healthcare system. They need not have consumer experience with the product which is being considered, but are required to bring their perspective as a user of healthcare in general to discussions and decisions. They are recruited either via national patient and carer organizations, web-base advertisements or the national press. They are reimbursed for the days they sit on the committee and any additional expenses which are necessitated by the process.
- *Patient interest group input (consumer involvement)* — National patient or voluntary organizations can register as stakeholders for individual topics. This means that they are able to help set the questions which are considered, comment on research evidence and draft recommendations. They may also be invited to nominate experts to attend meetings or join working groups.
- *Individual involvement (community or consumer involvement)* — Individual members of the public can comment on draft guidance through the NICE website. Part of the NICE process is held in a public space to allow for transparency of process.

Parts of the process are still conducted in private to allow for the presentation and discussion of material which is commercial in confidence.” (ibid., pp. 35-36).

“Key insights and perspectives gained during consultations from the UK experience were:

- *Citizens councils can be expected to provide a broader, more representative view than the lay members who sit on NICE committees.* The councils have 30 members with 10 members randomly rotated off periodically keeping 20 together to maintain cohesion. The lay members who sit on the committee [...] does not [...] represent all healthcare consumers or the consumers who are affected by the disease in question. [...] By contrast, the views that are gathered from Citizens Councils are considered to be representative of an informed, broad social perspective.
- *Lay member who sit on NICE committees contribute more during private sessions than public session [...].* An observation was raised during consultations that lay members may feel more comfortable presenting their own views, as is their remit, in the commercial-in-confidence sessions rather than the public sessions. It was reasoned that the lay members may feel pressured to represent public views under the scrutiny of the public eye or were concerned for the judgment of their views by the public.
- *There is a need take into consideration any conflict of interest which may impact on the contributions of consumer and community members involved in the process.* Lay members of NICE committees are not permitted to have any financial incentive to vote in favor of certain products. Moreover, this conflict check extends to their immediate family. Since the implementation of the extended conflict check to family members many lay members have been rotated off of the committee. This was seen as critical for the integrity of the process.
- *It was perceived that increased transparency had led to greater credibility of the process.* NICE provides significant public documentation to its approach and recently moved to make part of its meetings open to the public. This was perceived to have strengthened the credibility of the process with consumers. It was mentioned in the stakeholder consultations that it is typically the media which attends public meetings of NICE committees. This was not seen as a sufficient reason to stop holding them. It was the view of some interviewees that this openness of process added to the credibility of guidance issued.
- *Evaluation and monitoring was seen to be important.* NICE is implementing system for the review of the effectiveness of consumer involvement to ensure that the process remains credible and consumer participation continues to add-value to the process.
- *There is potential for consumer involvement in post-market surveillance activities.* NICE does not currently involve consumers or the community in post-market surveillance activities. In consultations, it was suggested that consumer involvement at later stages would be an effective methodology of assessing the effectiveness of consumer involvement at earlier stages. It could be measured whether consumers responded to the product (behaviorally as opposed to clinically) as they stated they would during the original HTA process.”
(ibid., pp. 37-38)

3.3.4 Canada

Canada is distinguished by its strong federal system of government. In Canada, policies pertaining to pharmaceutical coverage and reimbursement vary significantly among the ten provinces, three territories and certain drug plans under federal jurisdiction.

At federal level, “the Canadian Expert Drug Advisory Committee, a body within the Canadian Agency for Drugs and Technology in Health (CADTH) was charged with coordinating health

technology assessments of new drugs through the Common Drug Review (CDR). The CDR makes recommendations for listing on the basis of a cost-effectiveness assessment. This advice is provided to the provinces, which may adopt the CADTH recommendation, undertake their own assessments to reflect the unique needs of their local populations or seek to negotiate a lower price.

The involvement of community and consumers in CDR is currently limited to *Committee members (Community involvement)*, two public members who sit on the CDR committee are charged with providing the social/public perspective. They are both voting members, but as yet do not have a separate defined role other than contributing to the discussion as they see fit...(they).. may potentially assume a more defined role, summarizing at presenting patient group submissions at the committee level. It is yet to be defined how this information will be formally incorporated into the decision making process ” (Deloitte, 2009.pp. 38-39).

“The CDR provides recommendations to Provincial and Territorial health authorities who then conduct their own HTA processes [...] Various provinces are beginning to integrate consumer and community involvement into their processes as well. For example:

- In Alberta, consideration is being given to the formation of Citizens Councils to review and recommend pharmaceutical from the perspective of a member of the public;
- [...] Ontario formed a 25 member Citizen’s Council to provide biennial advice to the reimbursement of medicines recommended for listing on the public drug plan;
- In Nova Scotia, the Cancer Systematic Therapy Policy Committee provides the Nova Scotia Department of Health with advice on what cancer drugs should qualify for public funding.”
(ibid., p. 39).

“Key insights and perspectives gained during consultations from the Canadian experience, which covered discussions of both the Federal and Provincial HTA processes, were:

- *There is a need to provide an explicit role the lay members on the committee to encourage participation.* The consultation process revealed that the inclusion of a lay member may not be enough to encourage them to be involved in what could be a rather technical process. It was suggested that providing these members with an explicitly defined role and responsibility.... It may even serve to cement their position as an essential voice to be included in the committee amongst other committee members...
- *The meaningful inclusion of public members on committees requires a cultural shift* [...] (to combine) [...] scientific evidence analysis [...] (with a fully understanding) [...] of value of the ‘softer’ evidence [...].
- *Training is important to support lay member representatives* [...].
- *Patient groups which are more vocal and visible may have an indirect influence on drugs which are listed.* It was suggested that some patient groups, despite not submitting directly into the CDR process, may still have better access to the broader HTA system [...] through their public activities and that this potentially contributed to more listings for some conditions than for others where awareness of the condition was not as great, due in part to the limited resources of the group. This was cited as a

reason for creating a formal pathway into the HTA process for patient groups, giving all groups the opportunity to have their views heard.

- *There may be benefits from disease specific consumer input into CDR deliberations process.* As mentioned above, a mechanism for incorporating disease-specific input from consumers is currently being developed. In this development process, suggestions have been made that there must be clear guidelines as to how the information will be used in the CDR process. Also, it was raised that training material must be made available to aid patient interest groups put together submissions.
- *Enhanced post-marketing surveillance should be pursued with strong consumer involvement.”*
(ibid, p. 39)

3.3.5 Brief note on the impact of citizens' presence

Literature, as it turns out, puts a particular emphasis on the value of patients' evidence and on the inclusion of the public and communities in assessment processes. There is, however, a lack of detailed and comparative studies on the impact of such participation. **Two important limits can be seen in the actual approaches used by agencies - the first is a lack of resources to fully engage the patients in decision-making, the second the fact they keep on being considered not as a partner in all respects, but mere final users** (Messina, Grainger, 2012, p. 17).

This gap seems to take on a particular significance in Canada, where patients' representatives believe Governments consider the involvement as a matter of image rather than an essential issue, and complain about the difficulties to give their information weight and stand comparison with experts and professionals (ibid., p. 9).

Even in Australia patients' organisations consider to be often confined in a subordinated role (ibid., p. 15). The Consumer Impact Statements developed in a series of trials with the Consumer Health Forum has reported of a positive relationship with the Pharmaceutical Benefits Advisory Committee but they were not able to give precise information on the impacts of participation (Deloitte, 2009, p. 31).

The Scottish and, above all, the English system have implemented policies designed to overcome these limitations, and obtained important results. Patients' evidence, in fact, gave a major contribution to the improvement of various decisions, as shown by the following examples.

In Scotland, a drug combining more active ingredients in just one pill was taken out of the market, as considered expensive and lacking in evident clinical advantages. Patient interest groups made submissions into the process: the primary set of patients using the drugs often presented with xerostomia (dry mouth); they reported the difficulty they had swallowing multiple pills per day due to their condition. This view, which was not reflected in the clinical data presented, was influential in the final listing decision for that particular drug (ibid., p. 33).

In the UK, dialogue with patients was instrumental in the identification of correct criteria to evaluate the efficacy of a new drug for the skin. In addition, a consultation on the introduction of home haemodialysis for people with end stage renal failure has highlighted that, for many patients, it was important to maintain a distinction between place of residence and place of treatment. Despite home treatment initially being deemed to be more cost effective, the NICE

recommendation stated that all patients suitable for home haemodialysis should be offered the choice of having it administered at home or in a renal unit.

A further example of positive interactions regards the preparation of guidelines on various subjects (ibid., pp. 35-36)

In conclusion, it can be said the impact is relevant when involvement takes place within the framework of a well-structured program which shall include, among other things, a systematic monitoring of the activities and a consequent periodic review of procedures and processes.

3.4 The European Coordination (EUnetHTA)

The EUnetHTA¹¹ project, funded by the European Union, was created for establishing a sustainable European network on Health Technology Assessment. The Secretariat was entrusted to the Danish Centre for HTA (DACEHTA) in Copenhagen. The network connects national and regional realities, fostering the exchange of information and the standardization of approaches. The project involved 63 partners who have developed activities related to eight different Work Packages, the two most distinctive features regarding the so-called 'HTA core model' and tools to adapt the products made at a continental level to the individual national and regional realities.

The EUnetHTA experience became part of the Joint Action, promoted by DG Health and Consumer, that is a formal collaboration between EU Member States and the European Commission. Within the Joint Action has been developed a Stakeholder Involvement Policy (EUnetHTA; 2012).

3.4.1 Stakeholder definition

The EUnetHTA Joint Action uses the following definition of “stakeholder”:

“Groups or organizations which provide considerable insight into views of the groups they represent, and which will be affected by, or have an interest in, and may in a consultative role contribute to the actions or aims of an HTA organization, project or policy direction”.

The following four types of stakeholder groups have been identified as particularly important for the EUnetHTA Joint Action to interact with:

- Patient and healthcare consumer organizations
- Healthcare providers (professionals and hospitals)
- Payers
- Industry.

(ibid., p. 2).

¹¹ www.eunetha.eu

3.4.2 Different forms of stakeholder involvement

“The involvement of stakeholders takes the form of:

- Participation in the EUnetHTA Joint Action Stakeholder Forum
- Public consultations on deliverables
- Participation in the EUnetHTA Joint Action Work Packages (through advisory groups) subject to decision by the EUnetHTA Executive Committee.
- Facilitation of the provision of specific subject-matter information/knowledge on specific technical questions (ibid., pp 2-3).

EUnetHTA Joint Action Stakeholder Forum:

“In order to have a permanent structure for involvement of stakeholders during the EUnetHTA Joint Action a Stakeholder Forum will be created as part of the governance structure.

The aim of the EUnetHTA Joint Action Stakeholder Forum is to provide stakeholders with the opportunity:

- to participate as stakeholder representatives in the EUnetHTA Joint Action;
- to observe and comment on the EUnetHTA Joint Action work;
- to provide advice to overarching governance questions in the Joint Action and
- to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies and in line with the aims of the EUnetHTA Joint Action

The composition of the EUnetHTA Joint Action Stakeholder Forum should ensure a balanced representation of the four identified stakeholder groups. The EUnetHTA Joint Action encourages collaboration between all stakeholder organizations found eligible for participation in the EUnetHTA Joint Action Stakeholder Forum. The function of the EUnetHTA Joint Action Stakeholder Forum will be reviewed annually to ensure that the Forum remains representative of all relevant interests. The minutes of all its meetings will be made publicly available” (Ibid., p.3).

Actually, twelve are the organizations admitted at the Forum, three for each category of stakeholders. A further case confirming the attitude of European institutions to select their own partners and privilege umbrella organizations.

The 2012 Consultation:

In 2012, the Health and Consumer Directorate General opened a consultation on the involvement of stakeholders in the EUnetHTA network. In the final report, along with data processing, there is an observation, shared by the majority of participants, on the need to adopt at a European level more inclusive criteria as a basic condition for the production of high-quality evidence.

“Stakeholder involvement is necessary for increasing quality, relevance and acceptance of HTA-research, not for “democratic” reasons alone. It has to be organized wisely, otherwise it

can be very time-consuming. Therefore: the more focused and project- specific the better the gain/benefit in increasing quality, relevance and acceptance.

Generalists (“meta”-representatives of stakeholder-institutions: EU-patient organizations, EFPIA, etc.) should ONLY be involved in public consultation of methodology issues (e.g. REA-guidelines), but when a drug is actually assessed (guided by REA-guidelines) the respective company, the respective patient group, the respective provider-group concerned should/might be consulted (if a gain/benefit in increasing quality, relevance and acceptance is to be expected)” (DG SANCO; 2012, p. 22).

3.5 Towards an equal dignity?

Thanks to its diversity and stated attention to the involvement of citizens, the HTA approach makes clear a series of issues that, in hindsight, are - or should be - relevant to all processes of participation.

The information here presented, compared with the findings of other studies¹², suggest at least three kinds of problem.

The first problem is the existence of barriers that make participation difficult. The information asymmetry between the experts/professionals and not-professional citizens has a significant weight. Training initiatives like those of Scottish SMC and NICE and support to the independent activity of the associations (e.g. summer schools) are needed, also to ensure their competence, qualification and independence from possible sponsors.

An often overlooked aspect is timing. Deadlines for submissions are often too tight to permit reasoned actions, even more so when documents use a pure technical language and are not 'translated' - as it is the case with NICE.

Finally, the cost in terms of loss of work days, travel and accommodation to attend meetings and prepare submissions should be also taken into account.

A second set of problems has to do with transparency and accountability. The assessment criteria are not always clearly stated, submissions might not receive a verifiable feedback and the way some websites are organized can make it difficult at times to reach the desired links in online procedures.

The criteria for inclusion of civic organizations are a special case of lack of transparency. As it turns out, they are not always verifiable and still tend to favour larger organizations that cannot provide the required expertise and due representation in all fields. The result is a loss of valuable knowledge.

The third set of issues relates directly to the role of citizens, which, as already mentioned, are not always considered as actual partners but mere 'objects of observation' or interlocutors to be consulted on purely formal grounds.

¹² See in particular the final report of the seminar organized by the European Patient's Forum in 2010 (EPF; 2010).

As a result of such attitude, civic evidences are not considered in the same way as the clinical or economic ones. The still widespread tendency to delay consultation is another aspect of great importance. In the more extreme cases, consultation can even take place when the decision has essentially already been taken.

Overall, the problems above can all be traced to a common factor, namely the recognition of equal dignity for all the participants involved in the assessment, including the citizens.

Removing barriers and finding appropriate solutions, as it turns out, is not just a matter of formal democracy but an investment to improve the quality of assessment. In other words, it could be said that the impact improves when the rights of participation identified by the European Charter of Active Citizenship are recognized and enforced: the right to intervene, when it comes to public rights and interests; the right to carry out preventive measures; the right to consultation, when decisions are still under scrutiny; the right of access to information; the right to assess; the right to a qualified dialogue (ACN, 2006).

This is not a rhetoric consideration, but one that concerns the future role of Health Technology Assessment itself. A sufficient enough one to let governments make the most of such an approach, and to start seriously considering it as a valuable means to cope with the current crisis of sustainability of health systems. Unfortunately this is not yet the case, and there is rather the risk of a return to purely accounting forms of management. A strong bond with citizens and their rights appear to be essential to meet the challenge.

4. PARTICIPATION IN MEMBER STATES

4.1 Introductory note

The lack of studies on the involvement of citizens in health policies concerns not only impact assessments but, much more trivially, the rational collection of elementary information, such as forms of recognition adopted by the national authorities, the consistency of civic activism, the procedures for the protection of rights.

At a European level, there are only two available survey on Member States, which are however limited to specific topics. The first is the one carried out by the European Patient's Forum on patients' rights in the EU, published in 2010 and relating to the regulatory measures that should guarantee the rights to informed consent, to information concerning own health, to right to medical records, to privacy, to complain and compensation (EPF, 2010). The second is the Euro Health Consumer Index report which, in its 2012 version, assigns to each country two scores relating, respectively, to the provisions for the rights of the sick's protection, and to the involvement of civic organizations in decision-making. The scores were assigned on the basis of a survey conducted with healthcare officials in both public and private sector. The data are "no CUTS"¹³ (EHCI; 2012).

The Assessment on the EU Charter of Patients' Right of 2011 involved 20 countries and measured the implementation of each of the 14 rights in each country. About 100 indicators have been used, and on their basis the Patients' Right Euro Score have been defined.

To remedy, albeit in a partial way, to this gap, we have collected and organized the information available in the studies of the series "Health system in transition" of the WHO. To ensure a reasonable degree of updating, data published before 2010 have been discarded. Fourteen countries¹⁴ were thus selected, and it was possible to add Italy to the list thank to the availability of up-to-date studies.

For the sake of uniformity, the information has been ordered to correspond to the topics covered in the first chapter, and more precisely:

- **the consultation forms**, which may also include some information about **civic activism** (reports often ignore this topic, or treat it only with regard to the institutional activities);
- **empowerment**, which, on the basis of the information collected, relates to the formation of the user as a subject with strong bargaining power with the healthcare system by asserting the rights to choice, informed consent, further medical opinion, complaint and compensation¹⁵;
- the **Health Technology Assessment**.

¹³ CUTS= (Comprehensive Uniform Trustworthy Source).

¹⁴A report on Greece, updated to 2010, was also available, but the events that occurred in recent years advice against its use.

¹⁵The process of building a strong user as a resource to cope with the crisis of the European welfare state model has been discussed in the Civic Assessment on The EU Charter of Patients' Rights. (ACN; 2011).

It was not possible to treat the collection of the experiences of patients, due to lack of data. For some countries it was possible to integrate the information of WHO reports with those from other sources, which are mentioned in the respective paragraphs.

In order to report the information as faithfully as possible, the selected texts are quoted literally by introducing, where appropriate, short linking sentences. For a similar reason, the comments were postponed to the final chapter.

In order to facilitate a more comprehensive evaluation, the value of EHCI for the consultation forms, and the value of PRES for empowerment have also been reported under each paragraph's heading.

4.2 Belgium

Consultation and participation

Euro Health Consumer index: "so – so"

"Sickness funds in Belgium are more than simple insurers; their role is also to represent the patients and to make their voices heard in the health care policy-making process. Patients' associations also represent patients' interests. With the increase of patients' associations, French, Flemish and German federations have been created: the LUSS, the VPP, the Patiënten Rat & Treff and Radiorg. These federations receive public subsidies from federal and federated authorities and have representatives in the Federal Commission of Patients' Rights. The aim of the Federal Commission of Patients' Rights is to collect and treat information, to formulate notices to the Minister of Social Affairs and Public Health, to assess the application of patients' rights, to assess mediations processes and to treat claims related to mediations processes.

In order to increase patients' participation in the health care system, different initiatives have been undertaken and some organizations have included representatives of patients' associations in their management processes. For example, the Walloon Institute for Mental Health (IWSM) has included representatives of patients' associations in their administrative board and the Flemish Association for Mental Health (VGG) involves representatives of patients' associations in their management. Representatives of patients' associations for disabled people and their relatives are also involved in the management of the AWIPH and the VAPH. Subsidized homes for the elderly must also have a resident council included in their management." (WHO; Belgium, p.76).

Patient empowerment

Patients' Rights Euro Score: medium

"In August 2002, Belgium introduced legislation on patients' rights. The purpose of the Patients' Rights Act is to strengthen the legal status of the patient. Prior to this Act, patients' rights could be inferred from general legal principles, international treaties and constitutional and criminal stipulations. The Patients' Rights Act regulates the rights of patients with regard to health care professionals, including physicians, dentists, pharmacists, nurses, midwives, physiotherapists and paramedics." (ibid., p. 69).

“The law on patients’ rights also grants the right to a complaints procedure. Patients can submit their complaint to an ombudsperson. The ombudsperson should, in the first instance, support communication between the patient and the health care professional. If the patient and health care professional do not reach a solution, the ombudsperson has to proceed to mediation. If the ombudsperson’s mediation does not lead to a solution, the ombudsperson has to inform patients about other alternatives for taking the complaint forward. On the basis of the information obtained as a mediator, the ombudsperson makes recommendations to prevent similar complaints in future. Under the hospital legislation, and following the set standards, every hospital must appoint an ombudsperson.” (ibid., p. 74).

Health Technology Assessment

“In 2002, the KCE (Belgian Health Care Knowledge Center) was established with HTA as one of its core activities. Its overall objective is to support health policy decisions which offer value for money and so contribute to an efficient allocation of health care resources [...] but [...] the KCE is involved in neither the policy decisions nor their implementation.” (ibid, p. 40).

Even in this case the sickness funds were considered to be the stakeholder groups that is today de facto representing (most) the citizens and patients in the decision making process”. The KCE, however, rightly considers this solution as not appropriate and conducted a specific study on the issue of citizen involvement that confirmed the uncertainties also identified in the previous chapter and proposed a preferential scenario for a very diversified citizen intervention (KCE, 2012, p. 12).

4.3 Bulgaria

Consultation and participation

Euro Health Consumer index: good

“Public participation in health system management is regulated by the Health Act and, the Health Insurance Act. Yet, in practice, the opportunities for the public to influence health policy are still highly restricted. With a 2009 amendment to the Health Act, a civil council on patient rights was established at the Ministry of Health, albeit with advisory functions only. Although patient organizations have been established during the reform years, the dialogue between the civil organizations and the Ministry of Health only showed progress recently. The media play an especially active and stimulating role in this process. In practice, however, this dialogue frequently refers to post factum discussion of concrete legislative or organizational changes and not to real participation in health policy development.” (WHO; Bulgaria, p. 40).

Patient empowerment

Patients’ Rights Euro Score: weak

There is no law on patient rights. “Besides the Constitution (Art. 52 and 57)¹¹, patients rights are protected in several acts such as the Human Medicinal Drugs and Pharmacies Act (1995); the Health Insurance Act (1998); the Act for professional associations of physicians and dentists (1998); the Food Act (1999) and the Health Act (2004). The Health Act of

2004 is however the most important one as it regulates the status, rights and obligations of citizens in healthcare” (EPF, 2010, p. 8).

Procedures for complaints are only partially structured. “All patients have the right to complain about the quality and organization of medical services as well cases of corruption. Patients may lodge a complaint with different institutions and organizations at national, district and local level, such as the Ministry of Health’s Medical Audit Agency, the Regional Health Inspections, the National Health Insurance Fund and Regional Health Insurance Funds, and with the professional associations’ district branches. Accreditation regulation requires health care providers to establish procedures for collecting and responding to patient complaints. Furthermore, citizens frequently use patient organizations and the media as mediators in cases of patient rights’ violation”. (WHO; Bulgaria,p. 41)

Health Technology Assessment

“There is no agency conducting systematic assessments of effectiveness and cost-effectiveness of novel health technologies in Bulgaria. However, the National Centre for Public Health and Analysis participates in the European network for Health Technology Assessment (EUnetHTA). Although the idea to set up a national HTA agency is being discussed, there are no concrete results yet (ibid., p. 31).

4.4 Cyprus

Consultation and participation

Euro Health Consumer index: good

“The government is not obliged to safeguard population participation in governing the health system. Nevertheless, the Ministry of Health is receptive to the ideas of interested groups, including patients, citizens, providers, trade unions or local authorities on action plans and draft laws. Additionally, the Ministry of Health takes satisfaction surveys into account, as they provide important information about patients’ and citizens’ opinions and perceptions on various aspects of health care services” (WHO, Cyprus, p. 30)

Patient empowerment

Patients’ Rights Euro Score: weak

“The Safeguarding and Protection of the Patients’ Rights Law, 2004, addresses issues regarding patient rights, such as the rights to health care and treatment, dignified treatment, access to health care services, prohibition of unfavorable discrimination, health care in a medical emergency or in a life-threatening situation, medical examination in an emergency department, information, health care with the consent of the patient, medical information, health care without the consent of the patient, participation of the patient in scientific research or experimental treatment, confidentiality, protection of the patient’s privacy, keeping of medical records, and finally the right of a patient’s representation” (ibid.).

“The law for patients’ rights includes provisions for submission and management of patients’ complaints. Article 23 refers to the establishment of a Complaints Examination Committee in each district, which is responsible for investigating patients’ complaints. The committee

consists of five members appointed by the Minister of Health for a term of four years. The chairman of the committee and each member examining a particular complaint must be independent from the health care services and/or the medical institution to which the complaint relates.” (ibid., p. 31).

Health Technology Assessment

“Currently there is no system for health technology assessment (HTA). The Ministry of Health did, however, participate in the EUnetHTA (European network for Health Technology Assessment) project in 2006” (ibid., p. 21).

4.6 Denmark

Consultation and participation.

Euro Health Consumer index: good

“Patients’ participation takes place in three ways in Denmark: (1) through organized patient groups, nationally, regionally or locally; (2) through patient counselors; and (3) indirectly through feedback from national and regional surveys. A number of patient groups exist, which are formed around concerns about particular diseases or health problems, such as heart disease, cancer, arthritis, diabetes or sclerosis (see above). Since the mid-1990s, many of these groups have explicitly taken on policy advocacy as an important function. The groups are very active and they influence public debate. Between 200 and 300 active patient groups exist in Denmark. They act as the patients’ voices in the media towards the authorities and politicians, frequently giving input on the health debate so that patients’ views are not neglected. They also provide information, help and support related to health and sickness, and dialogue with the relevant authorities at all levels. The largest, best-known and most well-funded groups have a strong track record of involvement in health policy. This is often achieved through the formation of coalitions with doctors or across patient groups. Patient organizations that are entirely at the grassroots level and work independently of the health care professional sector tend to be much smaller, with non-paid volunteer staff. It is, therefore, a far greater challenge for them to navigate the different decision-making structures at the national, regional and municipal levels, and to have a greater influence. The larger groups are backed by large membership numbers and operating budgets, which enable them to maintain a professional staff. These organizations are generally invited to participate in parliamentary hearings that are relevant to their causes and concerns, while this is quite rare for the smaller organizations.

Danish Patients is an umbrella organization for 15 patient associations in Denmark, representing 830.000 members (Danish Patients, 2011). Danish Patients’ aim is to contribute to a patient-focused health system of international standard. Danish Patients develops policy based on documented knowledge and cooperates with authorities, research institutions and other health care organizations in developing the health system of the future based on the interests of the patients. The organization works with a large number of health policy issues; among the most prominent at the moment are integrated health care delivery, rehabilitation, patient safety and user involvement. Danish Patients is structured as a political organization, with the Executive Council as the highest decision-making organ. The daily work

to promote the aim of the organization is managed by experts from the member organizations and the secretariat of Danish Patients” (WHO, Denmark, pp. 50 – 51).

Patient empowerment

Patients’ Rights Euro Score: not detected

“In 1998, the Danish Government agreed on an act regarding a patient’s legal position. The act set out comprehensive legislation regulating the fundamental and general principles for the individual patient’s rights. The aims of the act were to help to ensure that the patient’s dignity, integrity and self-determination are respected; and to support the trust relationships between the patient, the health system and the various personnel involved. The act also contains rules on information about consent and life testimonials, information regarding patient cases and professional confidentiality, and access to health information” (ibid., p. 48).

“The National Agency for Patients’ Rights and Complaints (*Patientombudet*) was established on 1 January 2011 as an independent government institution. The former Patients’ Complaints Board was established in 1988. The National Agency for Patients’ Rights and Complaints is responsible for dealing with patients’ complaints and for contributing to the prevention of mistakes being repeated within the health services. example the overall treatment procedure, without directing the complaint against a particular health professional. The Agency also deals with complaints about the disregard of patient rights and with complaints about the Patient Insurance Association’s decisions over compensation (see below). Furthermore, the Agency administers the system for reporting inadvertent incidents within the health service and offers guidance on the rights to health care in other countries” (ibid, pp. 48 - 49).

Health Technology Assessment

“Decisions for the general use of technologies are supported with broad-based, systematic and well-documented information. There is no regulatory mechanism in the Danish health service requiring the use of HTA in policy decisions, planning or administrative procedures.

HTA is decentralized. This corresponds with the national strategy for HTA, which explicitly states that HTA should be applied at all levels of the health service as a systematic process in planning and operational policy, and as an underlying process for the routine clinical decisions of health professionals (National Board of Health, 1996). The newest national HTA strategy was released in 2008 by the National Board of Health. Staff members at all levels of the health service are responsible for identifying and drawing attention to areas where HTA is needed. This responsibility includes the need for new HTA as well as the evaluation of existing technologies. In areas where an independent national intervention is necessary, HTA projects can be undertaken as a basis for planning and operational decision-making. HTA carried out during recent years cover topics such as surgical treatment of patients with degenerative shoulder disorders, patient education, organization of treatment of diabetic foot ulcers, ventilation in operating rooms and assessments of new cancer drugs. At the national level, a number of comprehensive assessments of health technology have formed the basis for health policy decisions.

Since 1997, the National Board of Health has had HTA as part of its remit. The Danish Centre for Health Technology Assessment was established in 1997 and situated as a separate entity within the framework of the National Board of Health. In 2005, the Danish Centre for Health Technology Assessment was organizationally integrated into the National Board of Health. During the following years, HTA was given a lower priority even though the National Board of Health has been deeply involved in the development of the European network for Health Technology Assessment (EUnetHTA) and the EUnetHTA Secretariat is situated at the National Board of Health.” (ibid., pp. 35 – 36).

Nothing is known about the involvement of citizens and patient organisations in the assessment procedures.

4.7 England

Consultation and participation

Euro Health Consumer index: good (UK)

Starting in 2007, were established “Local Involvement Networks [...] they are associated with geographic areas corresponding to local authorities (with responsibility for social services) and, although support funding comes from central government, the funding is provided through these local authorities who must ensure that the networks are set up in their area [...] (they) consist of individuals, groups and organizations with an interest in local care services. Membership is on a voluntary basis and they are supported by an organization procured and funded by the local authority. They are intended to promote the involvement of local people in the commissioning, provision and scrutiny of local health and social care services. To this end they:

- obtain the views of local people about their experiences of health and social care services, and their needs for care;
- investigate specific issues of concern to the community;
- request information from health and social care commissioners and providers;
- carry out spot-checks to see if services are working well;
- make reports and recommendations to NHS bodies and receive responses;
- refer issues to the local overview and scrutiny committee.

As part of the assessment of NHS performance, the Healthcare Commission involved local groups such as the overview and scrutiny committees of local authorities and Local Involvement Networks in commenting on the submissions (known as declarations) of NHS providers for their annual performance review by the Commission.” (WHO, England, p. 63).

Patient empowerment

Patients’ Rights Euro Score: good (UK)

There is no general patients’ rights legislation in the UK. Human rights acts have created a situation in which patients can apply these rights in the context of patients’ rights. (EPF, 2010, p. 24). “However, for the first time, with the publication of the NHS Constitution in 2009, which was subsequently updated in 2010, the government established a set of rights

for patients, the public and staff with respect to the NHS. These were described as legal rights and, in the case of the public and patients, address seven areas:

- access to health services
- quality of care and environment
- nationally approved treatments, drugs and programmes
- respect, consent and confidentiality
- informed choice
- involvement in one's health care and in the NHS
- complaint and redress.

(WHO, England, p. 45).

“The complaints mechanism consisted of three tiers: (1) provider trusts and health authorities were required to have written procedures to deal with complaints: this was known as local resolution;(2) they should also have in place an independent review process if required; (3) once these two were exhausted, the patient could then refer the matter to the Parliamentary and Health Service Ombudsman. Finally, none of these processes prevented the patient from pursuing a complaint through the law courts.” (ibid, pp. 55-56).

Health Technology Assessment

The Health Technology Assessment approach is well developed and is part of the National Institute for Health and Clinical Excellence which, as we saw in the previous chapter, is a leading agency in the world scene and has a Patient and Public involvement policy (Nice, 2012).

4.7 France

Consultation and participation

Euro Health Consumer index: good

The WHO report does not provide any evidence on consultations, but notes that “the 2002 Act also further developed the role of patient associations, allowing them to act as patients’ representatives, to sit on the board of hospitals and to participate in both regional and national health conferences (WHO, France, p. 39). Recently, the *Institut National du Cancer* has set up a User and Professional Committee.

As concerns civic activism, “the activities of certain patient associations have been a factor in the development of patient rights. The AIDS epidemic was the trigger for a transformation in the types of action used by associations concerned with health care. Having achieved visibility through public interventions, these associations are no longer restricted to their traditional role (patient support, fund-raising to finance research) but seek to affect the direction of research and enforce the concept of the patient as an active agent in his or her own health care. Alongside the strengthening of these patient associations, there also has been a reinforcement of general-purpose organizations, such as consumers associations. The Inter-Association Collective of NGOs acting for patient rights (*Collectif interassociatif sur la santé*; CISS) was created in 1996 but gained additional power and legitimacy after the 2002 Act on Patients’

Rights and Quality of Care. It is the umbrella organization for 25 associations active in the field of healthcare (focusing on various groups such as patients, disabled people, consumers, families) and a member of the European Patient Forum (ibid., pp. 38-39).

Patient empowerment

Patients' Rights Euro Score: good

“A pivotal act was passed in 2002, the Patients' Rights and Quality of Care Act, also known as the Kouchner Act (after the name of the acting Minister of Health at that date). This Act defined:

- requirements of solidarity towards disabled people principles of health democracy (in particular, the rights and duties of patients and health professionals);
- quality requirements of the health care system;
- principles for compensating victims of health hazards;
- professionals' liability

(ibid., pp. 37-38).

As for the complaints, all institutions should ensure relevant offices and “in public hospitals, the first step of a patient's complaint (before a formal case is brought against the hospital) is dealt with by a conciliatory procedure, involving the hospital mediator (usually a senior physician) and the patient or the patient's family” (ibid., p. 40).

Health Technology Assessment

“Health technology assessment governance and organization are defined by the government and Statutory Health Insurance. The major HTA body in France is *Haute de Santé*, which has in-house expertise and also the capacity to commission assessments from external groups such as academic centres or professional societies (ibid., p. 129).

The representation of the citizen's point of view is entrusted to experts and civic organizations are excluded (Deloitte, 2009)

4.8 Hungary

Consultation and participation

Euro Health Consumer index: weak

“Patients associations are growing in number and influence [...]. Their participation has been institutionalized in waiting list committees, in the National Health Council and in hospital supervisory councils (1997/20, 1998/24, 1998/25, 1998/28). Members of the National Health Council have said that it is important to create closer links between government bodies concerned with health, patients' associations and patient representatives” (WHO, Hungary, p. 55).

Patient empowerment

Patients' Rights Euro Score: weak

“The chief significance of Act CLIV of 1997 on Health came from its declaration of patient rights, which had not been previously regulated in a comprehensive manner. The Act also established the institution of patient rights representatives and the institution of arbitration for resolving disputes between patients and health care providers (1997/20, 2000/9).

[...]

After the resolution of the National Assembly in 2002 (2002/2), representation of the rights of the patients and citizens participating in social welfare programmes were integrated in one public foundation, while the representatives were employed and supervised by the Foundation for the Rights of Patients, Social Service Beneficiaries and Children (2004/1)” (ibid., p. 53 – 54).

“In addition to patient rights representatives, there are parallel procedures for handling patients' complaints. Act CLIV of 1997 on Health introduced the institution and procedures of arbitration via so-called arbitration councils to resolve disputes between patients and health care providers without going to court (1997/20); the procedure was regulated in detail in 2000” (ibid., p. 55).

Health Technology Assessment

The use of HTA seems to be rather weak and still does not provide for the participation of patients. “In 2004 the National Institute for Strategic Health Research was established, which among other things assists in health policy decision-making through HTA, especially by providing technical support to the Health Technology Appraisal Committee of the National Health Insurance Fund Administration (NIHFA). This task is performed by the National Institute's Office of Health Technology Assessment, which carries out a critical review of the evidence submitted by producers. The Health Technology Appraisal Committee, which is responsible for making the final recommendations on the inclusion of new substances in the positive list, appraises this review along with all other available information from the NHIFA and other professional bodies (2004/4). HTA has since been expanded to include other medical technologies and equipment, and will, it is hoped, strongly incentive further development in the area” (ibid., p. 42).

4.9 Italy¹⁶

Consultation and participation

Euro Health Consumer index: good

Article 14 of the 1992 healthcare reform (also confirmed by the Reform Act of 1999) recognizes civic organizations as active agents in the protection of rights and enshrines their right to speak and to enter into agreements of cooperation with health authorities. The practical implementation of these principles, given the federal structure of the national health

¹⁶ The information is taken from three sources - Ceref (2010), Agenas, (2010), Terzi (2011) - dealing with the theme in a widespread and analytical way. For reasons of homogeneity were extracted only the data corresponding to those of the WHO studies.

service, is the responsibility of the regions; in fact, 95.2% of them issued their own rules in this regard, while 81% provides for forms of involvement of citizens, patients and organizations accreditation.

In reality these provisions are often interpreted in a purely formal way and there are deep differences between regions with regard to their implementation (CEREF; 2010).

Civic activism is well developed, and umbrella organizations exist for all major diseases, each of them composed by dozens of local or regional associations promoting services and involved in governmental and parliamentary hearings. There is also the very peculiar experience of the Tribunal for Patients' Rights, a protection network promoted and supported by Cittadinanzattiva¹⁷, with over 250 local groups that provide representation, monitoring and advocacy.

This network has promoted the Civic Audit of healthcare facilities: based on a scientifically validated methodology, it has nothing to do with satisfaction surveys and was the basis of the Assessment on the European Charter of Patients' Rights (ACN, 2011). Active since 2001, this form of evaluation has been adopted by the Ministry (2007-2009), by ten regions and about 200 healthcare companies, and it is at the base of an innovative project by the National Agency for Regional Health Services (Agenas) for civic assessment of the humanization of hospital care.

Patient empowerment

Patients' Rights Euro Score: good

There is no law on the rights of the patients, which are, however, included in the Code on Medical Ethics. In 1995, however, the Government has issued regulations (DPCM 05/19/95) requiring all companies operating in healthcare to issue a Charter of Services in which all services provided to citizens and their standard should be specified. The provision was accompanied by 87 indicators derived from the Charters of Patients' Rights proclaimed at a local level. The Decree has been fully implemented with regard to the drafting of the informative part, but it is not applied in about 60% of the companies for parts that require the direct involvement of citizens (shared control of the quality and presentation of data in public lectures, mixed conciliation commissions for handling complaints).

With regard to the handling of complaints, every healthcare organization has an Office for Relations with the Public (URP), while the conciliation commissions are poorly spread and citizens often have to resort to the advocacy services of the Tribunal for Patients' Rights, or those of patient and consumer organizations.

Health Technology Assessment

The HTA activity is headed by Agenas regarding medical devices. Authorization and reimbursement of medicines belong to the Italian Pharmaceutical Agency (AIFA). The Agency of Emilia Romagna and the Veneto region are also members of the EUnetHTA network. The

¹⁷ www.cittadinanzattiva.it

Italian society of HTA (SiHTA) has promoted a Charter of Principles (Carta di Trento) that recognizes the need for the involvement of citizens. However, this does not happen and to overcome this stalemate Cittadinanzattiva, Agenas and SiHTA have started from 2012 a Summer School for civic leaders, with the main objective to promote the development of a community that is committed to promoting the involvement of a 'civic' competent component within the processes of health technology assessment.

4.10 Latvia

Consultation and participation

Euro Health Consumer index: good

“Patient participation in the development of policy and health care services provision was non-existent during the Soviet period. Since the mid-1990s a number of different patient societies and associations related to specific diseases have been founded [...]. However, their ability to influence the policy agenda is rather limited, although in the context of growing importance of the mass media and social networks, patient organizations are starting to play a somewhat more important role.” (WHO, Latvia, p. 48).

Patient empowerment

Patients' Rights Euro Score: weak

“The 2010 “Law on the Rights of Patients” is the main legislation in Latvia with articles relating to the rights of patients. The purpose of the Law is to promote favorable relationships between a patient and the provider of health care services, facilitating active participation of the patient in their health care, as well as to provide an opportunity to implement and protect their rights and interests.

[...]

In practice, the main institution dealing with patients' rights is an NGO, the Patient Ombudsmen. The Health Inspectorate deals with patient complaints and in some limited cases has given rise to court proceedings with verdicts demanding that compensation be paid to patients who have suffered from inappropriate provision of services

[...]

Also for mediation between patients and providers, the Patient Ombudsmen is gaining increasing importance. The organization has members working directly in health care institutions to register patients' complaints and to mediate with providers” (Ibid., pp. 46-47).

Health Technology Assessment

The HTA is not mentioned in the report and, apart from the formal representation of the Ministry, there are no participating agencies to EUnetHTA.

4.11 Netherlands

Consultation and participation

Euro Health Consumer index: good

To facilitate the empowerment, the government encourages patient associations to participate in policy making discussions. The formal dialogue with both providers and insurers is guaranteed.

“Involvement with health care providers. Patients can influence the policies of health care institutions. Since 1996, collectively financed organizations in the fields of social care and health care are obliged to have a representative client council to safeguard the interests of the patient. This formal right for patients to be involved with health care has been laid down in the Client Representation ACT.

The client councils, resulting from the Client Representation Act, have not been shown to be meeting these goals in an effective and efficient way. Hospitals for example, experience difficulties in installing a representative council, since this requires a lasting relationship between the organization and patients. Also, compared with the costs of other forms of patient participation, the costs of the councils turned out to be relatively high.” (WHO; Netherlands, p. 43).

“Involvement with health care insurer. With regard to purchasing decisions in health care, health insurers are obliged to involve patients in these decisions. According to the Health Insurance Act , patients should be enabled to influence the policy of insurers to a reasonable extent. This influence can be realized in different ways. Examples include health insurers conducting satisfaction surveys among insured persons or health insurers setting up a Members Council. The councils consist of elected insured persons and may be given the authority to determine the annual accounts or to advise the board of directors. In 2000 a study among members of councils of the former sickness funds has shown that 39.4% found their influence to be low or fairly low, while 49.2% found their influence to be fairly high or high. The Health Care Authority supervises the obligation for health insurers to involve patients “ (ibid., p. 44).

“Different types of associations pursue different goals to provide a 'voice' for their members. There was a very slight decline in individual members when comparing 2007 and 2009. More than a third of all associations have professional, paid employees. Organizations for disabled or mental disorders have the most volunteers. Peer support meetings for their own members remain the most popular activities. There are many small organizations and a few big ones. Advocacy remains important although the motives differ between patient associations” (Kamphuis et al. 2012).

Patient empowerment

Patients' Rights Euro Score: not detected

“The rights of patients have a solid place in the Dutch legal system as several rights are placed in the Act on the medical treatment contract of 1 April 1995.³¹ The Act is a part of the Dutch civil code. The main purpose of the Act is to clarify and strengthen the legal position of the patient” (EPF 2010, p. 19). The legislation has been recently revised because

considered too fragmented and too tied to the obligations of healthcare providers rather than patients' rights.

“There are different possibilities for patients to file their complaints with regard to health care providers in the Dutch health care system

- Directly to health care provider; can also be mediated through complaints officer or complaints service;
- Complaints committee, obligation for all health care providers to set up complaints committees;
- Appeal only possible for patients of psychiatric hospitals Disciplinary board
- Appeal possible at Central Disciplinary Board Dispute committee; only applicable if provider has joined a dispute committee
- Financial compensation when caregiver agrees

Patients who want to lodge a complaint are not obliged to follow a certain pathway. It is possible for patients to lodge the same complaint more than once. If a patient chooses another pathway the process can have another outcome. It is not known, however, how often this happens” (ibid., p. 46).

Health Technology Assessment

There is no agency dedicated to the HTA and the Dutch presence in EUnetHTA was entrusted to the Health Care Insurance Board.

However, “since the 1990s, systematic evaluations of new medical technologies have been used as an important tool to support rational policy-making. In the early 90s, a special fund, the National Fund for Investigative Medicine was created to finance such evaluation” (ibid., p. 107). The HTA approach is also used in this kind of activity.

4.12 Northern Ireland

Consultation and participation

Euro Health Consumer index: good (UK)

“Each Health and social care (HSC) body is required to put in place its own arrangements for engagement and consultation with clients and/or local populations who may be clients.

The Patient and Client Council (PCC), in addition, represents the interests of the public along with other HSC bodies provides assistance to individuals making or intending to make a complaint relating to health and social care and promotes the provision of advice and information to the public by the HSC body about the design, commissioning and delivery of health and social care service.” (WHO; Northern Ireland, p. 20)

Patient empowerment

Patients' Rights Euro Score: good (UK)

"Patients in Northern Ireland have the same rights as those in England" (ibid.)

Health Technology Assessment

"The activity of Health Technology assessment is covered by NICE, which issues regular guidance on the range of therapies considered to be suitable for reimbursement within the NHS (not necessarily binding)" (ibid.).

"The PCC has a responsibility to represent an independent voice for patients and thus has to act both in cooperation with and independent of other HSC bodies. Given that the PCC is appointed and funded by the department, the extent of its independence might be questioned" (ibid., pp. 15 – 16).

4.13 Poland

Consultation and participation

Euro Health Consumer index: good

"Under existing regulation, patients have a right to indirectly participate in the decision-making process to define the basic benefits package. Under Article 31e of the Law on Health Care Services Financed from Public Sources (as amended in 2009), foundations and associations the statutory objective of which is to protect patient rights may submit, through a national consultant, a request to the Ministry of Health to remove a particular benefit from the list of guaranteed health care benefits or change the level or method of financing or the conditions in which it is provided.

[...]

Patients are actively involved in public life and there are many NGOs supporting their participation. These NGOs undertake various activities to influence policy-makers, often seeking support from the media, politicians, and formal research. According to an online NGO database (ngo-pl), there are 11.500 registered NGOs involved in health protection and promotion and in activities aimed at ensuring equal access to health care for all (WHO Poland, p. 51).

Patient empowerment

Patients' Rights Euro Score: medium

"At the end of 2008, the Law on Patient Rights and the Patient Rights Ombudsman, which entered into force in June 2009, gathered all dispersed patient rights in one well-defined legal act and established the post of Patient Rights Ombudsman. The Law defines a catalogue of patient rights, the rules for access to medical records, the obligations of entities providing health services with regard to patient rights, the competencies of the Patient Rights Ombudsman, as well as the rules for appointment and dismissal of the Patient Rights Ombudsman and procedures in the case of infringement of collective patient rights" (ibid., p. 47).

“The key competencies of Patient Rights Ombudsman include:

- taking action in cases of infringement of collective patient rights through the actions or inactions of health care providers that restrict the rights of patients or deprive them thereof, as well as through the activities of health care providers undertaken for private financial gain;
- taking action in cases of infringement of individual patient rights and participating in civil lawsuits related to infringement of individual patient rights;
- organizing and managing educational programmes aimed at raising awareness of patient rights; and analysing patient complaints in order to identify threats to patient rights and areas requiring improvement”
(ibid., p. 48).

“Complaint procedures are governed by the Civil or the Penal Code provided that a state prosecutor decides that a crime has taken place. The burden of proof lies on the side of the patient and a no-fault compensation system does not exist in Poland. A link between the physician’s action or inaction and the damages sustained has to be proved. [...] To avoid the often costly and lengthy legal procedures, patients may also seek an extra-judicial settlement with the provider’s insurance company” (ibid., p. 51).

Health Technology Assessment

“The Agency for Health Technology Assessment (AOTM) is a state-financed agency that serves as an advisory body to the Minister of Health to inform decisions on public funding of health technologies, particularly those that are included in the basic benefits package.” (ibid., p. 31).

“Recommendations of the AOTM are not legally binding and the final decision always belongs to the Minister of Health. Deadlines in the application process are in line with Council Directive 89/105 EEC of 21 December 1988.” (ibid., pp. 32-33).

4.14 Portugal

Consultation and participation

Euro Health Consumer index: weak

Actually, 'the 2004-2010 National Health Plan acknowledges that despite the healthcare legislation had already provided several mechanisms to encourage participation in the health system, in practice they have not yet been implemented and participation still continues to be 'confined' in the legislative references and good intentions expressed in official documents.

In recent years, several initiatives have been launched to increase the involvement and public confidence in the health system: a) an Observatory has been set up in each regional health authority (which is recognized to develop participatory mechanisms), in order to optimize the use of health services, improve customer satisfaction levels and ensure an effective involvement of citizens; b) direct communication lines (online) between users and their family doctors have been set up; c) the options of choice for users have increased and even the access to information about indicators and performance of health services has improved; d)

formalized procedures to file complaints have been introduced; e) several advisory meetings with different stakeholders have been organized; f) joint advisory councils (with users, professionals and decision-makers) have been created to support the management of health centres and hospitals; h) several surveys on user satisfaction for Health Centers and Family Health Units were carried out.

As it can be seen, a series of tasks which cannot be defined participation initiatives in *strictu sensu* (namely, initiatives that strengthen the partnership and empowerment of participants) have been made. They undoubtedly represented an interesting approximation strategy between the healthcare system and users” (Serapioni et al., pp. 270-271).

Patient empowerment

Patients’ Rights Euro Score: medium

“A Patient’s Charter (Carta dos Direitos e Deveres dos Doentes) from 1997 provides for the official protection of patients in the NHS. The Charter brings together the main legal aspects concerning patients’ rights and obligations [...]. There have not been any studies assessing the effectiveness of the implementation or impact of the Charter”. (WHO; Portugal, p. 48)

“There are formal mechanisms for patients to make complaints. In every public medical institution there is an office where patients can complain about any aspect of the NHS (called the Users’ Office). All complaints are dealt with through the Users’ Office and in case of medical negligence, may be referred to the Medical Association and to the Portuguese judicial system. However, patients are free to write directly to the regional coordinators or to the Minister of Health, or to pursue their case through the courts. This is, of course, expensive and few people do so” (ibid.).

Health Technology Assessment

“Portugal does not have a tradition of HTA, with the exception of pharmaceutical products. Infarmed (Autoridade nacional do Medicamento e productos de salude) is responsible for regulating HTA for pharmaceuticals and medical devices” (ibid., p. 36). The report does not provide any information on citizens’ participation.

4.15 Scotland

Consultation and participation

Euro Health Consumer index: good (UK)

Participation is very accurate. “NHS boards are required to involve people in designing, developing and delivering services they provide. These responsibilities were first made explicit in *Patient focus and public involvement* (2001) and were reinforced in the NHS Reform (Scotland) Act 2004, which placed duties of public involvement and equal opportunities on NHS boards.

[...]

To give people a greater say in the services they use, the Scottish Government published updated guidance on informing, engaging and consulting people in developing health and

community care services, which is supplemented by guidance produced by the SHC. Boards are also expected to follow the principles and practice for all public agencies set out in the *National standards for community engagement* (2005).

The current guidance, *Informing, engaging and consulting people in developing health and community services* (2010) states that where a board is considering a service development or change, it is responsible for:

- informing potentially affected people, staff and communities of its proposal and the timetable for involving them;
- ensuring that the process is subject to an equality and diversity impact assessment;
- ensuring that any potentially adverse impacts of the proposed service change on, for example, the travel arrangements of patients, carers, visitors and staff, have been taken into account in the final proposal;
- providing evidence of the impact of this public involvement on the final agreed service change.

Where a proposed service change will have a major impact on a patient or carer group, members of equalities communities or on a geographical community, boards are expected to seek advice from the SHC on appropriate public involvement processes and from the health directorates on whether ministerial approval will be required. In some cases, ministers may decide to establish, normally before the board's formal consultation process, an independent scrutiny panel (ISP) to undertake an expert and impartial assessment of the safety, sustainability, evidence base and value for money of proposals and of the assumptions that underpin them, so as to assure the public that all of the relevant factors have been explored thoroughly. The panel's report, which is published, provides a comprehensive and accessible commentary on the evidence presented by the board but does not reach a view on a preferred option. To date, three ISPs have been convened." (WHO; Scotland, 2012, pp. 39 – 40).

Patient empowerment

Patients' Right Euro Score: good (UK)

"The Patient Rights (Scotland) Act 2011 enacts the Scottish Government's commitment to improve patients' experience of using health services and to support them to become more involved in their health and health care. It places on ministers the duty to publish a charter of patient rights and responsibilities, bringing together in one place a summary of the rights and responsibilities that patients have when using NHS services; requires those who provide health care to take into account a set of statutory health care principles, such as patient focus, quality care and treatment, patient participation, communication, complaints and waste; and puts the 12-week treatment guarantee for planned treatment on an inpatient or day-case basis on a statutory footing. Guidance on the secondary legislation relating to the health care principles, the waiting time guarantee and the complaints procedure was issued in 2012 The Patient Advice and Support Service (PASS), run by Citizens Advice Scotland (an independent charity) also became operational in 2012, providing help to patients and members of the public to understand their rights and responsibilities and to give feedback. (ibid., pp. 37 – 38).

"Guidance issued by the Scottish Government in 2005 sets out how the NH should deal with comments, concerns and complaints. When something goes wrong and it has not been

possible to resolve it informally with the staff directly concerned, a patient or carer can raise the matter formally with the staff concerned or an NHS complaints officer. The complaint is acknowledged within 3 working days and a full response is made within 20 working days (10 days for complaints relating to GPs, dental and optical practices and community pharmacies). If the complaint is not resolved the individual can take the matter to the Scottish Public Services Ombudsman. Complaints must be made within 6 months of the event or within 6 months of realizing there is a valid reason to complain but no longer than 12 months after the event (ibid, p. 38).

Health Technology Assessment

The WHO report does not mention HTA. However, the activity is carried out and, as we have seen in chapter 3, it involves the participation of citizens.

4.16 Slovakia

Consultation and participation

Euro Health Consumer index: good

“Patients’ participation in formal decisions in health care is very limited. Representing organizations and associations have an opportunity to comment on new legislation, but they can only make recommendations. They are too fragmented and frequently lack adequate funding. Patient organizations can advocate for their interests by lobbying legislators and by influencing public opinion.” (WHO, Slovakia, p. 54).

Patient empowerment

Patients’ Rights Euro Score: good

“Patient rights in Slovakia are laid down in several acts. The Patients’ Charter was elaborated in 2000 as a project of the Ministry of Health, which was funded by the EU’s PHARE programme. It was ratified by Slovakia on 11 April 2001. A group of international and Slovak experts drafted the Charter according to laws in force and international organizations (United Nations, WHO, Council of Europe) cooperated in the project. The goal of the Patients’ Charter was to explain to patients their basic rights in health care. The Charter was approved by the Slovak government in 2001, but the document itself is not legally binding. [...] The 2004 Slovak health reform incorporated 14 patient rights from the European Charter¹⁸ into the new reform legislation” (ibid., p. 48).

With regard to complaints, “when patients or their relatives presume that a health care service was not adequately provided they can submit a written complaint to the health care provider. If a health care provider does not satisfy this appeal, it is the patient’s right to request the Health Care Surveillance Authority (HCSA) to assess whether adequate health care was provided. Other complaints (for example, regarding user fees, ethics, and organization of health care) must be submitted to the relevant body (for example, the Ministry of Health, self-governing regions, professional chambers).

¹⁸ It refers to the European Charter of Patients’ Rights of Active Citizenship Network.

The HCSA, as an independent body for monitoring health care, has become a credible advocate of patient rights” (ibid., p. 52-53).

Health Technology Assessment

“There is no special state institution in charge of health technology assessment in Slovakia” (ibid., p. 30).

4.17 Spain

Consultation and participation

Euro Healt Consumer index: bad

According to Health Consumer Powerhouse, civic organizations are excluded from decision-making (EHCI; 2012, p. 15).

The WHO states that 'In Spain the social participation within the National Healthcare System was introduced by the Ley General de Sanidad (Espanha, 1986), that recognized the involvement of citizens as one of the fundamental principles of the legal system. Successively, even autonomous communities established Health Councils with the participation of social organizations (trade unions, associations of neighbors and user groups, universities, etc.), although with a simple advisory role. In this regard, a number of criticisms on 'inadequacy' or 'inefficiency' have emerged, with respect to the existing channels of participation to be found in Health Councils and to the mere consultative form of participation.

In recent years, some autonomous communities – Castilla la Mancha, Aragón, Extremadura and Cataluña – have introduced new mechanisms of participation within their respective healthcare systems” (Serapioni et al, p. 64). The main topics are the assessment of services and the recognition of the patients’ needs (ibid, p. 265).

Patient empowerment

Patients’ Rights Euro Score: good

“Spain primary uses two Laws concerning patients’ rights; the General Law on Public Health (1986) and the Law on Autonomy of the Patient and the Rights and Obligations (2003 with regard to Information and Clinical Documentation)” (EPF, 2010, p. 22).

“In practice, the way to guarantee that citizens can exercise their rights is to ensure that all Autonomous Communities health services centres have guidelines stating users’ rights and obligations, the services available, their characteristics and also the procedure for submitting suggestions or complaints.” (WHO; Spain, p. 69). However, national control seems to be quite weak.

Health Technology Assessment

“At national level, the Health Technologies Assessment Agency (AETS) is located within the Carlos III Health Institute. At regional level, some of the ACs have created their own agencies:

in Andalucía (Andalucian Health Technologies Assessment Agency, AETSA, under the General Directorate of Training and Process Engineering of the regional health service); in the Basque Country (Health Technologies Assessment Service, OSTEBA, under the General Directorate of Health Planning and Regulation of the regional health department); in Catalonia CAHIAQ (Catalan Agency for Health Information, Assessment and Quality), functioning as a public company within the regional health service); in Galicia (Galician Health Technologies Assessment Agency, AVALIA-T, also under the regional health service); in Madrid (Technologies Assessment Unit of the Laín Entralgo Agency for Health Studies” (ibid., p. 129).

All agencies are part of EUnetHTA network and have programs aimed at citizens' involvement. AETSA has a “Linea de atención a la ciudadanía”; the Catalan Agency involves organizations in the drafting of guidelines; AVALIA organizes a Healthcare Public School.

4.18 Sweden

Consultation and participation

Euro Health Consumer index: “so – so”

“The responsibility for health and medical care in Sweden is shared by the central government, county councils and municipalities. The Health and Medical Service Act regulates the responsibilities of county councils and municipalities, and gives local governments more freedom in this area. The role of the central government is to establish principles and guidelines, and to set the political agenda for health and medical care. It does this through laws and ordinances or by reaching agreements with the Swedish Association of Local Authorities and Regions (SALAR), which represents the county councils and municipalities...”.

Consequently, “the most important means of public participation in Sweden are the general elections held every fourth year. In the 2010 election almost 85% of those entitled to vote exercised their right to vote in the general elections at the national, county council and municipal levels (Election Authority, 2011). Of particular importance for health care are the elections at county council level, since the most important task of county councils is health care” (Who, Sweden, p. 47).

Civic organizations have, however, a role. “There are more than 100 patient and consumer organizations in the country representing different patient groups. The size of the organizations varies considerably. The largest organization (*Reumatikerförbundet*) has more than 60.000 members whereas the smallest (*Föreningen för Neurosedyskadade*) has less than 300 members. According to a survey among 60 of the organizations in Sweden, the most important aim of the organizations was to safeguard the interests of their members by means of influencing decision-makers. The actual success in influencing decision-makers of course varies among the patient organizations and there is a lack of information about how influential such organizations have been in policy processes” (ibid.).

Patient empowerment

Patients' Rights Euro Score: not detected

“There is no specific law regulating patients' rights in Sweden, as opposed to in other Nordic countries. Instead, different rights for patients, such as patient choice or the right to

information, are incorporated in other legislation and are formulated in policy agreements between the state and the county councils through the SALAR” (ibid., p. 45).

With regard to complaints, there is a “ government agency (HSAN) that decides on disciplinary measures in the event of complaints or possible malpractice. It can enforce disciplinary measures such as a warning, or can limit – or even withdraw – a health care professional’s right to practice.” (ibid., p. 48).

Health Technology Assessment

“The SBU (Swedish Council on Technology Assessment in Health Care) has the mandate of the Swedish government to review and evaluate health care technology from medical, economic, ethical and social points of view” (ibid., p. 35).

“The main health technology assessment body regarding pharmaceuticals is the TLV (,Dental and Pharmaceutical Benefits Agency) which assesses the cost–effectiveness of both prescription and hospital drugs. Since 2002, the TLV has the mandate to decide if a drug should be included in the National Drug Benefit Scheme.” (ibid., p. 36).

“Sweden Patient and user organisations are offered the opportunity the give opinions on the investigation file and suggested decision on the reimbursement of medicinal products. During the consultation, neither the suggested decisions nor the opinions given are public”. (DG SANCO, 2012, p. 23).

5. FOCUS: THE PLANET OF ONCOLOGY

5.1 Introduction

There is a widespread - and ultimately well-grounded - belief that, in the context of oncology, patient involvement is particularly significant and relevant. Once again, however, literature reviews show a significant lack of comparative studies on the forms and impact of such participation (Mosconi, Roberto, 2011; Hubbard et al. 2007).

While waiting for the research to try and fill this gap of knowledge – hopefully in a reasonable time – it is possible to attempt a qualitative description on “what the citizens actually do”. We will try and do this by offering a reasonably neat description. Starting from the four types of involvement described in the first chapter, it is possible to emphasize certain traits that characterize the civic presence in this particular context.

As regards the first form of involvement, namely the **consultation forms**, the emerging feature is a rather widespread presence of representatives in comitology at all levels - European, national, regional and local. In fact, quite frequently patient associations are invited to designate their representatives - or otherwise trusted experts - in committees and commissions that support decision-making in the various areas of oncology policies. The criteria for the identification of the organizations and designation of representatives, however, are usually not very clear. Even in this field, then, unfortunately valid is the general observation that consultation is not seen as a right of citizenship but a Government prerogative (ACN, 2004b). It is therefore impossible to assess how this form of involvement has helped guiding public policy and professional behaviors, although the steady growth of attention (at least formally) to the overt centrality of the citizen supports the conclusion of a quite relevant impact.

Oncology is a privileged field of individual **empowerment**, as proved by and reflected in the large number and development of personalized treatments. Quotes in PubMed also indicate, in the United States rather than Europe, a significant focus on the empowerment of communities as a strategy to overcome discrimination between patients.

Civic activism is broad, widespread and multifaceted. An analysis, albeit brief, of the sites of various national associations highlights a prevailing attention to the issues of education, information and advocacy. A recurring feature is also the partnership with professionals and their organizations and services for the realization of innovative projects. Quite reasonably, this could also be considered the main means of intervention on governments' policies and agendas.

Nobody could deny a correct **representation of the experience of patients** should be an essential component of policies and scientific research, in the end, but practical actions are, in reality, not always consistent with this principle, and a review of the literature confirms that patients are still mostly confined to the role of objects of observation rather than that of active subjects. To give greater substance to this description, four areas of in-depth study have been identified: the activity of European umbrella organizations, the development of personalized treatments, the participation in scientific research and the services offered by associations, all integrated with a note on web 2.0 participation.

5.2 Presence in the European area

Umbrella organizations, regardless of any eventual reflection on their actual representativeness, have an important role in the European area, which includes not only the Union's political institutions but also a broad and diverse spectrum of subjects - scientific research bodies, professional federations, industries and more. Once again, reference studies are missing but the available knowledge lead us to believe they have a good ability to influence decision-maker and other stakeholder agendas.

To get a better idea, albeit entirely qualitative, on how umbrella organizations are involved in the European area, it is possible to use the information available on their websites about the activities they carry out. The four organizations of cancer patients to be found in the European Directory of Patients' Organizations of EPF have been selected for this analysis¹⁹.

5.2.1 European Cancer Patient Coalition²⁰

ECPC is perhaps the largest umbrella organization in the field of cancer. More than 300 cancer patient organizations from 45 countries have already joined ECPC as full or associate members. Its motto "**Nothing about us without us!**" defines also its mission: to give "one voice" to all cancer patients through our membership and democratic structure.

The coalition's activity is very wide and varied, and cannot be fully described within the limits of space granted by this report. It is nevertheless interesting to focus on some of the means the organization uses to intervene in the European area and on the results so far obtained. In this regard, particularly interesting are the information available on the last report published on the website in 2010.

In that year, in fact, the **FACE (Forum Against Cancer Europe)** has been created, in order to facilitate the communication between the human face of cancer - given a voice by ECPC and other patient advocacy groups - and the faces of policy-makers and subjects allocating funds in the European Parliament and Commission. This face-to-face dialogue in workshops allows both patient groups and policy-makers to better understand one another's needs and priorities, and enables them to work together effectively to provide timely and efficient information, prevention, screening, treatment and care for patients across Europe. Each workshop is focused on a particular issue affecting cancer patients, and invites stakeholders from the pharmaceutical industry, researchers and oncologists to participate in presentations and discussions.

The **first workshop** was dedicated to **cancer research** and aimed at promoting a greater coordination of research funding. Currently, three separate areas of research – basic, epidemiological and clinical research – are funded by government, pharmaceuticals and charities. The confrontation has involved all stakeholders and has produced a proposal for a Written Declaration on Cancer Research of the European Parliament²¹.

The **second workshop** was devoted to **Cross-Border Healthcare** and, among other things, it has addressed the issue of cancer patients legitimately preferring to receive treatments in their own homes, and the problem it may generate of not being able to access, this way, the best cures.

¹⁹ http://www.eu-patient.org/pos/pos_list.php?mastertable=Levels&masterkey1=European

²⁰ <http://www.ecpc-online.org>

²¹ http://www.easl.eu/assets/application/files/f2f51218cbe369d_file.pdf

The **third workshop** was devoted to **palliative care** and ended calling for deeper dialogue between stakeholders in promoting the inclusion of palliative care in health and social policies at a European level.

ECPC has participated in the design of the European Partnership for Action Against Cancer - a European Commission initiative to coordinate a collaborative European approach to cancer , launched on September 2009 - and in the promotion of the European Alliance for personalized medicine (to be better presented in the next paragraph).

Furthermore, ECPC is the only patient organization of the 28 participants in EUROCAN Platform. In addition to representing cancer patients when establishing priority areas for cancer research, it will be heavily involved in improving communication between researchers and patients. Focusing on decreasing cancer mortality through strategic research in prevention, early detection and improved treatments, the platform will build the resources and expertise for a variety of research types and methods, though with a strong focus on translational research.

The **lobbying action**, legitimized by these general activities, was significant and led, in 2010, to a number of important achievements. The ECPC position has been crucial in supporting specific provisions, to which the Council was initially completely opposed:

- a new article, specifically on rare disease (which includes rare cancers) has been added to the Directive, asking the Commission to support Member States in cooperating in the development of diagnosis and treatment for rare disease;
- the newly established European Reference Network will have a specific focus on rare diseases, most particularly in order to foster the development of diagnosis and treatment of rare diseases and to share expertise among Member States in domain the expertise is rare;
- when a patient affected or suspected of being affected by a rare disease applies for prior authorization, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice. This would facilitate the possibility for patient to seek a proper diagnosis (which is the first problem for patients affected by a rare disease).

*5.2.2 Europa Donna*²²

Europa Donna – The European Breast Cancer Coalition - is an independent non-profit organization whose members are affiliated groups from 46 countries throughout Europe. National groups membership is individual. Unlike other umbrella organizations, the national realities emerge as affiliations of the European Coalition, established in 1994 as an educational arm of the European School of Oncology. The Coalition works to raise awareness of breast cancer and to mobilize the support of European women in pressing for improved

²² www.europadonna.org

breast cancer education, appropriate screening, optimal treatment and increased funding for research.

In the report on the activities of 2012, three main types are identified. The first is the **dialogue with the European institutions**. The European Parliament houses for five years some of the activities of The Breast Health Day, with debates and insights. As for the relations with the Commission, Europa Donna works closely with two Work Packages of the European Partnership for Action Against Cancer (EPAAC) established by the European Commission, attended the Meeting with the European Commission's Joint Research Centre on the accreditation of breast services and received, in 2012, a grant from the Executive Agency for Health and Consumers

The most relevant initiative, for the purposes of the presence in the public debate, remains the co-organization with the European Society of Breast Cancer Specialists (EUSOMA) and the European Organization for Research and Treatment of Cancer (EORTC) of the European Breast Cancer Conference (EBCC) - one of the most important European scientific conference, which includes in its program issues on the development of participation and advocacy.

A second line of business is the **creation of the leading advocacy** through the implementation of annual conferences and organizational meetings and the production of operational guides. To support the national implementation of EU directives, a systematic spread of knowledge is operated with the help of "A Short Guide to the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis", approved in 2006. Similar attention is paid to relations with the world of research, through the publication and spread of "The Advocate's Guide to Understanding Breast Cancer Research".

Last but not least, regarding the research, Europa Donna **promotes the advancement of breast cancer research** and seeks to ensure that all women understand fully any proposed treatment options, including entry into clinical trials and their right to a second opinion. In accordance with the Brussels statement from the 2nd EBCC "Randomized clinical trials represent the most effective way of evaluating new therapies but also offer treatment opportunities. Obstacles to the participation for both patients and clinicians should be as low as possible".

Europa Donna collaborates with BIG (Breast International Group) on a number of important projects, serving on the BIG Scientific Committee, the Steering Committee of MINDACT, and the legal/ethics committee of MINDACT, as well as the NABCG working group on Survivorship. Other working groups will include those on informed consent process and a molecular screening trial:

Founded by leading European opinion leaders in 1996, BIG now constitutes a network of 47 groups based in Europe, Canada, Latin America, Asia and Australia. These research entities are tied to approximately 3000 specialized hospitals and research centres worldwide. About 30 clinical trials are run or are under development under the BIG umbrella. BIG also works closely with the US National Cancer Institute (NCI) and the North American Breast Cancer Group (NABCG), so that together they act as a strong integrating force in the breast cancer research arena.

The TRANSBIG consortium was launched in 2004 by BIG to promote international collaboration in transnational research. It comprised 28 world-class institutions present in 11 countries and was managed by the BIG Headquarters. This consortium was dedicated to:

- advancing individualized treatment for breast cancer patients
- integrating, strengthening and facilitating transnational breast cancer research in Europe and internationally within the framework BIG.

The main project launched by TRANSBIG is the MINDACT trial, Sponsored and coordinated by the European Organization for Research and Treatment of Cancer (EORTC) MINDACT compares a genomic prognostic test (Mammaprint®) developed with micro-array technology to traditional clinical-pathological methods for assessing the risk of breast cancer recurring in women with lymph node negative or 1 to 3 node positive disease. It is expected that this will help physicians and patients make better decisions about who can safely avoid chemotherapy and its potential side effects.

5.2.3 Myeloma Patient Europe²³

MPE acts as an umbrella organization for existing local and national myeloma associations and its members come from nearly 30 countries. It originates from the merger of two previous organizations: European Myeloma Platform and Myeloma Euronet. A Board is in place and has responsibility for setting strategy as well as for governance and accountability. The Board is multidisciplinary but is constituted to have at least 50% of its members as being patients or care-givers. The main activities detectable from the website and publications are: the representation of patients at the EMA and other professional institutions and organizing Master classes.

A few weeks after its founding in March 2012, **MPE was recognized by the EMA as an eligible member of committees, working parties and scientific advisory groups.** MPE representatives also carry out, on a regular basis, activities such as:

- a review of the documents addressed to the public (such as package leaflets, EPARs2 and Q&A documents) to make sure they are understandable and comprehensive for patients;
- collaboration in the drafting of guidelines, even with Eurordis (the umbrella organization of patients affected by rare diseases);
- the production of feedback on crucial aspects of the new pharmacovigilance legislation, much appreciated by the EMA.

Furthermore, MPE has a seat in the EudraCT & JOG (Eudra Clinical Trials and Joint Operational Group). This working group meets at regular intervals at the EMA and takes care of the website on the clinical trials register (www.clinicaltrialsregister.eu).

Myeloma Patient Europe collaborates with important professional umbrella organizations and it is part of the Patients Advocacy Committee, the European Hematology Association (EHA) and the Patients Advisory Committee of the European Cancer Organization (ECCO).

²³ www.myelomapatientseurope.org

With regard to **training**, two Master classes are provided each year, dedicated to examining issues related to policies and advocacy in myeloma but also to the development of organizations. One of them regards personalized medicine in multiple myeloma with a focus on genetic factors and the role of bio banks, considered from both a clinical point of view and that of patients.

A project on patient needs and wants and their role in research report is currently underway. With the cooperation of participating organizations, it aims to collect case studies and good practices to emphasize the importance and benefit of involving patients in research and demonstrating good examples of designing treatment and care in patient-centered ways. The success of the initiative could give an important contribution to bridge the repeatedly reported gap of knowledge.

5.2.4 Sarcoma Patients euronet (SPAEN)²⁴

SPAEN - Sarcoma Patients EuroNet - is the European Network of Sarcoma, GIST, and Desmoid Patient Advocacy Groups. Acting in partnership with medical experts, scientific researchers, the healthcare industry and other stakeholders, SPAEN works to improve treatment and care of GIST, Desmoid and sarcoma patients in Europe through improving information and support, and by increasing the visibility of sarcoma with policy-makers and the public. It currently represents 123 patient organizations from 13 European countries.

Site analysis pinpoints a prevailing interest towards research. SPAEN has formed its own Medical Advisory Board and **act as a partner of several scientific societies also for the implementation of clinical trials**. Prof. Dr. Jean Yes Blay (EORTC President and Director of Conticanet) said: “Sarcoma Patients EuroNet is a very welcome development. We need to involve patients in clinical trials at the design stage so that the relevance of what we do can be considered at the outset. In addition SPAEN will be valuable helping patients understand what being treated in a clinical trial could mean to them. Together we can complete research more quickly and introduce new treatments faster.”

SPAEN is a member of Eurosarc, a consortium of scientific institutions set up to design, structure and implement nine innovative investigator driven clinical trials of different scales, on a multinational level, evaluating novel treatment strategies. In this area it contributes to public information and exercise advocacy functions.

The site provides general information and advice for patients and care givers. A major section covers information on drugs: from marketing authorization to the actual availability, from the outcome of pharmacovigilance to clinical inspections. Ongoing trials and the results of the ones already concluded are also reported.

²⁴ www.sarcoma-patients.eu

5.3 Empowerment and the patient-centered care

The nature of the illness, the psychological implications, the necessary involvement of the families, they all seem to orientate the cancer patients' treatments towards a patient-centered care. This doesn't necessarily mean a patient – and possibly his/her family - empowerment in the decision-making and conduct of treatments. **The complexity underlying the concept of patient participation is not always recognized. It links the notions of 'passive patient' and 'active participant', hence its usage along with those of similar terms such as 'partnership', 'involvement' and 'collaboration' is often ambiguous.** Often, and with good reason, it is believed that the level of patient's involvement depends on the quality of professional conduct. Actually, cultural, psychological and social factors also come into play, and the adoption of passive attitudes by the patient may happen to be the result of a deliberate choice (Millard et al. 2006).

Health authorities claim that the personalization of treatments is an important priority, but it is not always clear what that means, and actions to consistently address professional behaviors are still lacking. Thus health professionals, educationalists, managers and patient representatives have all developed different meanings of patient-centered care to reflect their own particular backgrounds and role. (Gillespie et al., 2004). A look at the websites easily shows how in many situations patient organizations play, in this respect, a real subsidiary action that compensates for the weakness of public policies. A large part of it involves the implementation of initiatives to facilitate the meeting and positive interaction of their respective paths through conferences, trainings for professionals and civic leaders, researches and publications produced in partnership with scientific and professional societies.

The personalization of treatments, in Oncology, concerns not only the quality of life but also clinical aspects in the strict sense. The experiences of Evidence Based co-designed treatment carried out with individuals suffering from lung cancer and breast cancer have identified similar touch points in their respective situations, but these were translated into different improvement priorities for each tumor type (2012 Tsianakas et al). An equally important issue is the possibility of using a personalized medicine, in the strict sense, which involves medical decisions, practices, and/or products being tailored to the individual patient even with the use of genetic information.

The impact of the latter approach on health systems is clearly quite important with regards not just to the costs but also the adjustment of the organizations and the role of patients. **Tensions have risen with EMA and the national authorities regarding authorization and reimbursement of medicines.** Institutional answers have generally been uncertain and highly variable, and resulted in significant differences in treatment, with obvious effects on the application of the cross-border care directive.

To encourage appropriate responses to these new challenges, various professional and scientific organizations of patients (ECPC, EURORDIS, the European Patient Forum, European Parkinson Disease Association and International Diabetes Federation), buyers and producers gave birth to the **European Alliance for Personalized Medicine (EAPM)** which approved, in September 2012, the **“Personalized Medicines Manifesto: New Perspectives for patient in Europe”** containing recommendations for all stakeholders:

“..there is an urgent need for engagement of a wide range of stakeholders. Because the success of personalized medicine will depend on a shift in thinking across wide areas of healthcare, and a new form of multi-disciplinary engagement. To take advantage of the opportunities that personalized medicine offers, adaptations will be required to the current approach to healthcare in the following areas.”

- The regulatory environment will have to allow early patient access to novel and efficacious personalized medicine.
- Research and development into personalized medicine will have to be increased and incentives provided for translating laboratory innovation into medicines.
- Education and training of healthcare professionals will have to be adjusted.
- New approaches to reimbursement and health technology assessment will be required.
- Awareness and understanding of personalized medicine will have to be developed among patients and the general public.”

(EAPM, 2012, pg. 6).

The manifesto deals analytically with all these areas and proposes measures to firmly and effectively integrate all activities in a European framework. **With regard to empowerment, the recommendation reads:**

“Patients will be empowered to take decisions on their own therapeutic management. Effective information is essential for successful partnership, and for the patient to make informed choices that lead to compliance with prescribed treatments.

A patient-centered structure for risk communication should be developed in order to enhance patients’ awareness, competence and adherence to medication. Health professionals will commonly be called upon to explain risk profiles or computer models to patients in a manner that fosters clear understanding and can be acted upon appropriately. Patient adherence to treatment must be ensured, as this will govern effectiveness.

Recent developments in the legal framework for the reporting of adverse drug reactions by patients should be exploited in this context – effective pharmacovigilance will be essential as the use of personalized medicines becomes more widespread, and health professionals such as physicians and pharmacists should also ensure they maximize their contribution to effective reporting”

(Ibid., pg, 15).

For a more detailed illustration of the issue as seen by the patients, we asked Geoffrey Henning the contribution below.

5.3.1 Personalized Medicine in cancer treatment – Hype or Hope²⁵

The promise of stratified treatments for every cancer patients is a welcome change from the one size fits all approach that has dominated cancer treatment in the past. Treatment for cancer has until now been a one size fits all approach, with standard doses across the whole spectrum of treatment. As a result, patients in almost every cancer diagnosis have been given

²⁵ By Geoffrey Henning, Policy Director EuropaColon.

what was perceived to be the right treatment, but actually it was probably doing more harm than good, killing their cancer but most of their body also.

This shift in approach has been made possible by advances in science. The unraveling of the human genome has produced a huge amount of new knowledge that has sprung from this development and this is leading to new opportunities on a daily basis. The challenge is to turn this into medicines quickly and effectively and so deliver on the hype that is being created around its potential.

Personalized medicines is not new, I was working at Roche over 10 years ago when that company started talking about this new concept and they began to introduce it into their research and development activity. At the time the talk was to do with Herceptin and the HER2 gene diagnostic test. Unfortunately it has taken a long time for the promises offered by Herceptin and the diagnostic test for HER2 to be realized.

Today there are only 16 medicines that are approved for use in cancer patients that have a recognized diagnostic test. However there are many hundreds more for cancer and other diseases that will in due course bring significant benefits to patients. But the solution to this will not be just new medicines, there is much to be done before we can access these exciting new opportunities. All of society, from patients and NGOs to clinicians, the pharmaceutical industry to governments, regulators, payers and the media are all contributors to the successful adoption of this new opportunity in healthcare across Europe.

Changes will need to be introduced at every level in the process: the approach to R&D will need to change, instead of large scale randomized trials we will start to see smaller studies, possibly using medicines that are already in use, but could bring benefit in other areas. Patients will need to donate samples to build up bio-banks so that R&D can access samples to undertake small scale trials that might in themselves get registration approval for use in patients.

Marketing models will change. It is being realized that breast cancer, for example, is not a generic cancer of the breast but rather a collection of many, possibly up to a hundred different cancers. Not only marketing but thinking will need a shift so that this broader spectrum can be embraced.

Regulation will need to be modified as the strict criteria that are in place for drug registration today might well not be suitable for small proof of concept type trials that show a benefit for patients with a particular marker. Many of these studies will not have comparator arm in the trial but merely shows clinical benefit.

Sample testing is a major issue and will need to be offered by each government so that all testing is completed to a nationally approved standard rather than ad hoc laboratories across the country offering their own version of a test. This will lead to postcode outcomes, with some good quality laboratories existing alongside others that are merely cowboys.

Governments will need to review their approach to healthcare in the light of these developments and will need to adapt existing Cancer Plans and cancer services to accommodate these changes. Without making these changes, levels of cancer care across

Europe will remain very variable with more and more patients realizing that the Cross Border Directive is their only hope of good quality cancer care.

The media are also in this mix and we would like to see this population taking a much more responsible approach to advances in cancer care and possibly even signing up to be partners in primary health prevention. They can be a force for good and we believe this is an avenue they should consider developing.

Finally, we the patient are hugely involved at all levels in this new paradigm. Central to this whole debate is patient empowerment, a concept that has been around for many years but still there are many patients who sit on the sidelines and wait to be told what to do next. This must change and every patient must become fully involved in every step of their diagnosis and treatment. With personalizing medicine we cannot afford to wait for our moment of activation. We need to be fully engaged as patients in every step after diagnosis. It is our lives and our bodies that can benefit from these scientific advances and we must be engaged and empowered. Personalizing medicine is going to expand the boundaries of treatment dramatically and we cannot expect every clinician to be 100% up to speed with our particular needs. We must take charge of our diagnosis and take responsibility so that we can question and support them at every step. This is our opportunity to be empowered. There is no time to be in denial about any diagnosis no matter how distasteful or distressing it might be. Personalizing medicine offers each of us the chance to learn and be empowered but also to make a difference to patients in the future.

In this presentation we look at the issues and the opportunities and the contribution we can all make so that personalized medicine can achieve the promise that has been talked about. It is not a short term opportunity but instead a change in the paradigm of healthcare that will take years to fully implement. Until the hope of personalized medicine is fully realized in about 20 years there is much to be done at all levels as I have started to show. There is much, much more that will unfold in the years ahead. We all need to be engaged in the debate and the progress and turn the hype into hope for all future patients.

5.4 Patient organizations' involvement in research

As we have already noted in the first paragraph, **patient associations are regularly involved in research**. This applies not only to the umbrella organizations at European level, but also to a not-so-small section of local and national realities. Regular and intense communication circuits, both formal and informal, are established among individual patients, leaders of associations, professionals and researchers, and **it is reasonable to believe that this has a considerable effect on agenda implementation and research priorities**.

“Rationales for the agenda of involvement represent two polar characteristics of modernity: individualism and collectivism. In research, people acted as advocates, strategists, advisors, reviewers and as participatory researchers. In policy and planning, people were involved in one-off involvement exercises and in longer-term partnerships. Men, those with rare cancers, children, and people who are socially deprived have been rarely involved.” (Hubbard et., al. 2007)²⁶. The persistence of a paternalistic attitude towards patients still prevents a full development of partnerships (ibid.). Nevertheless, innovative tools for collaboration, similar to

²⁶ The quote is taken from the abstract available in PubMed.

those described in the chapter on Health Technology Assessment, have been implemented and many interesting experiences have been conducted, such as those collected in the following paragraph.

5.4.1 Involvement of Men Against Cancer (MAC) in research projects²⁷

MAC is a small support group of men who have had a prostate or testicular cancer diagnosis. Most members have had treatment or are on active surveillance. About a third of our members have been trained by the Irish Cancer Society to provide peer to peer support and we do this in a number of ways but in particular we are available to men or their families who call the ICS Helpline looking for help and information. We also take part in various awareness raising exercises and in advocacy. We are available to act as a patient voice or representative and given its position of influence in cancer matters in Ireland, it is usually the Irish Cancer Society that is asked to nominate a patient representative. Three Projects reported on here.

Project 1 - a prostate cancer survey 2010 - 2012

The National Cancer Registry Ireland (a Government body) wanted to survey men who had treatment for prostate cancer, about their treatment experience, the costs associated with it, and their post-treatment experience.

The researchers asked us to assist and we agreed. They came and discussed with our steering committee what they were thinking of including in the survey, they asked for our views and asked for any additional topics which we would find suitable for inclusion. We commented and later contributed some survey topics which were included in the final survey.

The researchers returned to us some months later with a draft questionnaire. By this stage they had secured funding . We critiqued the questionnaire in terms of its overall size, design, language as well as certain questions which we felt were either ambiguous or were asking for information that the patient or the patient's family was unlikely to have. The revised questionnaire was sent to us for final comment and we encouraged our members and contacts to participate in the exercise.

When the survey was completed we were briefed on the results and provided with copies of the research report. The National Cancer Registry Ireland had a press launch on the report. The results also fed into the National Cancer Control Program which was in the course of consolidating prostate cancer diagnosis and treatment into 8 centers and was rolling out the now completed Rapid Access Prostate Cancer Clinics in these 8 cancer centers.

Project 2 - patient representation on HTA body.

The Irish Government has established a number of Health organizations and one of them is to monitor to quality of health provision and to assess the efficacy and cost of new treatments. The Health Information and Quality Agency (HIQA) has a number of roles but one of them is in the area of Health Treatment Assessment (HTA). The Scientific Advisory Group (SAG) of HIQA advises the parent body on HTA issues although in practice the actual HTAs have been

²⁷ By John Dowling, Chairman Men Against Cancer.

contracted out to another agency - the National Centre for Pharma-Economics (NCPE) but the criteria for the assessments have been developed by the SAG.

There are a number of interest represented: Researchers, Government Department of Health, other agencies such as NCPE - patient representation on the SAG is two, one of which is nominated by the Irish Cancer Society. A member of MAC was nominated by the Society to the SAG. To date this committee has been engaged in the arid but necessary task of drawing up the criteria for the economic assessment of HTAs and similar tasks.

The MAC representative was involved from the outset. But given the technical nature of the topics it was necessary for the representative to undertake a period of learning and training in health economics so that he could participate effectively in the deliberations.

The economic assessment model was finally agreed and other agencies such as the National Pharma-Economics Agency and the National Cancer Control Program now use these assessment models. However, because of the extent of the financial restraints due to the public expenditure cuts required by the Troika it remains to be seen whether these HTA assessment criteria have remained in use or whether more crude criteria are being applied.

Project 3 - Patient representation on Cancer Hospital Research Proposals

One of the MAC members has been nominated as a patient representative to the Ethics Committee of the principal dedicated cancer hospital in Ireland - St Luke's in Rathgar, Dublin. St Luke's is now being amalgamated with a nearby large general hospital which is also one of the 8 designated cancer hospitals.

The role of the Ethics Committee is to evaluate the research proposals which come before it. As might be expected most of the research proposals relate to Breast, Prostate, Bowel and Lung cancers but also some rare cancers.

The patient input is numerically dwarfed by the clinical representatives but the patient representative has noticed in recent times that the clinicians are much more solicitous of the patient viewpoint and are ready to listen to and adjust their considerations in the light of the patient voice provided the patient has taken the trouble to be informed. Once a research proposal is approved the Ethics committee does not hear back from the researchers.

5.5 Patients' organizations and empowerment services

As seen in the previous paragraphs, patient organizations are, in all respects, agents of policies aimed at public institutions, the world of research, industry and professionals. **However, they also perform the other functions of active citizenship described in the third chapter, in particular patient support services to empowerment.** Of course, each of them has its own features and this contributes to create, on the whole, a very comprehensive offer. **Looking at the various sites, in fact, it is possible to find general information and medical research services, socializing and entertainment ones and advocacy and counseling support to people.**

5.5.1 General and medical information

Several associations produce constantly updated information on specific illness and, more generally, on tumors (symptoms, course, diagnostic and therapeutic paths, etc.). They are made available to the public through the websites, although the production of brochures in electronic and/or paper form is also very frequent.

The spread of information is also backed with communication activities (conferences, media speeches, campaigns, etc.): major organizations often organize national days devoted to specific subjects, normally used for fundraising.

The general information is often supported by a more timely medical information, with the aim of:

- facilitate the management of the disease, increasing the ability to control and reduce anxiety;
- promote a better use of healthcare;
- resolve any specific doubt about diagnostic and therapeutic treatments;
- improve the quality and efficacy of the relationships with professionals.

This type of information is normally reserved to members, which, in the restricted areas of the sites, may send questions and get answers by professionals members or supporters of the association.

5.5.2 Advocacy and advice

The protection of patient rights in oncology shows, together with the recurring general problems, some peculiarities:

- The possible difficulty of access to innovative and/or appropriate treatments, caused by living in disadvantaged places and/or an unequal organization of health services;
- The possible discrimination on the basis of age, which denies access to innovative and/or more expensive treatments to the elderly population;
- The risk of marginalization in places of work or study.

Patient organizations are not always equipped to assist individuals in the management of these problems. A fair number of them, however, provides listening and counseling facilities (sometimes even legal) with dedicated phone numbers or desks in treatment centers to help patients asserting their rights and finding practical solutions to their needs in terms of social security, labor, taxes. An important role in this context is that of the general organizations for the protection of rights - as the Tribunal for Patient Rights, in Italy, and various consumer organizations.

5.5.3 Support for individuals and families

It is common knowledge that the onset of tumor diseases is the cause of serious psychological problems and generates a load of assistance that services are not always able to

guarantee. The problem eventually concerns even to most advanced healthcare systems, as the presence of organizations involved in this area in all European countries clearly shows.

This justify the presence of counseling services, accessible by telephone and/or directly at the offices of the associations. In addition to that, in several countries the collaboration between patient organizations, voluntary associations and professionals has given birth to foundations and non-profit enterprises that provide home or in-hospital assistance.

The most original and, perhaps, most valuable form of support is the ability to provide counseling by expert patients, namely people who, having experienced the illness themselves, are able to understand the practical problems of the patients and their family and to collaborate in their solution²⁸.

5.5.4 Socialization and entertainment

Cancer expose patients to a high risk of exclusion and isolation, caused by the difficulty to maintain a normal social life. To cope with the problem, some associations organize specific programs.

Dedicated recreational and cultural activities are organized, but above all networking between patients and their families to encourage communication is fostered. Informal meetings are held to promote the exchange of information between patients, family members and doctors, the discussion of problems and solutions, the identification of common activities.

5.6 Participation 2.0, a trial

The involvement of patient associations, as we have seen, is conspicuous but certainly not able to cope with all needs of the large number of cancer patients. This does not only depend on the limits of organizations - which are still based on voluntary activity and self-financing - but also on the attitude of patients.

“Less than 20 % of patients get into contact with an association during their treatment. Most of them face cancer as an individual or familiar experience, or as an experience to share merely in non-associative contexts, such as collaborative areas on the web and social networks”. (Marsico, 2012).

The individual practice of active citizenship through the web is now well established. It is a process that has, as it is well known, significant criticalities (from the prefiguration of mythological forms of direct democracy to the diffusion of non-controlled information) but it opens unprecedented opportunities for intervention that can take on a particular significance in the reality of people affected by cancer:

“Access to information via the web, the lifespan with an often long-term or chronic illness, the impact it generates on patients’ views, the interactions with peers on social networks... all

²⁸ This type of intervention is particularly developed in the context of women breast surgery .

these elements allow the patient who wants it to become an informed interlocutor. **His/her expertise is not limited to emotional or psycho-social aspects of the disease, it is rich in medical knowledge that completely integrate his/her life and course of treatment.**" (ibid.).

This type of analysis has found an important and significant space in the design and implementation of the Cancer Campus association (www.cancercampus.com), that brings together the centers of excellence of Ile de France²⁹ and has set up a program based on three main axes:

- To improve an exceptional site for a new global development
- To reinforce the scientific and academic foundation focused on innovation and academic development
- The implementation of the Citizen Sector

"On the basis of reflection on the recognition of patients' expertise and in the interest of citizens' involvement in health issues, the citizen pole of the association Cancer Campus has created, in partnership with the National League against cancer, the collaborative platform www.CancerContribution.fr aiming at putting into practice this knowledge that patients develop about their experience. Through debates on sensitive aspects of the illness, Cancer Contribution promotes the knowledge of non-professional experts, creates a space for debate between cancer stakeholders, analyses and formalizes community input in order to produce best practice guidelines and policy proposals which will be included in a White Paper planned for late 2013. Cancer Contribution aims at acting as a lever in an approach of co-construction between different visions of the illness and its impact on individuals and the society" (ibid.).

The platform provides several priority working areas but, on the basis of a free and independent writing, even users can generate contents and enrich each other by sharing their experiences. A summary of the evidences is subjected to review by a group of experts to identify concrete actions to be implemented, on the basis of members' contributions. There is a double goal:

- To group together for the first time a community of different and complementary experts;
- To build together deliberation spaces and provide solutions for the improvement of the healthcare system.

The platform contributions are the object of syntheses and analyses. They are conceptualized by researchers and subject to the approval of the community, through a process of shared decision-making. This material will notably feed the Social Observatory of the National League against Cancer and the outcome of this process will be the basis for policy proposals and elaboration of future practices. In particular, attention is given to the awareness of public authorities in developing specific researches and to that of the industry, enterprises and providers of services to the person in taking into account the needs expressed by platform users.

²⁹"Cancer Campus is embedded in an high quality area, particularly the competences of the Institute of Cancer Research Gustave Roussy and of other healthcare, research and training institutions of duVal-de-Marne and the scientific Valley of the Bièvre. This environment and the collaboration which it provokes are important factors of visibility and efficacy of the performed researches" (<http://www.cancer-campus.com/fr/le-grand-projet/ambition-et-objectifs/reception>).

5.7 A small final note

The fight against cancer is, for decades, one of the pillars of advanced healthcare systems (regardless of their institutional form) and has a great anthropological and cultural relevance. The economic, institutional, organizational and scientific dimensions of the "planet" that has formed over time, can be compared to those of the entire healthcare organization of twenty - or at most thirty - years ago.

Based on what reported in the previous paragraphs, it is possible to draw the conclusion that, although well diversified, the repertoire of actors involved is incomplete when considering the vast number of subjects that inhabit this "planet". **Consequently, even concrete systems of governance are diversified and only partly attributable to institutional actions: any hypothesis of general government which doesn't take this aspect into consideration is likely to be ineffective and, in the worst cases, a source of damage.**

It can also be said that every corner of this "planet" is inhabited by citizens that, in individual or organized manners and in different forms, take on an active – and, as we have seen - very often significant role.

If these considerations are true, the lack of research and the opacity of public policies on participation - repeatedly reported here- are not marginal but strategic issues. We hope the framework here proposed, although partial, may help researchers and decision-makers, along with civic organizations, to address more seriously the problem of a better knowledge of citizenship resources, in order to make them valuable and give appropriate answers to the crisis of sustainability. We return on the issue in the conclusions.

6. CONCLUSIONS

6.1 A major concern

For at least thirty years, forms of civic activism that allow citizens to intervene in public life directly - i.e. without the mediation of political parties, trade unions and in general the bodies of representative democracy - have increasingly grown. As seen in the first chapter, this presence manifests itself in very different forms, and is particularly significant in the context of health policy.

At the same time, European citizenship became more and more consistent: the Treaties and the Charter of Fundamental Rights have defined a set of common rights, have established forms of consultation and civic organizations were often called to participate in the implementation of projects and programmes of great significance. It can be said that:

“European citizenship provides a paradigm of civic activism in public policy that does not exist in the traditional model of citizenship, which only provides for participation in the workplace. This paradigm finds expression in the guidelines of the highest institutional rank, such as the decision of the European Council to launch a program to support the development of an ‘active European citizenship’, but especially in the activity of the Union policy, where a practical and concrete dimension of citizenship is taken for granted and citizens, as such, are considered EU partners on a daily basis.”(Moro, 2009, pp. 68 – 69).

It is pretty easy to verify the correctness of this assertion: just think about - with all the limitations already pointed out - the existence and activities of umbrella organizations (both general ones and those that practically cover the whole range of diseases) and, as far as we are more closely concerned, to **the proclamation of the European Charter of Patients' Rights** and the civic audits to assess on its implementation, carried out in 2007 and 2011 with the participation of dozens of national organizations (ACN; 2002, 2007, 2011), or also to the European Charter of Active Citizenship (ACN; 2006).

It can therefore be said that active citizenship is a constituent part of the European construction. However, there is a paradox that the current crisis makes all the more obvious:

“The paradox lies in the fact that while on the one hand citizens and their autonomous organizations are commonly called upon to help and bridge the democratic deficit of the European Union, on the other hand they are scarcely considered and often even treated with suspicion by the public institutions. This paradox is due to a regulatory gap: while the EU documents contain several references to the activities of the organizations of citizens in the public sphere, they are completely devoid of legally binding texts defining the roles, rights and responsibilities of such organizations, as well as the obligations of public authorities towards them.” (ACN; 2006, from the preamble to the European Charter of Active Citizenship).

In recent years, an important consideration on 'civil dialogue' has taken place, but unfortunately it seems to have remained at a level of general principles. Instead, a particular concern emerges about the 're-nationalisation' of policies that, as some particularly attentive commentators point out, causes a risk to bear (namely, a reduction in social guarantees in the perhaps illusory hope to increase competitiveness). **In the absence of binding rules and**

mandatory standards, the paradox might become the marginalisation of active citizenship, which is one of the most qualified resources produced by the process of European integration.

Below, we will attempt to identify areas of work that could help to counteract this risk and to support relevant responses to the crisis. However, we cannot avoid to stress that, if the credits just made are true, the problem must be treated with the utmost seriousness and find a priority place in political agendas. This means, among other things, working to remedy the lack of significant studies we repeatedly reported. **The absence of relevant legislations and the approximation of various policies, in fact, depend also - and perhaps above all - on the sufficiency with which such an intense and diverse reality has been taken into consideration.** A reality we have so far tried to describe in all its complexity that cannot be treated with simple common sense, as some still claim to do.

6.2 Recognizing and promoting areas of active citizenship

The issue of the sustainability of healthcare systems precedes, of at least a good ten years, the problems caused by the financial crisis and has its roots in the same successes of health policies (e.g. the increase in life expectancy and the ability to effectively treat chronic illnesses). For quite some time healthcare systems are struggling to cope with rising costs caused by this situation, and the first civic Audit on the implementation of the European Charter of Patients' Rights (ACN, 2007) had already highlighted signs of crisis in the European social model, confirmed by the 2011 assessment, "as concerned the universal right to health care and the consequential reduction of levels of protection." (ACN; 2011, p. 81). Also the EHCI 2012 report signals an upward trend in out-of-pocket spending, "most detectable in less affluent CEE countries, and in countries associated with being victims of the financial crisis" (p. 20).

The issue is of the utmost importance, both to the economic dimensions of healthcare systems and, more importantly, the fact **that the universal protection of the right to health is a fundamental part of Europe's identity.** It is a widely shared opinion that, in order to find adequate responses, it is necessary to revise the overall organization of healthcare systems. The public debate in this regard, though, is quite poor and struggling to get out from the narrow limits of budgetary maneuvers. **The belief that relationships with citizens are not only a problem but also a strategic reserve of resources for solving the problem, is consolidating.**

With this in mind, it is possible to verify that the reality of patient involvement we have illustrated (although not completely) in the previous chapters, allows the identification of **at least five highly significant areas of intervention:**

1. The opening of arenas for debate and discussion;
2. The management of innovation and technologies;
3. The empowerment of individuals;
4. The empowerment of local communities;
5. The monitoring of national and European policies.

It is pretty easy to see how, in different forms, all such areas have a strong influence on the systems that link the subjects operating in healthcare policies. This fact is crucial when you consider that a more accurate assumption of responsibility on the part of all such subjects is,

clearly, a necessary condition for the construction of healthcare systems capable of ensuring the universality of rights. It is worth noting that this corresponds to a revival and enhancement of the **principle of subsidiarity**, already recognized in the Treaties, and that it is the basis of the major achievements of the European Union. Its 'circular' extension to all subjects (Brown, 2009), starting from active citizens, allows all available resources to come into play and give positive responses to the problem of sustainability.

6.2.1 The opening of arenas for debate and discussion

An effective circulation of knowledge and ideas is a prerequisite for designing efficient policies, but also for creating shared assessments, developing synergies and reducing the weight of conflicts of interest.

An intelligent strengthening of the consultation procedures can make a decisive contribution in this regard and favor, at least in some cases, the opening of arenas of debate and discussion. It is necessary, in this regard, to overcome the issues related with the formal representation and encourage the maximum possible inclusion of civic organizations since the early stages of the discussion of problems and processing of the solutions.

It might be useful, with regard to the issue of representativeness, to resume the guidelines proposed by the 2004 research *“Participation in policy making. Criteria for the involvement of Civic NGOs”*, in which it is confirmed that:

“all citizens' organisations have the right to be identified as a partner in the process of policy-making on the basis of equality and without discrimination. **Public institutions can not consider the involvement of such organizations as their own prerogative or as a privilege to guarantee only if and when they consider it appropriate, useful and necessary.** “ (ACN 2004, cited in Moro, 2009, p. 162).

In many cases – particularly for the formation of committees or working group – it is obvious the need to select organizations and their representatives according to their **relevance**, namely the acquired competence and the ability to carry a significant point of view. The guidelines developed by ACN and its partners offer important information in this regard.

A **better selection of stakeholders** may improve the quality of the contributions but can not solve the problem of representativeness. It is necessary to provide steps in which all interested parties may intervene. The Commission already uses such practices which, however, should be animated with greater intensity and also allow circular debates among stakeholders.

The **space 2.0** offers important opportunities, especially if backed by intelligent directions, able to guide the debate and to draw significant conclusions and recommendations from it. The experience of Cancer Contribution seems particularly interesting and the Commission could encourage the creation of a network of centres of independent discussion implemented with the collaboration of civic organizations.

6.2.4 The management of innovation and technologies

A substantial part of the sustainability of the systems is based on the ability to effectively managing the technologies. This not only means the assessment of innovations, but also taking decisions on the disposal of obsolete technologies – an aspect that is often overlooked.

In the previous chapters we have seen how the representation of the experiences of patients is - or at least should be - an essential component of scientific research and assessment processes. **We have also seen how civic participation does not intervene only in this area but may extend its intervention to the entire process:** horizon scanning, priority setting, planning, implementation, assessment, appraisal, dissemination. It is a confirmation of the fact that active citizenship is an exercise - albeit generic - of practical sovereignty that can significantly improve the overall quality of decisions and policies.

Two underlying problems must however been reported. The first is that, with few exceptions, **the systems' management of technologies are rather weak.** The WHO reports highlight a limited diffusion of Health Technology Assessment and lead us to believe that the assessment processes are often not clear and, however, not well structured.

The **second problem is the gap between the theoretical and the actual practice of agencies,** that is often reduced to late – and thus little influential – consultations. To this, it should be added the fact that civic organizations know little (or even ignore) about HTA and struggle to organize significant interventions in this area. The example of NICE, on the one hand, and the training initiatives of HEE, London School and Cittadinanzattiva, on the other, eventually indicate possible solutions.

6.2.5 The empowerment of individuals

It is very difficult to imagine a reorganization of healthcare systems, respectful of the principles of universality, that does not consider the ability of citizens to use services in an appropriate and effective way as one of its fundamental basis. It is just as hard to think of developing a similar capability without recognizing the citizens themselves effective powers.

The empowerment of individuals, as has been said, takes place in at least **two directions:** the formation of a **empowered user** and the **participation in the implementation of personalized treatments.**

Regarding **the first aspect:**

“ As already revealed, in recent years various countries have adopted measures directed towards recognizing and promoting certain rights, and in particular those relative to consent, free choice and complaint and compensation. It was also noted that this ought to contribute to the training of "empowered users", capable of facing reductions in protection caused by the crisis of the European social model.” (ACN , 2011, p. 84)

Rights that should characterize the empowered user, however, are often not sufficiently implemented. In particular, the right to information is scarcely observed (ibid., p. 81). The right to complain is only partially met (ibid.) and, as can be seen from the WHO reports, there

are few countries with a well-structured organization in this regard. Yet the user's strength depends, to a large extent, on the possibility of intervening to report the violation of rights and to demand their restoration. Not coincidentally, in the more attentive countries the activity of complaint is considered a powerful improvement factor.

Participation in the construction of personalized treatments is definitely spreading but still faces at least two types of obstacles. Firstly, **not always professionals and services are well oriented in this direction** and access to individual plans remains an organization's discretion rather than a right of patients. Secondly, a **strong asymmetry between patients, professionals and organization remains**, only partly justified by the nature of the disease.

“Patients will be empowered to take decisions on their own therapeutic management. Effective information is essential for successful partnership, and for the patient to make informed choices that lead to compliance with prescribed treatments.” (EAPM; 2012, p. 7).

In treatment paths, particularly home care, patients and their families invest a significant amount of cultural (acquisition and production of knowledge, ability to interpret the symptoms, and more), organizational (care giver and monitoring the compliance of programs) and economic resources (energy and transport costs, and other additions), that contribute to a significant extent to ensure the sustainability of treatment. **Personalized treatments are - or at least should be - the result of a comparison between professionals, citizens and services** designed to ensure the optimum use of their resources and to define the respective commitments. **They are, therefore, contracts** and they should be considered as such even from a legal point of view, if only to ensure the enforceability of the obligations assumed by the healthcare organizations. Experiences of this kind already exist in the areas of chronic care and long term care, and they could become paradigmatic.

6.2.6 The empowerment of local communities

Local communities are the place where services are actually delivered, and where civic participation can take on particularly intense forms. They are, therefore, **a privileged forum for the politics of development of subsidiarity**, although a **recurring ambiguity** has to be reported in this regard.

“If one takes a **top down perspective**, on the one hand there seems to be a transfer of power and of competencies to the local level under way (often limited, however, by acute financial constraints), while on the other hand there are emergent forms of support for social concerns that carry out collective interest activity. Adopting a **bottom up point of view** reveals the widespread capacity – confirmed by some studies conducted in Italy (Agenas, 2010) – of citizens organized in various ways, of services and of professionals to interact at a community level and to produce organized responses to needs with innovation solutions and with the mobilization of additional resources. Such a capacity, however, is often limited by bureaucratic procedures and by administrative discretionary power. **These considerations permit the statement that the empowerment of citizens and horizontal subsidiarity may be considered strategic resources for a transformation of services capable of joining compatibility and universality.** In particular they permit the interpretation of the latter not as a simple application of abstract principles of equality but as a capacity to adapt services to the concrete situation of the individual (and in particular the most fragile subjects), eliminating

wastefulness, valuing personal and local resources and countering the dangers of social exclusion. This requires, however, a new and precise acceptance of responsibility on the part of public institutions, which cannot excuse themselves from the work of sustaining the processes of reorganization, of keeping watch over quality, safety and efficacy of care and assistance, of intervening to support those who are weakest and of ensuring equity of access and sufficient financing.” (ACN, 2011a, p. 9).

In other words, the empowerment of local communities cannot be a simple transfer of (a few) resources and expertise - that would undermine the universality of the system - but the recognition of a social entity that must be supported with programs such as the “Patient focus and public involvement” active in England and Scotland.

6.2.7 The monitoring of national and European policies

' **Nothing about us without us!** ' is not only the motto of ECPC, but also that of other civic organizations and, basically, of all active citizenship. In the context of a crisis of sustainability - exacerbated in recent years by the financial crisis - which requires critical choices in order to maintain a universal welfare, the motto calls on all institutions to ensure very high levels of accountability.

This opens a new space of confrontation between the establishment and civic organizations. **In the first place, a definition of shared criteria for assessing the performance and compliance of the services to citizens ' rights should be reached, and then periodic monitoring to follow the evolution of the situation and measure the actual impact of policies should be implemented.**

It clearly is a large-scale cultural, political and institutional undertaking, which cannot be fully implemented in the short term and that, however, offers a new meeting ground between citizens and institutions.

Even in this case there are already some significant experiences. For years some organizations such as the European Patients' Forum, the Health Consumer Powerhouse and the Active Citizenship Network carry out significant survey. The Civic Audit approach, developed in Italy, offers a methodological apparatus still partial but tested by fifteen years of fieldwork.

European and national institutions can deal with this first group of experiences to find feasible solutions to be implemented together with the citizens. It is quite reasonable to conclude that this could significantly increase the quality of health policies.

6.3 Final recommendations

The main recommendation that emerges from this report is the need to consider the patient involvement as a system and not a mere collection of random initiatives. This approach made it possible to define the five areas of intervention, as defined above, which can be useful to create intervention strategies capable of sorting and enhancing the enormous amount of activities that the previous chapters have only partially documented.

To make a modest contribution to this work of synthesis of the activities already carried out, we thought it appropriate to collect the recommendations already made by various organizations, reducing to a minimum the formulation of new indications:

A) The opening of arenas for debate and discussion

First, it is necessary that the consultation is considered a right of citizenship and not simply a government prerogatives. To ensure this principle, authorities should adopt the guidelines proposed by ACN at the end of the research on *Participation in policy making. Criteria for the involvement of Civic NGOs.*

As regards the involvement in consultation bodies and comitology (European and national), the principles of the Eu Civil Society Contact Group should, at least, be adopted:

- ✓ “representativeness is not a matter of numbers, but rather a mix of skills built on the field and the ability to enhance the voices of the members of organizations;
- ✓ representation on specific issues should not be a monopoly of the European network [...] valuable inputs can be collected by NGOs working on specific issues that never existed on a European basis;
- ✓ representativeness should therefore be measured on a qualitative approach based on the relevance to specific processes and issues.” (Fazi, Smith, p. 46).

The creation of forums for organized and guided debates should also be fostered, using the example of Cancer Contribution.

B) The management of innovation and technologies

In the first place, it would be necessary to ensure that decisions on technology and authorization of innovative technologies should be accompanied by joint assessment procedures, such as those covered by the Health Technology Assessment approach, that should be interpreted as a general tool of management rather than a simple technique for cost containment.

In this context, it must be accepted the principle that the acquisition of the citizens' point of view is a development resource and not a problem. Valid and to be applied, then, are the final recommendations of the seminar on HTA organized in 2010 at the European Patients Forum, with particular reference to the development of methodologies to better involve the individual patients and patient organisations:

- “Provide training for both patient organisations and HTA professionals in order to create a common culture of thinking and working together;
- Provide tools for dissemination of information on HTA at different levels (individual, organisational and professional);
- Indicators need to be improved and/or developed and integrated into HTA methodologies in order to capture effectively the social, ethical, and quality of life aspects relevant to patients;

- Patients have a role to play both in the process of HTA as well as in committees appraising the results of assessments and making the decisions;
- HTA agencies need to develop tools to better value qualitative research which is most often at the basis of patients' evidence versus quantitative research. (EPF; 2010, p. 18).

All this requires an appropriate investment of financial resources, time and expertise, but remains the right way, even in terms of cost reduction.

C) Individual empowerment

In this area it is possible to find three concomitant **lines of action: the first concerns the empowerment of patients in patient-centered care:**

“Patients will be empowered to take decisions on their own therapeutic management. Effective information is essential for successful partnership, and for the patient to make informed choices that lead to compliance with prescribed treatments.

A patient-centred structure for risk communication should be developed in order to enhance patients' awareness, competence and adherence to medication. Health professionals will commonly be called upon to explain risk profiles or computer models to patients in a manner that fosters clear understanding and can be acted upon appropriately. Patient adherence to treatment must be ensured, as this will govern effectiveness.

Recent developments in the legal framework for the reporting of adverse drug reactions by patients should be exploited in this context – effective pharmacovigilance will be essential as the use of personalised medicines becomes more widespread, and health professionals such as physicians and pharmacists should also ensure they maximise their contribution to effective reporting” (EAPM, p. 15).

The **second line of work** concerns the possibility to assign a legal value to personalized treatments, recognizing the value of resources brought by the sick and their families and to make commitments taken by the organization and professionals payable in the event of non-compliance.

The **third area is the formation on an "empowered user"** capable of interacting authoritatively and appropriately with healthcare services and towards the construction of clinical directions. In this context, the practices of the right to active citizenship, established in the European Charter of Patients' Rights are important (ACN, 2011°, p. 86), and equally relevant is the support provided by the activity of complaint. The European Commission, together with civic organizations, should produce some guidelines in this respect.

D) The empowerment of local communities

“The development of subsidiarity: local communities must be positioned to freely make use of their own resources without useless bureaucratic obstacles. This assumption of responsibility

must however be facilitated by an adequate and certain flow of financial resources which cannot be revoked at discretion, as well as by a group of actions for the support and training of local leadership, starting with already existing civic organizations.” (ACN, 2011, p. 87)

At national levels, this action should be fostered and supported by programs as the *“Patient focus and public involvement”* active in England and Scotland.

E) The monitoring of national and European policies

All institutions, at national and European level, should set up monitoring and assessment programs with the collaboration of citizens, using the experiences already carried out by civic organizations.

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