Report

Patient and citizen participation in health care systems

Good practice in selected health care systems

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Executive Summary

Social change is giving rise to new forms of civil engagement. Citizens are increasingly demanding to be involved in decisions which affect them; more and more ways to participate, be it individually or collectively, are being devised. The ability to participate obliges citizens to articulate their interests and thus contribute to the improvement of systems. In the health care sector, international, European and also German bodies advocate an extension of patient involvement, giving patient representatives a greater role in shaping health care provision.

This study describes collective patient and civic involvement in Germany and eight other systems. The aim is to identify good participation practice. The countries described are Australia, Denmark, England and Wales, France, the Netherlands, Sweden, Scotland, and additionally the European Medicines Agency.

In order to identify good practice, indicators were developed around four criteria:

- legal obligation to involve patients and citizens
- good conditions for good patient and citizen participation
- transparent structures, processes and results
- legitimacy of patient representatives

With the help of the criteria, patient and citizen participation in a number of organizations such as advisory committees, in the provision of health care, in HTA institutions, in bodies deciding on benefits catalogues and quality assurance, in accreditation authorities and in umbrella organizations can be described.

The study identifies numerous examples of good practice in the various countries.

With regard to legal obligations to involve patients and citizens, experiences from France and Scotland are of particular interest. In both countries, mandatory patient and citizen participation has led to a wider acceptance of the principle of participation.

Favourable conditions for good patient and civic participation exist in France, England, Scotland and at the EMA.

In France, this results from the remuneration of patient representatives. At the EMA favourable conditions stem from specific qualification programmes. In England and Scotland good conditions arise from continuous improvement processes in terms
of actively addressing potential patient representatives, supporting active patient representatives, institutionalized feedback and differentiated participation procedures, which enable broad access.

Especially transparent structures, procedures and results are found in France, England, Scotland and Australia. In all countries, agendas and minutes are published on the internet. Moreover, the names of patient representatives are disclosed to the public. Thus, the latter may follow and understand the actions of patient representatives and the respective issues being dealt with. Online-consultations are another feature of transparent procedures, which likewise facilitate interested parties to gain access to decision-making processes.

In all four countries, interesting models of legitimacy have been developed. In France, the question of legitimacy has been answered by an accreditation procedure for patient associations, which grants a license to participate either at national or regional level. In England and Scotland, patient and citizen representatives are recruited by public tendering. Transparent selection by health care organisations guarantees legitimacy. In Australia, tendering is public and centrally organised by the patient umbrella organisation CHF.

Based on these considerations, the study identifies ten building blocks of good patient and citizen participation practice in order to improve the general conditions and increase the binding character, transparency and ultimately the legitimacy of patient and citizen participation:

- Legal obligation to involve patients and citizens in all areas of the public health system
- Transparent rules of procedure allowing patients and citizens to follow the discussions
- Transparent participation opportunities, so that patients and citizens know that they can participate
- Recruitment by public tendering or
- Register/list of patient representatives in order to increase legitimacy
- Actively addressing patient groups so as to broaden the knowledge base of decisions
- Funding patient representatives in order to recognise their commitment and to stabilise participation
- Online-participation in order to guarantee a broader participation of all affected groups

- Mandatory feedback thereby continuously improving the quality of patient and civic participation

- Advocacy-training for patient representatives in order to promote their ability to actively perform their role as representatives.
1 Patient and citizen participation: background and motivation

1.1 Reasons for patient and citizen participation

Social change is giving rise to new forms of civil engagement. Citizens are increasingly demanding to be involved in decisions that affect them; more and more ways to participate, be it individually or collectively, are being devised.

Participation is meant to ensure citizen representation in the alignment of interests of all affected groups and thus to increase the legitimacy of the decisions being taken. Furthermore, participatory procedures require citizens to assume greater responsibility, thus strengthening civil society in general. Citizens are no longer simple beneficiaries in a welfare state. The ability to participate obliges each citizen to articulate his interests and thus to contribute to the improvement of the relevant system. This development also applies to the health care system and has been put on the international, European and German health care agenda. As early as in 1996, the Ljubljana Charter of the World Health Organization (WHO) demanded: „The citizen’s voice and choice should make as significant a contribution to shaping health care services as the decisions taken at other levels of economic, managerial and professional decision-making. The citizen’s voice should be heard on issues such as the content of health care, contracting, quality of services in the provider/patient relationship, the management of waiting lists and the handling of complaints."

In 2000, the Council of Europe recommended, that “patient/citizen participation should be an integral part of health care systems and, as such, an indispensable component in current health care reforms.”

Germany has taken many steps towards citizen and patient participation. Examples include the right to a free choice of medical practitioner, the right to change between health insurance funds, progress towards joint-decision-making between doctor and patient but also participation opportunities for patient representatives in the joint self-government organs of the German public health system. These developments only account for a first step: Volume 32 of the Federal Health Monitoring demands a greater influence of citizens on the health care sector.

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The developments discussed so far represent **normative approaches**. In general terms, they represent the right to self-determination (in terms of participation on the part of those affected) and further elements of democratic participation leading to an effective coordination of interests.

Taking further considerations into account, there are also **functional (or impact-related) approaches** which show the need to promote citizen participation.

Functional approaches are concerned with the actual impact of patient and civic participation. What effect does participation have on the quality of the health care sector? Patient and citizen participation has several positive effects.

Collective patient and citizen participation is seen to improve the quality of the health care sector. Angerhausen⁴ points out that only by means of user participation can all relevant aspects be considered – perspectives of the service providers, of the payers and of the beneficiary. Both the quality of treatment, error prevention and implementation of individual patients’ rights can be raised by collective patients and civic participation⁵. Knowledge on patients’ demands and needs is increased and directly integrated into decision-making processes. The involvement of those directly affected can in particular reduce structural discrimination.

Furthermore, such participation generates transparency and thus leads to a better level of information about the system itself. Likewise, the implementation of social or (welfare-) economic objectives is an expected effect of citizen participation. Hence, increased transparency is not only a pre-condition but also a result of more citizen participation.

We assume that actual and effective citizen participation results in a higher acceptance and identification on the part of the users. Especially in a system consisting of public health insurance funds as in Germany, this should contribute to stability and satisfaction with the health care system. Decisions, for instance, are more likely to be accepted when the persons affected (patients and insurees) have been involved in the decision-making process.

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1.2 Classification of citizen participation

In order to develop a better understanding of the various forms of patient and citizen participation, the latter are classified according to Forster and Nowak\(^6\).

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Following Forster and Nowak, the different forms of participation are organised either individually or collectively.

- "Choice" refers to the options in the health care system, for example with regard to the institutions or health insurance funds;

- "Voice" refers to the possibility to express opinions, for example to make a complaint, to take part in surveys and to support self-help groups;

- Representation (or involvement) goes beyond "voice" and refers to the structural integration of patients and citizens in the planning, implementation and evaluation of measures as well as in the governance structures themselves.

The different forms of participation are linked to different levels: the micro-level, focusing on the individual treatment of patients; the meso-level, focusing on participation in the management of the provision of services (involvement on the level of hospitals, health funds etc.); and the macro-level, focusing on comprehensive decision-making structures of welfare and parliamentary systems.

Even though the different forms of participation are mutually dependent, the report focuses on collective participation of patients and citizens on the macro-level and – in selected cases – on the meso-level (shaded dark grey in figure 2).
1.3 Aim and design of the report

This report describes collective patient and citizen participation in Germany and in eight other systems and aims to identify good participation practice.

After a first screening, the following countries were selected: Australia, Denmark, England and Wales, France, Netherlands, Scotland and Sweden. In addition, the opportunities of patient and citizen participation of the European Medicines Agency (EMA) are analysed. All systems have already implemented various mechanisms of patient and civic participation.

The report followed three phases:

- At first, both the aims of the project and criteria of good participation practice were identified. They are illustrated in chapter 2. The definition of criteria aims to address and solve the problem that generally accepted criteria clearly identifying “good” patient and civic participation have not yet been defined.

- The second phase was to identify health care systems with patient and citizen participation for this study. Then, a research of legal texts, scientific articles, self-presentations and other written sources was conducted for the selected systems. The literature research was validated by telephone interviews with patient representatives or academics. The results are found in chapter 3. The structure of this chapter follows the different forms of organizations, and Germany’s situation is given particular attention.

Interviews were conducted with a series of experts. In Germany with Stefan Etgeton (Federation of German Consumer Organisations), Dieter Möhler (Deutscher Diabetiker Bund), Manfred Pfeiffer (AVK-Selbsthilfe), Harry Kletzko (Schmerzliga), Anita Waldmann (Deutsche Leukämie- & Lymphom-Hilfe), Stefan Lange, (IQWiG). In France with Veronique Ghadi (former CISS, currently patient representative, HAS), with a representative of EMA Mary Baker (Patient representative, EMA Management Board), in England with Judy Birch (Patient representative, NICE), Prof. Rob Baggott (De-Montfort-University of Leicester) and in
Scotland with Sheila Tunstall-James (Chairman, PAPIG of the SMC). The third phase included an appraisal of the different systems of patient and citizen participation according to the above-mentioned criteria, and the identification of good practices. The results are illustrated in Chapter 4.

Figure 3: Report design

It is always difficult to compare different health care systems: the legal, political and historical conditions in the respective systems vary to a high degree. It is not the aim of the report to compare the individual systems. Rather, the report aims to identify and to highlight distinct measures of good practice in order to contribute to the development of patient and civic participation in the health care system.

Source: Prognos AG 2011

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7 All relevant patient organisations mentioned in the Ordinance on Patient Participation were asked for an interview. Except for the Federation of German Consumer Organisations none of the organisations were available for an interview. HAS in France and CHF in Australia were also not available.
2 Four criteria for “good” patient and citizen participation

Currently, there are no generally accepted criteria with which patient and civic participation can be evaluated. Without such a set of criteria it is difficult to identify good participation practice in the various bodies and organisations of health care systems. The European Charter of Patients’ Rights, for instance, refers to voice- and choice-mechanisms but does not refer to patient representation as such. Consequently, the study had first to draw up specific criteria in order to evaluate the respective systems.

The criteria used in this report imply four dimensions. All dimensions depict an ideal type of patient and citizen participation. Thus, they enable an evaluation of the actual degree of patient and civic participation with respect to the defined ideal type.

Figure 4: Criteria for good patient and citizen participation

- The involvement of patients in the process of policy planning and of decision-making is legally binding.
- Patients are legally recognised as equal partners in the health care system.
The first indicator expresses the need to establish patient and citizen participation as a feature of structural and process quality in all aspects of the health care system. We have left the question of potential voting rights open, as participation is a feature of deliberative policy making. Furthermore, in some systems the decision-making competence is solely found in the remit of elected representatives in parliament.

To allow patient and citizen representatives to participate as equal partners particular basic conditions have to be fulfilled. Effective patient and citizen representatives must be able to obtain information in order contribute added value of the system. Moreover, they must not be systematically barred from decision-making processes. Hence, the following indicators were developed:

- Patient organisations and their representatives are systematically qualified.
- Patient organisations have adequate resources at their disposal.
- Patient organisations and their representatives are in the position to participate.

The last indicator leads to the question of transparency. Transparency means freedom of information on persons, contents and processes and is an important element of participation.

Both the question who decides what is to be decided and the decision-making processes are to be included when considering transparency. Moreover, transparency is a necessary precondition of any form of participation, since only informed citizen and patient representatives can be involved in participatory processes. Therefore, transparency implies the following indicators:

- There is the greatest possible transparency concerning committee members.
- There is the greatest possible transparency with regard to agendas in committees.
- There is the greatest possible transparency concerning conflicts of interests.

Last but not least, patient advocates need to possess adequate legitimacy. This is only possible if they are appointed by democratic structures and processes. Furthermore, it is important that the persons be accountable – also as a means of preventing corruption. The following indicators were defined:
- Patient organisations are democratic bodies.
- Patient organisations and their representatives can be held accountable for their actions and decisions.
3 Patient and citizen participation in selected health care systems

3.1 Overview of selected organisations

The results of the study are presented according to the type of organisation in order to facilitate a functional comparison within health care systems. The following types of organisations were analysed:

- Arbitration bodies,
- HTA-institutions and organisations assessing the benefits of pharmaceuticals,
- Organisations that influence benefit catalogues and quality management,
- Market authorisation bodies,
- Umbrella patient organisations.

Due to the different legal statutory tasks, a comparison between the different organisations is very difficult. Instead, the involvement of patients and citizens is described in order to identify good means and instruments of patient and citizen participation independent of the systems.

Figure 5 gives a detailed overview of the selected organisations:
3.2 Patient and citizen participation in arbitration committees

3.2.1 Germany: arbitration committees

(Spruchkörperschaften der Gutachterkommissionen und Schlichtungsstellen)

No involvement of patient representatives except for Rhineland-Palatinate

In Germany, arbitration committees (Spruchkörperschaften der Gutachterkommissionen und Schlichtungsstellen) are affiliated to the regional Medical Associations. Prior to or in lieu of a lawsuit in connection with a case of suspected medical malpractice patients are able to appeal to the responsible Gutachterkommission or Schlichtungsstelle. The idea of out-of-court and shorter proceedings was born due to a rise of law cases related to cases of medical malpractice. So called arbitration proceedings were installed to the patient’s advantage and founded by the Medical Associations.

A Gutachterkommission consists of one person holding the qualification for a judge’s office and two medical doctors. A
Schlichtungsstelle consists of one medical chairman, one person with the qualification for the judge’s office and two more medical doctors.

Generally, patient advocates are not involved in the decision-making processes. However, since 2002, in conformity with the Health Care Profession Act (Heilberufsgesetz), the arbitration committee in Rhineland-Palatinate has consisted of one lawyer, two medical doctors and two patient representatives. A qualified majority of 4:1 is needed. As a result, decisions cannot be enforced against both medical members or against both patient representatives.

In the current debate on the patients’ rights law the inclusion of patient advocates into the Gutachterkommissionen und Schlichtungsstellen is being discussed.8

3.2.2 France: CRCI

Legal obligation to involve patient representatives

The „Loi du 4 mars 2002 sur la modernisation du système de santé“ is the most important French law with regard to patient representation.

The law extends the scope of representation to all hospitals and introduces a license for associations in order to represent patients. The „Commissions régionales de conciliation et d’indemnisation des accidents médicaux, des affections iatrogènes“ (CRCI) are also based on this law.

The CRCI are arbitration and compensation committees. They are tasked to give an expert report on whether a medical accident resulted from a “therapeutic coincidence” or has to be considered as medical malpractice.

The CRCI consists of six user representatives nominated by patient and consumer associations. The associations must be certified at regional level or if they possess a national certification must additionally have a representation at regional level (for further information on licensing of associations, see Chapter 3.6.3). After the representatives have been nominated by the patient and consumer associations they are appointed by the “Agence régionale de santé” (ARS) for the respective CRCI. 9

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8 Motion of the SPD parliamentary group from 3.3.2011, Bundestags-Drucksache 17/907.
9 Article R1142-5 of the Code de la santé publique.
commission, patient representatives have the same voting rights as the other commission members. All patient representatives work in the CRCI in a voluntary capacity. The specific expert reports are elaborated by medical experts.\textsuperscript{10}

\textit{Patient advocates' remuneration}

Commission members or their deputies are remunerated, if their participation at the respective meeting leads to a loss of income. The French Ministry of Health determines the total compensation.\textsuperscript{11}

The “Office national d’indemnisation des accidents médicaux” (ONIAM) offers detailed information on the mode of operation of the CRCI on its homepage. Meeting places and lists of CRCI members can also be found online.

\section*{3.3 Patient and citizen participation in HTA-institutions}

The organisations in this chapter assess the current state of medical knowledge on diagnostic and therapeutic procedures on the basis of the available evidence.

\subsection*{3.3.1 Germany: Institute for Quality and Efficiency in Health Care (IQWiG)}

\textit{Legal obligation to involve “key patient representative groups”}

The Institute for Quality and Efficiency in Health Care (IQWiG) is an independent scientific institute that investigates the benefits and harms of medical interventions for patients. The institute provides evidence-based reports, for instance on drugs, non-drug interventions, methods for diagnosing and screening and treatment guidelines (CPGs) and disease management programmes (DMP). Furthermore, IQWiG provides health information for patients and citizens.

The governing body of the Institute is the Foundation for Quality and Efficiency in Health Care. The latter was founded by bodies represented in the Federal Joint Committee (G-BA). IQWiG is thus an institution of the joint self-government system in the German

\textsuperscript{10} Article R1142-8 of the Code de la santé publique.

\textsuperscript{11} ibid.
health care system. The Board of Trustees includes patient representatives.

The contracting agencies of IQWiG are the Federal Joint Committee (G-BA) and the Federal Ministry of Health (BMG). However, in line with a general commission by the G-BA, the Institute can also select topics for scientific evaluation independently: The Institute has different products: reports, rapid reports, dossier assessments, IQWiG opinions, health information and working papers.

According to § 139a Section 5 Social Code, Book V (SGB V) IQWiG has to give the following groups the opportunity to submit comments: medical, pharmaceutical and health economic experts from research and practice, pharmaceutical manufacturers, the relevant organisations responsible for representing the interests of patients and self-help groups of chronically ill and disabled persons, and the Federal Government Commissioner for Patient’s Affairs. The submissions must be taken into consideration.

The modus operandi of IQWiG is explained in detail in its paper “General Methods”. Patients and citizens have three different options to participate:

- **Definition of patient-relevant outcomes**: The paper “General Methods” states, that "[a]s a rule, relevant patient organisations are involved, especially in the definition of patient-relevant outcomes", Chapter 3.1.1 “Definition of a patient-relevant medical benefit” elaborates: “Those outcomes that reliably and directly represent specific changes in health status are primarily considered. In this context, in particular individual affected persons as well as organisations of patient representatives and/or consumers are involved in the topic-related definition of patient-relevant outcomes. In the assessment of quality of life and patient satisfaction, only instruments should be used that are suited for application in clinical trials and have been evaluated accordingly.”

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12 § 139b SGB V. The Federal Health Ministry has to date commissioned IQWiG on three occasions.
13 see Methods Paper 4.0, draft dated 9 March 2011.
15 In the following we quote the Methods Paper „General Methods“ Version 4.0 dated 9 March 2011. The quoted passages are identical in Version 3.0.
16 General Methods Version 3.0, p. 16.
17 General Methods Version 3.0 Chapter 3.1.1, p. 33.
- **Submissions to IQWiG’s products:** In addition, patient groups – as all other stakeholders and the public – are given the opportunity to submit comments to the IQWiG’s products. Hearing procedures (written comments) are elements of the report production – for the preliminary report plan and preliminary report. Optionally, an oral scientific debate including persons submitting comments may be held.\(^{18}\)

- **Health information:** Topics for health information can be suggested.

**Recourse to structures of the Federal Joint Committee (G-BA) for the identification of patient-relevant outcomes**

For the identification of patient-relevant outcomes IQWiG interviews several patient representatives.\(^{19}\) Until 2010, the procedure was coordinated by a member of staff in the institute management section. Around four to six weeks prior to the planned discussion, the coordination group for the relevant organisations responsible for representing the interests of patients and self-help groups of chronically ill and disabled persons at the Federal Joint Committee is asked to nominate a patient organisation. The task of nominating a patient group is currently undertaken by the Bundesarbeitsgemeinschaft Selbsthilfe (Federal Working Party of Self-Help Groups). Afterwards, IQWiG invites representatives of the nominated organisation to a meeting. IQWiG retains the right to invite other persons affected or groups who were not nominated by the coordination group. Past experience about the respective groups shapes this decision. Patients must reveal their potential conflicting interests in accordance with the Institute’s methods. Those are evaluated for internal purposes.

The discussion is structured according to guidelines. Generally, two or three patient representatives take part at a meeting. IQWiG is usually represented by the project manager, representatives of the specific department and the institute management. The discussion is documented for internal use and does not appear in the final report. In the final report, IQWiG does however mention the patient organisations but not the names of the representatives.

In case of dossier assessments the coordination group of the relevant organisations at the G-BA is asked to nominate eligible patient groups. At the beginning of the evaluation process, the latter are asked to complete a questionnaire (experiences with the disease, necessary consideration of special patient groups, experiences with the current treatments available in the respective

\(^{18}\) General Methods Version 3.0, p. 16f.

\(^{19}\) The following information is based on an interview with IQWiG.
area of interest, expectations regarding a new therapy and optional further information).

In matters which have already previously been covered by the Institute, IQWiG retains the right to transfer patient-relevant outcomes to a new product.

**Participation in the submission process**

At the moment, there is no specific contact point for patient groups at IQWiG. As with all other interested parties, patient groups may obtain further information on IQWiG’s activities on the internet. Via IQWiG’s homepage, they can subscribe to the *IQWiG-InfoDienst*. This provides information on new projects, ongoing projects, calls for tender, press releases and other announcements.

After the online publication of the preliminary report plan or the preliminary report, the public is given the opportunity to submit written comments for a period of at least four weeks. All submissions must meet certain formal requirements. The requirements and official forms can be accessed online. When submitting a comment, all potential conflicting interests must be disclosed; a summary of the information contained in the declarations of interest are published. IQWiG publishes the submissions, evaluates them and assesses all submitted comments. This serves to evaluate the validity of the submitted arguments. If IQWiG deems an argument to be valid, the necessary changes to the report are correspondingly listed. In case IQWiG however considers an argument to be invalid, a decision is made on how the argument will be treated. How those comments are dealt with, is stated in the assessment. There is no personalised feedback.

In addition, an optional oral scientific debate may be held to discuss any unclear aspects of the written comments. IQWiG invites those groups and people who have submitted a written comment and declared their interests to the debate. Verbatim records of the debates are published online.

With regard to health information, issues can be suggested by the general public. Unlike IQWiG’s reports, there is neither a preliminary publication online nor the possibility to submit comments. Instead, the institute’s committees are requested to submit a comment, including the Board of Trustees, consisting of 30 members, comprising inter alia the relevant organisations responsible for representing the interests of patients and self-help groups of chronically ill and disabled persons, as well as the
Federal Government Commissioner for Patient’s Affairs.20 Parallel to this, the drafted health information undergoes external user testing, reviewing the reports’ information content and clarity.21

3.3.2 The German Agency of Health Technology Assessment of the German Institute of Medical Documentation and Information (DAHTA@DIMDI)

Public Proposition and Identification of Topics

As part of DIMDI, DAHTA@DIMDI is part of an agency within the scope of the Federal Ministry of Health. DAHTA@DIMDI represents HTA in the national and international community. According to the Information System for the Assessment of Medical Technologies Act (Gesetz über ein Informationssystem zur Bewertung medizinischer Technologien) (MTInfoG) DAHTA@DIMDI is legally mandated to:

- Setup and maintain a database-supported information system for the assessment of the effectiveness and costs of medical procedures and technologies,

- Promote access to national and international databases,

- Grant research assignments for the assessment of procedures and technologies relevant to health in the form of HTA reports.

Unlike IQWiG, DAHTA@DIMDI’s assessments are not commissioned. On this account, there is a web-based procedure to identify the topics to be dealt with. Anyone can propose a topic.22 Afterwards, the HTA-Board of Trustees, on which two representatives of the relevant organisations responsible for representing the interests of patients sit, sets priorities, which are in turn assessed by external experts. There is no public submission of comments.

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21 Ibid.
3.3.3 France: Haute Autorité de Santé (HAS)

**The HAS is legally obliged to cooperate with selected patient and user associations**

The „Haute Autorité de Santé“ (HAS) was created by the „Loi du 13 août 2004“. It cooperates with selected patient and user associations and has for this purpose founded a cooperation network.23

The task of HAS is to provide health authorities with the information needed to make decisions on the reimbursement of medical products and services. Furthermore, it is responsible to improve quality of care in health care organisations (e.g. accreditation of hospitals) and in general medical practice and to promote cooperation between the relevant stakeholders.24

Working groups are responsible for HAS products. Patient representatives are involved in the advisory bodies and contribute their knowledge as members of the steering committee and working groups (surveys, elaboration of observations, documents) as well as members of the review group.25

Patient representatives have the same rights and obligations as other stakeholders within HAS; this also covers voting rights. For this reason, patient representatives must be involved before a decision can be taken. With regard to reviews, the responsibility lies with the individual working groups to decide how changes proposed by patient representatives are justified and if they should ultimately be implemented. Optionally, representatives of the affected groups can be asked to participate.26

The acceptance of patient representatives by professionals seems gradually to have increased with time. At first, patient representatives had a low level of participation in the consultations; this has changed. Today, there is no project without the involvement of patient representatives. Stakeholders are said to be quite open to cooperate with patient representatives.

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23 [http://www.has-sante.fr/portail/jcms/c_452559/presentation-de-la-has.](http://www.has-sante.fr/portail/jcms/c_452559/presentation-de-la-has.) / [http://www.has-sante.fr/portail/jcms/c_415958/missions.](http://www.has-sante.fr/portail/jcms/c_415958/missions.)

24 Ibid.


26 Ibid.
Patient representatives with expert status

In HAS, patient representatives have an expert status. It is for this reason that patient representatives are paid like other experts. Only if the activity appears to be incompatible with the professional occupation does the patient organisation and not the patient representative receive the remuneration. The remuneration covers participation at meetings (inclusive of travel and accommodation expenses) and in certain circumstances the self-employed are reimbursed for a loss of income. However, participation in review groups is not remunerated.27

The quality of patient representatives must be confirmed by the registered association they belong to (cf. chapter 3.6.3). Each patient representative is obliged to report his performance to his association.28

A general framework exists for the cooperation with patient and user associations.29 Patient representatives have a contact person within HAS whom they can approach. There are several educational opportunities, for example in 2011 a training course on accreditation was offered for representatives. All the other training courses are coordinated by the patient umbrella organisation CISS.

HAS publishes its opinions and decisions on its website. Currently, merely the minutes of the “Commission de la Transparence” are published. Each set of minutes lists the participants in the meetings.

Prior to each committee meeting, working group etc., all experts must provide a declaration of interests.30 With regard to the efforts of promoting transparency, all experts’ declarations of interest are published.

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28 Guide CISS du représentant des usagers du système de santé, édition 2011, Chapter 1: The role of user representatives.


30 At present it is not necessary to submit a declaration of interests to work on a review group.
3.3.4 England: National Institute for Health and Clinical Excellence (NICE)

General conditions for patient and citizen representation in NICE

The National Institute for Health and Clinical Excellence (NICE) was founded on 1 April 1999. The general objective was to ensure access to medical treatments and high quality care by the National Health Service (NHS). In 2001, the Health and Social Care Bill 2001 legally regulated patient and citizen participation in England for the first time. Since then, the NHS has been obliged to involve the public. The Public Health White Paper of 2004 “Choosing Health: making healthier choices easier” defined the role of NICE with regard to patient and citizen participation. The rights of patients in NICE are not legally defined.

In accordance with NICE’s tasks (knowledge transfer and advisory service), patient representatives operate in several different domains: advisory committees, guideline development committees, and the Citizens’ Council. The Patient and Public Involvement Programme (PPIP) overlooks the cooperation between patients and lay people.\(^\text{31}\)

NICE supports the implementation of its guidance by engaging stakeholders, patients and the public in the selection of topics and in the guidance development process. The selection of topics is not dependent on commissions.\(^\text{32}\)

Patients must be involved in the decision-making processes within NICE. Patient and citizen participation is documented in the minutes and reports of NICE. Furthermore, NICE is obliged to record the extent to which patients influence decision-making. It must justify a non-consideration of patients’ recommendations. Although NICE has the right to make recommendations, the final decision regarding implementation is taken by the Department of Health (DOH).

Other stakeholders seem to have been unsure of patient representatives at first. There was uncertainty whether patient representatives would concede to overlapping interests or be too industry-friendly. Measures to provide transparency were implemented by the adoption of a code of practice and declarations of interest.

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\(^\text{31}\) [http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/ppipinvolvementprogramme.jsp](http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/ppipinvolvementprogramme.jsp)

\(^\text{32}\) [http://www.nice.org.uk/aboutnice/whatwedo/what_we_do.jsp](http://www.nice.org.uk/aboutnice/whatwedo/what_we_do.jsp)
The Patient and Public Involvement Programme (PPIP)

Patient representatives receive attendance fees as well as compensation for travel and lodging expenses. In general the attendance fees depend on the time spent. Some patient organisations remunerate their patient representatives on their own initiative; this depends on the solvency of the organisations. The expenses for each representative are published on the website on a quarterly basis. Furthermore, the compensation conditions of, for example, travel expenses are disclosed.

Lay people acting as patient representatives in NICE work on a voluntary basis. NICE looks explicitly for lay people with no medical education. Otherwise, a conflict would arise due to the lack of patient perspective. Recruitment follows public tendering procedures. It is the patient representatives' task to report on their own experiences or those of the patients they represent. Their work cannot be measured quantitatively, yet it has qualitative value for NICE.

The Patient and Public Involvement Programme (PPIP) provides patients representatives in NICE with continuous support during their time as committee members. All lay people who cooperate with NICE obtain an introductory training. Furthermore, specialist trainings are offered, having been tailored to the patient representatives' needs. These offers require appropriate funding.

The PPIP evaluates patient representatives’ involvement in NICE. Corresponding reports have been published (so far in 2004 and 2008).

Issue-related registration procedure for interested persons

The first step of each drafting process of a report is a so-called “scoping workshop”. All stakeholders who have registered their interest in the topic are invited. Each report is produced by a working group, including two lay members. Everyone can comment on the draft reports on NICE’s website. Each guideline is

33. [URL](http://www.nice.org.uk/aboutnice/whatwedo/niceandthenhs/nice_and_the_nhs.jsp)
34. [URL](http://www.nice.org.uk/aboutnice/whoweare/board/boardexpenses/boardexpenses.jsp?domedia=1&mid=2A506E39-19B9-E0B5-D4D6021E316FAE0C);
35. [URL](http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/patientandpublicinvolvementpolicy/patient_and_public_involvement_policy.jsp?domedia=1&mid=5D00F560-19B9-E0B5-D48225F724082ED8).
36. [URL](http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/patientandpublicinvolvementpolicy/patient_and_public_involvement.jsp);
   [URL](http://www.nice.org.uk/media/D44/49/AboutPPIP.pdf).
37. [URL](http://www.nice.org.uk/media/D44/49/AboutPPIP.pdf).
38. Scoping is not referred to in Germany. It would have to be established at the Federal Joint Committee.
available in a special version for patients ("understanding NICE guidance” series).\(^3^9\)

All dates of the public meetings can found on the website and each set of minutes can be downloaded from the website. Both the members and the invited experts are mentioned by name in the minutes; the declared interests are also published.\(^4^0\) Other patients or lay experts who have registered for the issue but are not part of the working group, are invited to the meetings so as to illustrate the experiences of patients and the public. Committee sessions are held in public.

**Association membership is not required**

Patients are represented by lay representatives and in certain topics by national organisations. For issues of special interest, national patient or non-profit organisations are invited to register as representatives. In order to get involved in NICE it is not necessary to be a member of a patient association. Nevertheless, personal experience is necessary in order to adequately understand a patient’s perspective. The appointment follows public tendering procedures.\(^4^1\)

### 3.3.5 Scotland: Scottish Intercollegiate Guidelines Network (SIGN)

SIGN (Scottish Intercollegiate Guidelines Network) has existed since 1993. In 2005, SIGN has become part of the NHS QIS (cf. chapter 3.4.3). The aim of the network is to develop evidence-based guidelines for clinical practice in the NHS in Scotland.

SIGN’s guidelines are developed by multidisciplinary Scottish working groups (e.g. health care professionals, managers, researchers and patients). SIGN has its own administration that supports the work of its members.\(^4^2\)

SIGN Patient Network is a “virtual” group of patients and citizens within NHS Scotland. Currently, about 400 members help by:

- Reporting on issues relevant for patients (for guidelines)

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\(^4^0\) NHS NICE: Code of Practice for Declaring and Dealing with Conflicts of Interest v1.1 (Issue date: April 2007, Review date: December 2009).


\(^4^2\) [http://www.sign.ac.uk/about/introduction.html](http://www.sign.ac.uk/about/introduction.html).
- Designating persons to be involved in the development of guidelines
- Commenting on guidelines and preparing patient versions
- Inviting people to events where SIGN promotes its own work
- Helping to provide information to relevant groups
- Helping to gather patient views via surveys and focus groups

Members also receive the newsletter illustrating patient and public involvement opportunities at SIGN.43

**Application procedure for patient representatives**

In the development process of specific guidelines volunteer organisations and members of the patient network are invited to nominate prospective members. Then, the nominees state their reasons of interest and submit a short application. After an evaluation of the applications by SIGN, a first informal meeting takes place prior to the first guideline meeting. In principle, everyone can contribute to the development of guidelines. Neither particular knowledge nor competencies are required. However, certain competencies considered to be useful are listed on the website. They cover both hard skills such as direct experience with the development of guidelines and knowledge of patients’ needs, and soft skills such as experience of working with large groups and communication skills.

**Differentiated participation procedures**

The involvement in the guideline development process includes the following options: full group member, key stage member and advisor.44 Full group members attend all group meetings over a period of two to three years. Key stage members attend all group meetings until all key questions are finalized (3-4 meetings). They can also attend the National Open Meeting. Advisors have in-depth knowledge of the condition but do not have the capacity to commit to attending meetings for the lifetime of the group. They are expected to attend the first two meetings of the group. Afterwards they support the guideline development group with specific issues.

Draft versions of guidelines are open to a national consultation process, on which the people affected (professionals as well as patients) are invited to comment. In principle, any group or individual may propose a guideline topic to SIGN. Guideline topics are selected for inclusion in the core programme on the basis of

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43 [http://www.sign.ac.uk/patients/network.html](http://www.sign.ac.uk/patients/network.html)
44 [http://www.sign.ac.uk/patients/joining.html](http://www.sign.ac.uk/patients/joining.html)
the existence of variation in practice, and the potential to improve outcomes.\textsuperscript{45}

3.3.6 Australia: Medical Service Advisory Committee (MSAC) und Pharmaceutical Benefits Advisory Committee (PBAC)

Recruitment by CHF

The Medical Service Advisory Committee (MSAC, 1997) and the Pharmaceutical Benefits Advisory Committee (PBAC, 1953) assess new methods of treatment and pharmaceuticals with regard to medical and economic criteria. This is an integral part for the listing of new medical technologies and services on the Medicare Benefits Schedule (MBS) by the government.\textsuperscript{46}

The public is involved in the decision-making process of both institutions in different ways. For instance, citizen and patient representatives are directly appointed into the committees of MSAC and PBAC by the Consumer Health Forum (CHF).\textsuperscript{47} There, they are joined by experts.

In addition, online published assessment records can be read and be commented on. Within a six week-period, written opinions can be directed to MSAC or PBAC.

3.4 Patient and citizen participation in organisations that determine benefits catalogues and perform quality assurance

The following organisations either provide recommendations with regard to the scope and content of benefits catalogues as well as to quality assurance measures in the specific systems. Alternatively, they actually decide on reimbursement issues in the framework of self-government.

\textsuperscript{45} [http://www.sign.ac.uk/about/proposal.html].
\textsuperscript{47} For a detailed description of nomination procedures, reimbursements etc., please see chapter 3.6.2.
3.4.1 Germany: The Federal Joint Committee

Patient representatives with the right to advise and to submit motions

The Federal Joint Committee (G-BA) is the supreme decision-making body of the joint self-administration of physicians, dentists, psychotherapists, hospitals and health insurance funds in Germany. In the G-BA, the relevant organisations responsible for representing the interest of patients have the right to participate in consultations and to submit motions according to § 140 of the Social Code, Book V (SGB V). This right does not extend to procedural and financial issues. Consequently, both issues are dealt with without patient involvement.

Decisions are taken in the plenary sessions of the G-BA. Each decision is prepared by one of the eight sub-committees. For specific issues, the latter can set up working groups. Patient representatives are present in all committees but have no voting rights. The main points of the submissions of patient representatives must be considered in the explanatory statement. During the consultation stage, points brought up by patient representatives are recorded in the minutes. Each group represented in the G-BA nominates “jointly and unanimously” ("gemeinsam und einheitlich") a spokesperson. Thus patient representatives must agree a joint approach, differing personal opinions cannot be submitted. Travel expenses are reimbursed and voluntary members receive a daily allowance according to a legal ordinance.

The secretariat of the G-BA must be informed about the patient representatives in the G-BA committees (§ 7 GO G-BA). The notification must include the meetings and the issues to be dealt with. This ruling also extends to the G-BA’s sub-committees. In order to consider the perspective of the people affected, so-called “sachkundige Personen” (“qualified persons”) can be nominated in addition to the representatives of the relevant organisations. The names of these people and the issues and meetings for which they are nominated must also be declared to the secretariat.

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48 § 20 Abs. 3 GO G-BA
49 § 20 Abs. 2 GO G-BA
50 § 8 GO G-BA
51 § 18 Abs. 5 GO G-BA
Coordination group of patient representation at the G-BA

Patient representatives are represented in every committee. Recruitment problems only seem to occur in the Pharmaceutical Subcommittee and the Dental Treatment Subcommittee.\textsuperscript{52}

The nomination of patient representatives and “qualified persons” is carried out by a coordination group of the relevant organisations responsible for representing the interest of patients and self-help groups of chronically ill and disabled persons at the federal level. The coordination group regulates the “nomination of patient representatives on federal and state level” – also, for instance, for IQWiG and AQUA – and prepares the meetings in the different committees of the Federal Joint Committee (G-BA).\textsuperscript{53} The coordination group meets monthly for one day and has developed a transparent criteria paper for the nomination of ‘qualified persons’. The patient group NAKOS organises, facilitates and records the meetings of the coordination group in cooperation with the Federation of German Consumer Organisations (VZBV).\textsuperscript{54} The coordination groups’ rules of procedure, a member list, agendas or protocols were at the time of writing not publicly disclosed.

Issue-related patient representatives are suggested by the German Disability Council (represented by BAG-Selbsthilfe).\textsuperscript{55} The relevant organisations must agree by law unanimously on a nomination.\textsuperscript{56} Representatives are nominated for meetings and issues discussed. As a result, it may be the case that different persons represent patients in the course of a consultation procedure.

Issue-related representatives and their groups do not have to be member of one of the four relevant organisations. Yet, they should meet those criteria, the relevant organisations have agreed upon.\textsuperscript{57} The criteria are:

- Mandate to represent (consensual nomination, member of a self-help organisation)
- Expertise (professional and networking competence acquired by work and function in organisations)

\textsuperscript{52} Information given by interview partners.
\textsuperscript{53} Patient involvement according to § 140 f SGB V in the Federal Joint Committee; http://www.gesundheitberlin.de/index.php4?request=search&topic=1920&tipo=infotext.
\textsuperscript{54} Ibid.
\textsuperscript{55} The information comes from several interviews.
\textsuperscript{56} § 4 (1) PatBeteiligungsV.
\textsuperscript{57} http://www.g-ba.de/institution/sys/faq/53/.
- Independence and transparency of the qualified persons (independent from payers, health service providers and industry)

- Independence and transparency of the sending organisations (payers, health service providers and industry, letter of self-commitment)

In principle, the Federal Joint Committee does not publish the names of sub-committee or working group members, nor does it publish agendas or minutes.

**Patient Representation Unit**

A unit affiliated to G-BA’s secretariat and consisting of two officers and one secretary supports patient representatives. According to the website of G-BA, there are currently about 100 patient representatives. The unit supports them organisationally. Currently, patient representatives are demanding further support in the fields of medicines and quality assurance. The unit organises training for patient representatives. Furthermore, the coordination group may commission reports in order to improve the knowledge on certain subjects.

### 3.4.2 Germany: Agency for Quality in Medicine (ÄZQ)

**Patient representation in the drawing up of clinical guidelines**

The Agency for Quality in Medicine (ÄZQ) is a joint scientific institution of the German Medical Association and the National Association of Statutory Health Insurance Physicians. The ÄZQ develops national health care guidelines and patient guidelines for primary health care sectors, supports and disseminates selected guideline programmes for ambulatory and secondary care and appraises quality indicators.

For the elaboration of national guidelines, patient participation is a methodological pre-condition of quality. In addition to a body of experts, a patient committee is constituted. The moderator of the Agency for Quality in Medicine (ÄZQ) informs both the patient forum of the German Medical Association and the BAG Selbsthilfe about each newly launched process. The BAG Selbsthilfe then suggests potential organisations. Other groups

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58 [http://www.g-ba.de/institution/sys/faq/55/](http://www.g-ba.de/institution/sys/faq/55/).
60 The Patient forum comprises BAG Selbsthilfe, the Forum of chronically ill and disabled people in the Paritätische and the Deutsche Arbeitsgemeinschaft Selbsthilfegruppen.
also involved in the Patient Forum may also bring forward proposals. *BAG Selbsthilfe* serves as a clearing house and selects the organisations.

The aim is to ensure for each topic the involvement of all the relevant self help organisations. Where possible these self-help groups should be organised in the *BAG Selbsthilfe* or in the forum for chronically ill and disabled people. If the self-help organisations in any particular area are not a member in one of the aforementioned umbrella associations, they must fulfil certain criteria.\(^{61}\)

The criteria for an organisation being nominated by the *BAG Selbsthilfe* are national representation, factual independence, charitable status, financial independence as well as free access and continuity.

Subsequently, the moderator contacts the organisations and asks for the nomination of the representatives. The representatives of the organisation should be mandated, they should make a statement on financial independence and on conflicts of interest. They should be competent (with regard to generalising patient experiences with clinical provision for the diagnosis at hand) and prepared to enter into an exchange with patient representatives of other self-help organisations. Only travel expenses are reimbursed.

The patient body nominates a representative for the author group, whose task it is to represent all members of the patient body. The patient body verifies the extent to which patient interests have been considered.

For every national guideline a patient guideline is developed. The patient guideline it is decided upon by consensus in the patient forum.\(^{62}\) Drafts of the guidelines are publicly put up for discussion via online-consultations. Here, everyone has the opportunity to get involved.

### 3.4.3 Scotland: NHS Quality Improvement Scotland\(^{63}\)

*Legal obligation to promote patient and citizen participation*

Currently, NHS Scotland consists of 14 local Health-Boards. They are supported by eight Special Health-Boards providing national

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\(^{63}\) On 1 April 2011, Healthcare Improvement Scotland came into existence and will build on work previously done by NHS Quality Improvement Scotland and the Care Commission.
services. In 2002, NHS Quality Improvement Scotland (QIS) was founded as a Special-Health Board in order to improve quality and safety of health care in Scotland.

Both the “Participation Standard” and the National Health Act of 2004 articulate the guidelines for participation. Scotland’s “Participation Standard” is based on an agenda which was developed over several years. It contains three issues:

- Rules on patient focus in treatment
- Rules on patient participation
- Rules on governance (management)

The National Health Act delegates responsibility for participation and equal opportunities to the Health Boards (National Health Service Reform Act 2004). This act obliges all Health Boards to promote patient and citizen participation, which includes the involvement in planning and development as well as in decision-making with regard to health service provision.

In 2005 the Scottish Health Council was established in order to make sure that the NHS Boards meet their involvement obligations. The assessment contains for instance self-evaluations of Health Boards as to whether they comply with the Participation Standard. Each self-evaluation is examined by user and participation groups as well as by the Scottish Health Council.

“In Patient Focus and Public Involvement” constitutes a strategic objective of NHS Scotland

In order to support NHS Scotland’s staff in involving citizens and patients, a strategy paper called “Patient Focus and Public Involvement” was formulated in 2006. The involvement of the public, NHS users or their carers, volunteers, as well as representatives of patient organisations is of particular importance.

The following national standards for the involvement of patients and citizens are to be applied:

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64 NHS Quality Improvement Scotland (2009), Involving People Strategy 2009 – 2011 - How we will involve people in our work to improve the quality and safety of healthcare in Scotland.
65 National Health Service Reform (Scotland) Act 2004, Part 1 Section 7.
- Participation: Identification and participation of interested people and organisations
- Support: Identification and overcoming of all obstacles to participation
- Planning: Identification of needs and available resources
- Methods: Agreement on and usage of methods of engagement
- Cooperation: Agreement on and usage of clear processes that enable participants to cooperate effectively and efficiently
- Information transfer: Ensuring the communication of necessary information between the participants
- Cooperation: Effective cooperation with others, who are interested to be involved
- Improvement: active development of capabilities, knowledge and trust to all participants
- Feedback: Informing the public and the relevant agencies about the results
- Supervision and evaluation: Supervise and evaluate the achievement of objectives and if national standards are met.

3.4.4 Scotland: Scottish Medicines Consortium (SMC)

Involvement of patients and citizens in evaluation of new medicines

The Scottish Medicines Consortium (SMC) evaluates new medicines in order to enable their use in the National Health System (NHS). In view of a positive cost-effectiveness the SMC’s purpose is to secure a quick reimbursement of such medicines. SMC’s members are public partners, physicians, health economists, pharmacists, nurses, financial experts, health service managers as well as representatives of the pharmaceutical industry.

The SMC has three sub-committees:

- New Drugs Committee (NDC): The NDC is SMC’s scientific body. It consists of 20 members mainly coming from the medical and pharmaceutical field as well as two representatives from the pharmaceutical industry.
The Patient and Public Involvement Group (PAPIG): The PAPIG consists of six members. Three members are public partners, having been selected by an application process, the other three members are members of the SMC.

SMC User Group Forum (SMC UGF): The SMC User Group Forum comprises representatives of the pharmaceutical industry as well as members of the SMC and the NDC. The SMC UGF concentrates on matters of procedure which concern the SMC.

The PAPIG is responsible for the social, emotional and economic evaluation of medicines from patients’ and citizens’ view.

During the eight-week evaluation process of the SMC, patient groups may file submissions using an official form. Patient groups are actively invited to comment on how far a particular medicine influences the patients’ situation.

PAPIG evaluates the submissions and provides a summary, which is attached to the documents of the SMC. In addition, each evaluation process to a new medicine comprises a presentation by a member of PAPIG focusing on the key patients’ concerns.

The three public partners in PAPIG work on a voluntary basis. The expected work load averages two days a week. Only travel expenses are reimbursed. Neither attendance allowances nor other financial compensations are granted.

SMC’s selection process

In principle, the selection process for the three public partners follows standard application processes. The position is advertised. All applications received are reviewed and a shortlist is drawn up. Subsequently, interviews are held. Particular selection criteria are previous experience as a public partner in the health care system; "significant involvement" must be proven. Certificates and references are similarly required as in standard application procedures.

The work within PAPIG mainly consists of reading specific literature. The interaction with relevant stakeholders in the health care system is also of vital importance. Consequently, new PAPIG-members receive training which lasts six weeks and informs new members about all aspects of their work. This includes for instance economic aspects, the functioning of the NDC, a special PAPIG-introduction as well as a shadowing of SMC-meetings.
Submission support for patient groups

A part-time patient and public involvement officer is employed to support patient organisations in the preparation of submissions. In view of a lack of resources on the part of non-profit organisations, the patient and public involvement officer advises them with regard to compliance with formalities and accuracy. The position is financed by the Scottish government, the Association of the British Pharmaceutical Industry as well as the Long Term Condition Alliance Scotland (LTCAS), an umbrella organisation. The latter also provides office space.

Each submission is responded to individually. Each response highlights whether and why the submission’s arguments have been followed. In consideration of the feedback, patient organisations may improve the potential success of future submissions.

Every two years, patient organisations are invited to a free training course, explaining the SMC processes and in particular the possibility to make submissions. In 2011, 18 organisations participated for the first time.

Transparent procedures

The decision-making process is disclosed on PAPIG’s website. The Scottish Freedom of Information Act covers further detailed information on request. Any information related to competition is confidential and may not be made public. SMC’s monthly sessions are held in private. However, representatives of the relevant patient groups are invited.

3.4.5 The Netherlands: Raad voor de Volksgezondheid en Zorg (RVZ)

Government-nominated patient representatives

The Raad voor de Volksgezondheid en Zorg (Council for Public Health and Health Care) is an independent body advising the government on public health and care. The body consists of nine members appointed by the government. The members are not official representatives of any organisation. The consideration of patient interests depends on the chairman.68

The RVZ provides advisory reports on various issues. Each advisory report is prepared by one or two members of the Council,

68 The information is based on statements by the Secretary-General, please see also www.rvz.nl.
supported by a project team from the Secretariat and then presented to the Council for adoption. The RVZ may also consult external specialists, both from in- and outside the health service.

Patients are involved in the preparations of advisory reports, for instance in the committees and background groups. Collective patient interests are always presented to the Council. There are formalised relations to the Dutch Patient and Consumers Federation (cf. chapter 3.6.4), the Council for Disabled People and the Dutch Consumer Association as well as to disease-specific patient groups. The NPCF usually publishes a press release after the publication of an RVZ advisory report.

Participation is not a formal requirement. Moreover, relevant organisations and stakeholders are invited to participate, where and when necessary.

3.4.6 Sweden: Tandvårds- och läkemedelsförmånsverket und Socialstyrelsen

For the Swedish system two different organisations are described. In Sweden, provinces and municipalities are responsible for the provision of health services. Thus, the discussion of citizen and patient participation is different than in systems with separate health care systems.

**Government nomination of patient representatives of the Pharmaceutical Benefits Board (PBB)**

The PBB is responsible for pricing medicines and other medical items covered by the high-cost threshold for pharmaceutical purchases.69

The PBB provides a systematic evaluation which pharmaceuticals should be subsidized from a social, medical and health economic perspective. Based on specific criteria, the PBB decides whether a medicine should be included on the Pharmaceutical Benefits Scheme. Only in this case are medical costs reduced for the patient.

Within the PBB, there is a committee which for instance:70

- Rules on general pricing guidelines

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70 Ibid.
- Rules on subsidy and price regulations for new medicines and products
- Decides whether a medicine or specific product should be included on the pharmaceutical benefits scheme
- Decides on a change in the conditions pertaining to whether a medicine or specific product should be included on the pharmaceutical benefits scheme

This committee consists of a chairman and ten committee members. Its chairman and its members are all appointed by the government. Alongside four members of the provinces (län), responsible for health care, there are four members from government agencies and other actors with expertise in the field of medical products as well as two representatives of user groups.

The user representatives of the PBB are nominated by the government. They possess the same voting rights as the other members. They are paid an attendance allowance. Thus, by virtue of the nomination, all parties of the PBB are legitimated by the government.71

**Government nominations in the Socialstyrelsen**

*Socialstyrelsen* (National Board of Health and Welfare) is a government agency under the Ministry of Health. The majority of its activities focus on the compilation and analysis of health care information, the development of standards, monitoring the observation of standards as well as maintaining health data registers and official statistics.

Since 2008, *Socialstyrelsen* has had an advisory committee (*Insynsrådet*), which is mandated to advise the General-Director on the different issues the agency has to deal with.72 The committee members are appointed by the government. In order to ensure a broad democratic basis, the government considers different interest groups (like patient groups), professions and political parties. Members receive an attendance allowance. Formal membership requirements, for instance, an university degree, professional expertise in the medical field etc., do not exist.

Further mechanisms ensure an input of patient and other interest groups. The management of *Socialstyrelsen* has regular meetings with patient representatives and other stakeholders. In addition,

71 Information provided by the communications department of *Tandvårds- och läkemedelsförmånsverket*.
72 [http://www.socialstyrelsen.se/omsocialstyrelsen/organisation](http://www.socialstyrelsen.se/omsocialstyrelsen/organisation).
there are formalised meetings with specific groups, for instance, children, elderly and disabled persons.\textsuperscript{73}

3.5 Patient and citizen participation in authorisation bodies

The following section analyses three examples of patient and citizen participation in market authorisation bodies.

3.5.1 Germany: Federal Institute for Drugs and Medical Devices (BfArM)

\textit{Patient representatives in authorisation commissions}

The BfArM is an independent higher federal authority within the portfolio of the Federal Ministry of Health. BfArM’s main tasks include authorisation of finished medical products, registration of homoeopathic medicines, monitoring, evaluation and prevention of drug-related dangers (pharmacovigilance) as well as central monitoring and evaluation of risks related to medical devices.

The BfArM involves patient representatives in authorisation procedures, in the wording of texts (e.g. patient information leaflets), in risk-management plans and in special monitoring programmes.

According to Section 25 of the Medicinal Products Act (\textit{Gesetz über den Verkehr mit Arzneimitteln} - AMG), authorisation commissions are to be heard prior to final decisions on authorisation. Members of the commissions are appointed by the Federal Ministry of Health “taking into account the proposals of the chambers of the medical professions, the professional societies of medical practitioners, dentists, veterinarians, pharmacists, alternative medical practitioners as well as the main central associations of the pharmaceutical entrepreneurs, patients and consumers responsible for representing their interests”.\textsuperscript{74} Membership in the commissions represents a personal honorary office, according to the commissions’ rules of procedure. Travel expense and attendance allowances conform to the Directives of the Federal Ministry of Finance.

Examples of commissions involving patient representatives are new medicines, herbal medicines (phytotherapy), homoeopathic

\textsuperscript{73} Information of the communication department of \textit{Socialstyrelsen}.

\textsuperscript{74} Section 25 sub-section 6 sentence 4 AMG.
medicines and “traditional” medicines. The minutes of some commissions’ meetings are published on the website. Some commission members’ names are disclosed as well. All members have the right to vote.

The graduated plan outlined in section 63 AMG provides for the involvement of the Patient Representative of the German Government. Patients are not involved with regard to decisions on prescription and pharmacy only issues, narcotics as well as in the Permanent Vaccine Commission.

3.5.2 Denmark: Council for Adverse Drug Reactions (Bivirkningsrådet)

The Bivirkningsrådet serves as example of the Danish system.

No distinction between consumers, physicians and pharmacists in Bivirkningsrådet

The Danish Medicines Agency (Lægemiddelstyrelsen) is an agency under the Ministry of the Interior and Health. Lægemiddelstyrelsen’s aim is to ensure that medicinal products used in Denmark are of satisfactory quality, are safe to use and that they have the desired effect. To do so Lægemiddelstyrelsen administers the Danish legislation on medicinal products, reimbursement, pharmacies and medical devices.

Lægemiddelstyrelsen is advised by several committees and councils consisting of experts and stakeholders. One of the councils is the Bivirkningsrådet, which comprises representatives of industry, therapists, patients and consumers. This is regulated by the Danish Medicines Act and is specified by the rules of procedure of Bivirkningsrådet.

The members of Bivirkningsrådet are nominated by their organisation. In principle, possible candidates may nominate themselves as well. Bivirkningsrådet advertises vacancies, collects the nominations and appoints the members in consideration of the different stakeholder groups which are to be included.

In July 2011, several patient and consumer representatives were members of Bivirkningsrådet (of Parkinsonforeningen – Parkinson

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75 U. Hagemann, Beteiligung von Patienten an der Bewertung von Arzneimitteln bei der Zulassung und der Nutzen-Schaden-Bewertung, presentation held on 10 November 2008.
76 Ibid.
77 Bekendtgørelse om forretningsorden for bivirkningsrådet, executive order no. 710 of 13 August 2003
78 Danish Medicines Act, § 101 (2)
Society, Forbrugerrådet – Danish Consumer Council; Danske Patienter – Danish Patients). There are no professional requirements with regard to education etc. Attendance allowances are paid.79

The meetings’ minutes are published on the website and also list the names of the attendees or announce the next scheduled meeting. Furthermore, each council member has to answer a questionnaire. The latter is also published on the website.

3.5.3 EU: European Medicines Agency

Establishment of the Patients and Consumers Working Party (PCWP) to promote and maintain contacts to patients and consumers

EMA is obliged to develop contacts to consumer and patients.80 The “Framework of interaction between the EMA and Patients’ and Consumers’ Organizations” was adopted for this reason in 2005.

The PCWP was 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.81 Currently, 15 consumer and patient organisations are members of the PCWP. In order to become involved, a patient group must represent patients and consumers throughout the European Union, have its mission/objectives clearly defined, have, as part of its activities, a specific interest in medicinal products, have democratic governing structures and fulfil the criteria for transparency.82

Expenses related to travel and accommodation for meetings and a daily allowance of € 220 are covered by the EMA. The daily allowance is paid to one representative per organisation for every attended meeting day, unless the organisation receives other financial compensation.83

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79 Information of the DMA
83 EMA (2009): Rules of Involvement of Members of Patients'/ Consumers' and Health Care Professionals' Organisations in Committees related Activities.
**Maximum transparency as PCWP’s aim**

PCWP’s rules of procedure are published online on the website of EMA.\(^{84}\)

In order to disclose the dates of the meetings, the agenda of the meetings is published. Agenda and minutes of the meetings are published on the EMA website.\(^{85}\)

Representatives of the European Commission may attend meetings of the PCWP; observers may participate with the agreement of the chairpersons. When considered appropriate by the PCWP, oral presentations by interested parties can be made during working party meetings on matters directly related to the activities of the working party, following agreement with the EMA. Members who want to bring additional participants with relevant experience for a specific topic must notify the EMA Secretariat in advance of the meeting. Participation is subject to the agreement of the Chairpersons.\(^{86}\) At the beginning of each set of minutes all attendees are listed.\(^{87}\)

Patient representatives must make an annual declaration of their financial interests, in particular with regard to the pharmaceutical industry. At the beginning of each meeting, members of the working party and experts attending the meeting must declare any specific interests which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations are available to the public.\(^{88}\)

**Patients’ participation opportunities within the bodies of EMA**

Patient representatives are members of the Management Board and of three Human Scientific Committees: the Committee for Orphan Medicinal Products (COMP), the Committee for Advanced Therapies (CAT) and the Paediatric Committee (PDCO). Other activities include:\(^{89}\)

- Participation in the activities of the Committee for Medicinal Products for Human Use (CHMP):


\(^{85}\) Ibid.

\(^{86}\) Ibid.

\(^{87}\) For example EMA/790515/2010: Minutes of the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) together with all other eligible organisations - meeting of 30 November 2010.


\(^{89}\) EMA (2010): Working with patients and consumers.
- Interaction with scientific advisory groups (SAGs) and working parties
- Ad-hoc Consultations

- Review of product information
- Membership of the Steering Group of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
- Membership of the Working Group on Clinical Trials in Third Countries
- Acting as observers in the Pharmacovigilance Working Party (PhVWP)
- Participation in workshops and conferences organised by the Agency

As full members of the Management Board and the Human Scientific Committees, patient representatives have the right to vote. In the CHMP, however, patient representatives have only an advisory role.\textsuperscript{90}

In the EMA Management Board, it is the patient representatives’ role to evaluate the Management Board discussions from the patients’ point of view. In case patient representatives have concerns with regard to the Management Board’s work, they are able to articulate these and publish them on the EMA website.

All patient representatives at EMA work on an honorary basis. Expenses are reimbursed and an attendance allowance is paid in order to secure that representatives have sufficient resources to finance their voluntary work.

\textsuperscript{90} Ibid.
Qualification of patient representatives: Cooperation agreement with the London School of Economics

EMA promotes the qualification of patient representatives. The driving force behind this was the fact that patient representatives often had problems taking part in and contributing to the discussions as they lacked the necessary background information. As a result, a cooperation agreement was concluded with the London School of Economics. Each year, three courses are held, two for all European organisations and one for British patient organisations. Each course lasts three days. Target groups are patient organisations on national (not EU-) level with the aim to promote the understanding of patient representatives with regard to HTA, legislative processes and the costs related to the market launch of medicines. In particular, patient representatives involved in HTA must be able to put forward correct health economic arguments. Patient representatives should be in the position to assume their role as patient advocates. Furthermore, it is a matter of acquiring an appropriate medical vocabulary in order to be heard and accepted by experts.

Closed meetings and comprehensive „Declarations of Interest“

The meetings of the Management Board are not public. Upon request, non-members of the Board may participate at the meetings.

Specific interests must also be declared in the EMA Management Board. However, patient representatives doubt if this form is suitable for them. Given the fact that patient representatives do not have the right to vote on the authorisation of new medicines, the fact that they still have to declare the same specific interests is seen as overly strict.

Legitimacy through patients setting criteria for the selection of patient associations

Patient representatives on the EMA Management Board are nominated by organisations such as the Council of Europe. As the criteria for the selection of organisations with patient representatives were defined by a working group consisting, amongst other, of patient representatives, patient representatives accept the criteria.
3.6 Patient organisations: Umbrella organisations

3.6.1 Germany: Ordinance on Patient Participation

*Several organisations with one common structure*

In Germany, no single umbrella patient organisation has a sole right of representation. Instead, patient representation on federal level is regulated in the so-called Ordinance on Patient Participation (*Patientenbeteiligungsverordnung*). The Ordinance mentions “relevant organisations responsible for representing the interest of patients and self-help groups of chronically ill and disabled persons at the federal level” and establishes criteria for their identification. Characteristics of relevant organisations are:

- To promote the interest of patients or self-help organisations
- To correspond to democratic principles in internal structure
- To exist and to be active nationwide for at least three years
- To work neutrally and independently and to deliver proof by disclosure of funding
- To pursue charitable purposes.\(^\text{91}\)

\(^\text{91}\) § 1 Ordinance on Patient Participation (*Patientenbeteiligungsverordnung* - *PatBeteiligungsV*).

§ 2 Ordinance on Patient Representation acknowledges as relevant organisations the German Disability Council, the Federal Association of Patient Centres and Initiatives (BAGP), the German Association of Self-Help Groups and the Federation of German Consumer Organisations. § 3 Ordinance on Patient Representation regulates the procedure for the recognition of other organisations.

§ 140f SGB V (Social Code, Book V) defines the areas in which relevant organisations are active:

- Federal Joint Committee (right to advise and to submit motions)
- in the advisory committee for the working party of data transparency according to § 303b SGB V (right to advise and to submit motions)
- in the state committees (§ 90 SGB V), in the accreditation committees (§ 96 SGB V) and in the appeal committees (§ 97 SGB V) (right to advise)

- in the modification, revision or repealing of framework conditions, recommendations and directives of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the medical aid directory as well as in the definition of reference price groups and determination of reference prices (§ 36 SGB V) (right to advise).

- Furthermore, relevant organisations are to be consulted in the course of the nomination process of members of the authorisation commissions of the BfArM.

As already illustrated in chapter 3.4.1, the relevant organisation have formed a coordination group at the G-BA, in order to coordinate the nomination of patient representatives in organisations at federal and state level. Information on its mode of operation and on its members is not yet publicly disclosed.

None of the relevant organisations is a full member of the European Patients' Forum92. This is due to a lack of resources and because of concerns with regard to the latter's independence. The Federation of German Consumer Organisations is a member of the European Consumers' Organisation (BEUC).

3.6.2 Australia: Consumer Health Forum

**CHF as a patient representative agent**

The Consumer Health Forum (CHF) is a mainly publically funded, independent non-profit umbrella organisation for citizen and patient interests in the Australian health care system. Founded in 1987, the CHF prepares statements on draft legislation as well as reform plans and is involved in general public relations.

CHF’s main responsibility is to nominate, support, train and coordinate patient representatives for national health committees (Consumer Representatives Program).93 Currently, there are approximately 200 citizen and patient representatives placed by the CHF.

Patient representatives cover, *inter alia*, the following topics:

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- Development or evaluation of health care reform or health care bills
- Assessment of new health technologies, medicines, treatment or health care services
- Recommendations on the admission of new methods of treatment or medicines in benefit catalogues of public health insurance funds
- Recommendation on education standards for qualified personal
- Advice of health care institutions

Specific examples of patient representatives are CHF-representatives in the PBAC and MSAC, where recommendations on the admission of new methods of treatment and medicines in the benefit catalogue are issued to the government (cf. chapter 3.3.6).

The placement of representatives is organised by the CHF. Interested institutions or bodies may liaise directly with the CHF. The latter is then in charge of formalities. Vacancies can be found on the website of CHF. Patient representatives, who are members of a patient organisation and have already gained experience as patient representative, may apply for available positions. All applicants must be endorsed by their patient organisation in order to be eligible. The decision to place an applicant is taken by the CHF.

3.6.3 France: Collectif Interassociatif Sur la Santé (CISS)

**CISS comprises more than 30 associations**

The Collectif Interassociatif Sur la Santé (CISS) was founded in 1996 in order to ensure user representation in the various health care bodies. The CISS is sponsored by the Ministry of Health. The annual budget is about € 2 m. Meanwhile, CISS comprises more than 30 associations.

CISS is ostensibly occupied with user information as well as training of patient representatives. CISS enables patients and

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96 [http://www.leciss.org/qui-sommes-nous/rapports-annuels](http://www.leciss.org/qui-sommes-nous/rapports-annuels)
users to give their opinion as part of “Discussions en cours” and “Appels à témoignage”.97 CISS is full member of the European Patients’ Forum (EPF).

Legal right to training and to take leave

As patient representatives of CISS are members of accredited patient organisations, the same law is applied to them as to all other patient representatives in France: employees are reimbursed for a loss of income (7,10 € per hour).

For the length of the representation duties, representatives are entitled to special leave (with a maximum period of 9 days per year). Upon presentation travel expenses are also reimbursed. The training of patient representatives is free of charge.98

As with all other patient representatives, patient representatives in CISS work on a voluntary basis. CISS is responsible for the training of all patient representatives in France. The current training programme calendar is found on the CISS website.99

Differentiated participation procedures and accreditation guarantee legitimacy

France has a license system for patient associations. Representatives and independent organisations may obtain a national or local licence. Only licensed organisations can represent users of the health care system in the committees of the health care institutions. Other (non-licensed) associations are however not excluded. They may also participate, but do not formally represent users in the committees. They can be appointed on a temporary basis in order to bring in their experience and their additional knowledge.100

The placement of patient representatives is carried out by the searching organisations: hospitals, for example, ask regional health administrations for suitable representatives, subsequently, the hospital may select a patient representative. Often, the choice is very limited. HAS also draws its patient representatives from the CISS.

100 Loi n° 2002-303 (März 2002), chapter 4: Involvement of users in the workings of the health system; http://www.sante.gouv.fr/l-agrement-des-associations-de-malades-et-d-usagers-du-systeme-de-sante.html.
Implementation problems

As in France patient representation is regulated by law at all levels, each organisation must involve patients in its working groups or departments. This has led to patient associations not being able to meet the demand. There are not yet enough patient representatives and especially not enough good patient representatives.

3.6.4 Netherlands: Niederlandse Patiënten Consumenten Federatie (NPCF)

Dutch government promoted the creation of an umbrella organisation

In the Netherlands, there is a variety of patient organisations, both disease-specific and non disease-specific (for example for the elderly). At the highest level, patient interests are represented by the Dutch Patient and Consumer Federation (NPCF). In principle, patient organisations are asked to represent patient interests in formal decision-making processes. According to Van de Bovenkamp et al., the Dutch health care system is considered to be neo-corporatist, applying the poldermodel (Dutch version of the principle of consensus). Thus, patient organisations are accepted as legitimate stakeholders and serve as third parties next to health care supplier and insurers. They also receive public financial support. Patient representatives are mostly nominated by the government, except for in the case of quality assurance. The nomination of patient representatives is not a statutory requirement.

The NPCF was founded in 1992. It incorporated hundreds of patient and consumer organisations via their national umbrella organisations. The federation has 24 direct member organisations, representing together more than 3 million people.

The NCPF’s establishment was promoted by the Dutch government as it was felt that the NCPF’s predecessor umbrella organisation did not represent all organised patient interests. In view of the potential influence and the actual participation by the diverse organised groups, the government endorsed a strong umbrella organisation. The NCPF was also founded against the background of an evaluation on effectiveness and cooperation

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102 The Quality Act stipulates the involvement of insurers and patient organisations.
possibilities. The government pushed to prevent overlapping between the different member organisations. Financial incentives encouraged cooperation and collaboration. The Dutch government benefits as patients speak with one common voice and thereby avoid the existence of multiple contact persons with unclear legitimacy. 103

The NPCF aims to represent the interests of its member associations by interacting with political actors at all levels. The NCPF is a full member in the European Patients’ Forum (EPF). It also provides relevant information for patient organisations and identifies the impact of government policy on patients.

To become a member an organisation must apply to the NPCF Board. All members must work from the patient’s perspective, be representative and work at national level with the main part of their work focussed on health. Organisations are expected to have multiple funding sources to ensure their independence.

A general assembly (Algemene ledenvergadering) is held four times a year. The general assembly elects the Board (bestuur) which consists of five members drawn from each of the strategic areas (chronically ill/physically disabled persons; mentally disabled persons; psychiatric patients; persons in need of nursing care; hospital and “front line”-patients). The Board meets six to seven times a year. There is also a council for the general managers of member organisations that meets monthly to discuss operational issues.

NPCF’s office has a staff of about 40 people. The NPCF has representatives on several national advisory bodies, such as the Healthcare Insurance Board (CVZ) and the Council for Public Health and Health Care. Furthermore, about 25 people from member organisations have currently been appointed to various national committees and councils. There are three financial sources: membership fees, grants from the Ministry of Health and grants from some foundations. 104

### 3.6.5 Schweden: Handikappförbunden (HSO)

The Swedish Disability Federation or Handikappförbunden (HSO) is a patient umbrella organisation representing common member interests before government, parliament and national authorities. It

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104 [www.npcf.nl](http://www.npcf.nl).
consists of 39 national disability organisations with about 500,000 individual members.

HSO is a member of the government’s disability council. Furthermore, HSO is member of some “governmental inquiry committees”. It receives their reports with the right to comment officially. HSO is involved with other patient organisations in the work of Socialstyrelsen (National Board of Health and Welfare, cf. chapter 3.4.6).

Five times a year the presidents of the member organisations meet to discuss important policy questions and organisational matters. One of the meetings constitutes the Annual General Assembly. The Board prepares the meetings and draft decisions of the Presidents’ Meetings and implements their decisions.

The Swedish Disability Federation is funded by membership fees, financial support from the state, income from information materials, conferences and legal consulting as well as project funding for employees with disabilities. In principle, an organisation is granted state support funds, if the following conditions are met:

- Pursuit of changes in social system for persons with illness
- Democratic structure
- Political and religious independence
- Nationwide organisation with local and regional branches in at least 10 regions
- In existence for at least two years
- At least 500 members.

105 http://www.hso.se/vi-ar-handikappforbunden/In-English/.
4 Good practice in patient and citizen participation

The relevant criteria for good patient and citizen participation were developed in chapter 1. In this chapter, these criteria are used to identify examples of good practice.

4.1 Evaluation based on the criteria

4.1.1 Legal obligation to involve patients and citizens

With regard to the legal obligation to involve patients and citizens, two indicators were particularly emphasized:

- The involvement of patients in the process of policy planning and of decision-making is legally binding.
- Patients are legally recognised as equal partners in the health care system.

Legal provisions exist in many examined countries. Only in two however does the statutory obligation to involve patients and/or citizens extend to all parts of the health service: France and Scotland. In the other countries, patient involvement is provided for in some areas, whereas in other areas it is not.

Furthermore, there is a legal recognition of patient representatives as equal partners in the French and Scottish health care systems. In France for instance, this is expressed by the recognition of patients as HAS experts. In the Netherlands, there also seems to be an equality of patient representatives with other actors, yet this derives from a consensual system.

4.1.2 Basic conditions

With regard to basic conditions, the following indicators were established:

- Patient organisations and their representatives are systematically qualified.
- Patient organisations have adequate resources at their disposal.
- Patient organisations and their representatives are in the position to participate.

Qualification programmes for patient representatives exist in many countries. Very consistent and systematic are however the EMA’s modular training courses, which see patient representatives more as advocates.

The level of resources varies greatly from country to country. In the interviews, the following point was emphasized very strongly: patient and citizen participation will have no significant effect without sufficient resources. Hence, the remuneration of patient representatives as well as the legal right to training and to take leave in France and at the EMA is of particular interest. In the Netherlands, the number of staff employed by the umbrella organisation points to a high degree of professionalization. Patient organisations’ activities are also ensured by public funding in Sweden.

Patient representatives need access to participation opportunities. The study presents examples of low-threshold information opportunities which inform patient groups on procedures. IQWiG’s InfoDienst is a good example of such an offer. NICE, which has more staff than IQWiG, actively pursues the involvement of patient groups. Both NICE, SIGN and HAS have developed participation strategies, have appointed contact persons and have elaborated support programmes for patient groups. Differentiated participation procedures ensure, that, in these countries, many patient groups (and individuals) have the opportunity to get involved. With regard to support programmes for patient groups, SMC’s personalised feedback in Scotland, giving tips on how to improve the structure of statements, stands out.

4.1.3 Transparency

According to chapter 1, transparency is to be judged on the following indicators:

- There is the greatest possible transparency concerning committee members.

- There is the greatest possible transparency with regard to agendas in committees.

- There is the greatest possible transparency concerning conflicts of interests.

In order for patient representatives to represent patients, they need to be responsive to patients and citizens and ensure that other
non-represented groups can follow what is being discussed. Transparency is therefore a key element of good patient and citizen participation.

Transparency with regard to names of patient representatives can be found in England, in Scotland, at the EMA, at the BfArM in Germany, in Australia and in France. Many agendas and minutes are published in France, in England, in Scotland and in Australia as well as by the BfArM. Thus, the public may follow who it is represented by and which issues are being dealt with. Online-consultations complement transparent procedures and also enable a broader participation of interested parties in decision-making processes. The Australian procedure, whereby all participation vacancies are advertised, increases transparency for patient groups and interested citizens.

In all organisations analysed, similar rules apply concerning the disclosure of potential conflicts of interests. Differences exist only with regard to their publication.

### 4.1.4 Legitimacy

The last criteria referred to legitimacy:

- Patient organisations are democratic bodies.
- Patient organisations and their representatives can be held accountable for their actions and decisions.

Each country specified criteria for the recognition of patient groups that require a democratic internal structure. France has solved the problem of legitimacy by an accreditation procedure. Hence there is a register of patient representatives. Patient groups obtain either a national or regional participation license. In England and Scotland, patient and citizen representatives are recruited by public tendering. Legitimacy is guaranteed through a transparent selection by health care organisations. In Australia, tendering is public and centrally organised by the patient umbrella organisation CHF. In the Netherlands and in the German BfArM, patient representatives are nominated by the government. Representatives are thus legitimated by parliamentary control over the ministries.
4.2 Ten building blocks of good practice

The examples of good participation practice refer to measures and instruments. Hence, they may be considered as building blocks of good patient and citizen participation. They can help to improve general conditions and increase the binding character, the transparency and ultimately the legitimacy of patient and citizen participation.

*Figure 6: Building blocks of good practice*

The report shows numerous examples for good practice in the countries analysed.

- **Legal obligation** to involve patient and citizens in all areas of the health care system. Examples can be found in France and in Scotland. Patient and citizen participation can cover the entire health care sector.

- **Transparent rules of procedure** allowing patients and citizens to follow the discussions. Openness about issues being discussed, for example at NICE and HAS, has enabled a broad discussion between patient groups and gives them the possibility to contribute their experiences.

- **Transparent participation opportunities**, so that patients and citizens know that they can get involved. The Australian
CHF, for instance, pools all participation possibilities and discloses them in one place.

- **Recruitment by public tendering**, as in England, Scotland and Australia, increases the quality of patient representatives and gives them a kind of “seal of approval”. Public tendering ensures professional decisions which everyone can follow.

- **A register of patient representatives**, as in France, can be established by an accreditation procedure. As in the case of public tendering only those are accredited who comply with certain criteria. Both public tendering and accreditation increase patient representatives’ legitimacy.

- **Actively addressing patient groups**, as practised by NICE in England, expands the knowledge base for decisions and avoids a loss of engagement.

- **Funding patient representatives**, in order to recognise their commitment and to stabilise participation. France and EMA are examples of a systematic remuneration. Sweden serves as an example of financing of patient groups.

- **Online-participation** has been established in numerous countries. This ensures a broad, low-threshold participation of all persons concerned as well as of those who have not passed accreditation and tendering obstacles.

- **Mandatory feedback**, as exercised by the SMC, helps to ensure a continuous improvement process of patient and citizen participation quality. Furthermore, a mandatory feedback on contributions in decision-making processes increases the acceptance and intention to get involved. It also establishes transparency about how patient contributions have been considered.

- **Advocacy-training** for patient representatives, as systematically implemented by EMA, ensures that patient representatives may actively perform their role as patient advocates. In addition to a focus on training system knowledge, it is important to train soft skills in order to pursue an effective representation of interests.

Düsseldorf, 30 September 2011