

**Exchanging knowledge on participation  
of health consumers and patients in  
research, quality and policy**



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## **This report is written for ZonMW**

The Netherlands Organisation for Health Research and Development

ZonMw funds health research and stimulates use of the knowledge developed to help improve health and healthcare.

ZonMw's main commissioning organisations are the Ministry of Health, Welfare and Sport and the Netherlands Organisation for Scientific Research.

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## Contents

|   |      |
|---|------|
| 1. Summary  | p 4  |
| 2. Inleiding, bevindingen, aanbevelingen                                      | p 8  |
| 3. Literature, interviewed stakeholders, people who have provided information | p 15 |

### Annex: Participation of health consumers and patients at EU level and in eight EU countries

|                    |      |
|--------------------|------|
| 1. EU              | p 19 |
| 2. Belgium         | p 28 |
| 3. France          | p 31 |
| 4. Germany         | p 36 |
| 5. The Netherlands | p 43 |
| 6. Poland          | p 50 |
| 7. Spain           | p 53 |
| 8. Sweden          | p 57 |
| 9. UK              | p 60 |
| 10. Denmark        | p 67 |

# 1. Summary:

## Introduction:

ZonMw, the Netherlands Organisation for Health Research and Development, funds health research and innovation and stimulates use of the knowledge developed to help improve health and healthcare in the Netherlands.

ZonMw's main commissioning organisations are the Ministry of Health, Welfare and Sport and the Netherlands Organisation for Scientific Research.

Strengthening the position of health consumers and patients and their organisations and stimulating participation in the health care system is one of the priorities in the work of ZonMw. In recent years, ZonMw took a considerable number of initiatives in this area.

ZonMw is interested in exchanging knowledge and experiences on this issue with organisations in other countries. ZonMw has asked Bob Keizer to do a short exploratory study to find out what the feasibility is of organising such an exchange of knowledge, possibly in the form of an (invitational) conference.

He has been asked to elaborate on his previous study on the position of HCPOs<sup>1</sup> in seven EU countries<sup>2</sup> (France, Germany, The Netherlands, Poland, Spain, Sweden, UK), by updating this study and by expanding this to the EU (European Commission) and Belgium

This feasibility study is done on basis of literature study, Web search, attending conferences and meetings, interviews, study visits, telephone interviews and e-mail correspondence.

On basis of this, the following questions can be answered:

1. What is the state of play regarding health consumers/ patients' participation in research, quality development and policy?
2. Which knowledge is available on this issue?
3. Is there a need for exchanging knowledge on this issue and how could this be organized?

## Findings:

### - State of play:

"Participation" is a very broad subject, covering many kinds of activities, connotations, expectations, aspects, etc. It was within the limited framework of this feasibility not possible to give a comprehensive overview. But the information as collected in the Annex is sufficient to get a general impression about the state of play

As regards this state of play: a lot is happening in the area of "participation". The impression is that both at national and at EU level participation in medicines research/innovation and quality (see the activities of Patient Partner<sup>3</sup>, Eurordis<sup>4</sup>, EPF<sup>5</sup>, etc) is further developed than participation in policy issues (with EMA<sup>6</sup> as a positive exception). However especially regarding this latter aspect of participation, there is a lack of (comparative) overviews and studies.

In many countries, as well as at the EU level, participation has been stimulated by developing programs, by funding activities, etc. but there are no overviews of these stimulating policies, neither of their results.

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<sup>1</sup> Health Consumer and Patients' Organizations, see also note 36 for definition issues

<sup>2</sup> Keizer, Bob and Bless, Ruud (2010), Pilot study on the position of health consumer and patients' organisations in seven EU countries. ZonMw

<sup>3</sup> A project of EGAN, the alliance of both national genetic alliances and European disease specific patient organisations, see Annex chapter 1

<sup>4</sup> European organization for rare diseases, see Annex chapter 1

<sup>5</sup> European Patient Forum, see Annex chapter 1

<sup>6</sup> European Medicines Agency, see Annex chapter 1

On basis of the interviews with stakeholders and collected information, some common issues can be identified:

- Participation can only be successful if patients'/consumer organizations are able to fulfill these tasks. This deserves a proper level of empowerment. Therefore, assessing patient's participation is difficult without assessing the empowerment of patient'/consumers organizations, and this knowledge is very often lacking.
- In many countries, especially regarding participation in policy, there is the issue of representation. Both at the national and at the EU level the repeating question is: who represents the consumer/patient? As regards the EU level, the EPF and some big categorical organizations are representing their interests. However, as a matter of fact, many national organizations are not capable of (or interested in) being active at international level (and this is certainly not encouraged by the national authorities, for instance by funding international activities of patients' organizations). As the importance of the development of health policy issues at EU level is growing, the question is relevant how to fill in the gap between national and international HCPOs.
- In connection to this issue, there is the discussion about the role of the pharmaceutical Industry. The pharmaceutical industry is a major contributor and stimulator in the area of patients' participation in medicines innovation and research. The impression is that the less national authorities are supporting their patients' organizations, the more these organizations are inclined to accept funding from the pharma industry. The opinions on this differ widely. Some are of the opinion that the pharma industry should refrain from funding HCPOs. However others, both in- and outside the patients' movement, see no problem in funding by this industry, as long as all parties adhere to the principles of transparency and respecting each other's responsibilities.
- A changing environment, changing roles: many respondents point at the growing importance of Internet and of the social media. Others notice changing roles of patients' organizations (like raising their own funds, in order to invest directly in medical research), and again others point at the changing health care systems (commercialization, growing influence of insurance companies, cuts in State budgets, etc. All of this has consequences for HCPOs and their participatory activities. Some suggest that it is time for a fundamental update of policy visions on the roles of HCPOs in participatory processes.
- More in general, many respondents had the feeling that the whole issue of patients' participation is still not taken seriously by all stakeholders. This could partly be blamed to doubts about the effects of participation. Some policy makers even suggest that participation only leads to generating more costs. One of the explanations for this could be that there is a knowledge gap between policy makers and the patients' organizations, and that too little information about good practices, positive results, etc. is conveyed to these and other stakeholders.
- This might also be the explanation for the observation that most governments adhere today to the principles of involvement of consumers/ patients, but this is very seldom translated into a coherent and comprehensive governments policy, aiming at stimulating this involvement.<sup>7</sup>

#### **- Which knowledge is available on this issue ?**

There is a lot of literature and other forms of knowledge available, mostly in the area of participation in research and quality. Less is known about participation in policy, about current policies to stimulate participation and their results, about the empowerment of the HCPOs, etc. And the available information is very often just descriptive and very seldom analyzing or evaluative. The general picture is that knowledge on participation is difficult to find, to overlook and to understand.

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<sup>7</sup> See : chapter Findings, Pilot study on the position of health consumer and patients' organisations in seven EU countries. ZonMw, Keizer, Bob and Bless, Ruud (2010), ZonMw

The available information is often collected for specific events or purposes, there is not a structural, continuous way of collecting comprehensive knowledge.

There are some experts operating in this field, but they are very often experts in their own working field, and even they lack overview regarding other working fields.

Much information and knowledge is shared between patients' organizations and the pharma industry in think tanks, but this is mostly on participation in medicines research/innovation, and other stakeholders like researchers and policy makers are not participating in these meetings.

The start with EUPATI<sup>8</sup> however looks very promising, and it can be expected that this organization will develop into an important and professional centre of knowledge and training on participation in therapeutic innovation. A point of discussion could be that this centre is partly funded by the pharmaceutical industry.

There are many others sources of information, like organizations comparable with ZonMw (INSERM, NICE, INVOLVE, KBS, FAS, ViBIS), patients' (supporting) organizations like le Ciss, NAKOS, PGO-support, HSO, UPD, Spanish Patients Forum<sup>9</sup>, etc, and furthermore universities, research organizations, etc.

However, there is hardly any systematic exchange of information between these actors.

### **Is there a need for exchanging knowledge on this issue and how could this be organized?**

According to almost all the interviewees there is definitely a need for more exchange of information regarding this issue. It is very likely that this could prevent many wheel being re-invented and that better collection, assessment and "translation" of the available knowledge can help bridging the gap between science, practice and policy.

Exchanging knowledge could focus on three priorities:

- creating overview: who is doing what, what kind of information and knowledge is collected where, who is investing in research, etc?
- creating insights into specific issues: how to stimulate participation, how to measure results, how to empower the patients' movement, etc?
- stimulating communication, co-operation and collaboration: exploring ways to exchange knowledge, to identify gaps in knowledge, to divide working areas, to work together in projects, to apply together for EU funding, influencing the EU research agenda, etc.

### **Recommendations**

It is recommended that ZonMw takes initiatives aiming at the improvement of exchange of knowledge on this issue. However, this subject is rather comprehensive and complicated, and investing in this deserves time, energy, patience and a (modest) budget. Before further proceeding on this, ZonMw has to take a go/no go decision.

If this decision is positive, it is recommended that ZonMw invites a small group of foreign experts and stakeholders, at the occasion of the mid-term presentation (or the closure) of the ZonMw program "Patients' participation in research, quality and policy"<sup>10</sup> (fall 2012)

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<sup>8</sup> European Patients' Academy on Therapeutic Innovation, see Annex chapter 1

<sup>9</sup> INSERM: French research institute, see Annex chapter 3

NICE: The UK National Institute for Health and Clinical Excellence, see Annex chapter 9

INVOLVE: this organization supports active public involvement in the National Health Service, UK. See Annex chapter 9

KBS: Koning Boudewijn Stichting, Belgium. See Annex chapter 2

FAS: Swedish Council for Working Life and Social Research, see Annex chapter 8

ViBIS: national knowledge centre of user involvement, Denmark, see Annex chapter 10

Le Ciss: French Umbrella organization of HCPOs, see Annex chapter 3,

NAKOS: National Contact and Information Service for self help groups, Germany. See Annex chapter 4

PGO-support, support organization, The Netherlands, see Annex chapter 5

HSO: Swedish Disability Federation, see Annex chapter 8

UPD: Unabhängige Patientenberatung Deutschland, supporting organisation, zie Annex chapter 4.

Spanish Patients Forum: umbrella organization for HCPOs, see Annex chapter 7

<sup>10</sup> See Annex chapter 5: The Netherlands

This conference could be split into two parts; at the first day (afternoon/evening) a plenary meeting could be organized (open to the Dutch researchers involved in the projects and to those who are otherwise interested in this subject) where a selection of the completed ZonMw projects can be presented, and where the invited foreign experts can have the opportunity to present briefly the state of play in their countries regarding (research on) patients' participation. This part of the conference could end in a plenary discussion about obstacles and challenges in stimulating patients' participation (and last but not least in an opportunity for informal networking and discussions).

The next day (morning) could be dedicated to an invitational meeting between the invited foreign experts and a selection of Dutch stakeholders, to discuss the findings of this feasibility study and the possibilities on exchanging knowledge, co-operation, etc. as described above.

It is important to take time to prepare this meeting, by exploring more in depth who else might be interested in exchange of knowledge, by finding out what will happen in the framework of EUPATI, EATRIS<sup>11</sup>, etc, which other conferences and important events are scheduled (see for instance the initiative of le Ciss<sup>12</sup>). On basis of this a discussion paper could be drafted and sent to those who are invited.

Those who have reflected positively can have the opportunity to give their own input (comments, suggestions, proposals, etc) on the possibilities of knowledge exchange in this discussion paper. This approach could create the necessary level of support and would probably lead to the most effective way of exchanging knowledge in the future.

BK 10 April 2012

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<sup>11</sup> The European Advanced Translational Research Infrastructure in Medicine, see Annex chapter 1

<sup>12</sup> Currently, the Ciss is considering to organize an international conference in fall 2013, aiming at increasing the awareness of patients' organisations in the different EU Member States of their role in implementing the EU Directive on cross-border health care. See Annex chapter 3: France



## 2. Inleiding, bevindingen, aanbevelingen

### 2.1. Inleiding

Binnen ZonMw geldt participatie in beleid, onderzoek en kwaliteit als speerpunt. In het verlengde hiervan wil ZonMw op internationaal gebied haar kennis en ervaring uitwisselen met andere (internationale) organisaties die op dit terrein actief zijn.

Aan Bob Keizer is gevraagd te onderzoeken of er belangstelling is voor een dergelijke internationale kennisuitwisseling, met als doel te verkennen wat mogelijke aandachtspunten zouden kunnen zijn en welke mogelijkheden er zijn om tot een netwerk te komen. Daarbij is aan hem gevraagd voort te bouwen op zijn eerdere rapport 'Pilot Study on the position of health consumers and patients' organisations in seven EU countries" (Bob Keizer en Ruud Bless, ZonMw, 2010).

In het hierna volgende wordt verslag gedaan van deze verkenning, die uit de volgende bouwstenen heeft bestaan:

- Het uitbouwen en actualiseren van kennis die in bovengenoemde Pilot Study is verzameld (de stand van zaken m.b.t. de patiëntenbeweging, onderzoek, monitoring, participatie, overheidsbeleid, etc., in Frankrijk, Duitsland, Nederland, Polen, Spanje, Zweden en het VK).
- Additioneel is soortgelijke informatie verzameld wat betreft de EU en België

Deze kennis is geactualiseerd, c.q. verzameld door middel van literatuuronderzoek, Web search en gesprekken/correspondentie met een dertigtal sleutelfiguren die in betrokken landen, c.q. op Europees niveau werkzaam zijn (zie bijlage). In deze gesprekken/correspondentie is expliciet gevraagd naar de belangstelling voor internationale kennisuitwisseling.

Voorts is in het kader van deze verkenning een aantal conferenties/bijeenkomsten bijgewoond:

- The Meeting, Optimal Role of patients' Organizations in drug development, 24 maart 2011, Amsterdam
- Health Activism in Europe Today, 14-16 september, Lancaster
- ZonMw studiemiddag Patiëntenparticipatie in Wetenschappelijk Onderzoek, 22 september 2011, Den Haag
- Studiebijeenkomst Koning Boudewijn Stichting, 29 september 2011, Brussel
- EGAN-Roche workshop, 12-13 januari 2012, Basel

Op grond hiervan kunnen de volgende vragen beantwoord worden;

- wat is de stand van zaken in betrokken landen, c.q. op EU niveau wat betreft participatie ?
- welke kennis is daarover beschikbaar en in welke vorm(en)?
- is er behoefte aan internationale kennisuitwisseling? En hoe kan zo iets georganiseerd worden?

## 2.2. Bevindingen:

### a. Wat is de stand van zaken in betrokken landen, c.q. op EU niveau wat betreft patiëntenparticipatie?

- Het begrip participatie is erg breed: zowel participatie in beleid als participatie in onderzoek/kwaliteitsontwikkeling omvatten een groot aantal activiteiten en aspecten. Participatie blijkt ieder keer weer maatwerk te zijn, en in belangrijke mate afhankelijk te zijn van de structuur en cultuur van de gezondheidszorg in het betreffende land. In de onderzochte landen wordt participatie op allerlei verschillende manieren opgevat en vorm gegeven.

Er zijn verschillende opvattingen en connotaties inzake het doel en de functie van participatie (zo wordt bijv. in het VK een onderscheid gemaakt tussen "participation", "involvement" en "engagement"). Dan is er het onderscheid tussen de "consumenten-invalshoek" en de "patienten-invalshoek", etc.

Het was in het kader van deze beperkte verkenning dan ook niet mogelijk een goed en volledig overzicht van de stand van zaken te geven. Om een echt goed overzicht te krijgen is uitgebreid onderzoek nodig.

Bijgaande Annex geeft echter wel volgens de geraadpleegde deskundigen een redelijk algemeen inzicht in de stand van zaken, in ieder geval genoeg om de hoofdvraag te beantwoorden: "is er behoefte aan kennisuitwisseling?"

- Er gebeurt veel. Zoals uit bijgevoegd overzicht blijkt gebeurt er zowel op EU niveau als in de verschillende landen van alles op het terrein van patiëntenparticipatie. Dat betreft dan vooral participatie in onderzoek en kwaliteit. In de onderzochte landen zijn allerlei activiteiten gaande, vaak in kleinschalige vorm (wat het moeilijk maakt dit in kaart te brengen). In toenemende mate zijn (met name de grotere) patiëntenorganisaties rechtstreeks betrokken bij participatie in clinical trials en andere vormen van medicijnontwikkeling en innovatie. Vooral op EU niveau is wat dat betreft de laatste jaren grote vooruitgang geboekt, zie de activiteiten van Patient Partner<sup>13</sup>, van EURORDIS<sup>14</sup>, etc. Deze vooruitgang is niet vanzelf gegaan, ze is in belangrijke mate door initiatieven van de patiëntenorganisaties zelf bereikt en gesteund en gestimuleerd door EU subsidies en later door de farmaceutische industrie.

- Participatie in beleid heeft zich goed ontwikkeld bij een organisatie als EMA<sup>15</sup>, maar het algemene beeld is dat dit aspect van participatie tot nu toe minder goed tot ontplooiing is gekomen dan participatie in onderzoek en kwaliteit; ook dit geldt voor de onderzochte landen als voor de EU. Ook hier doen zich allerlei verschillende modaliteiten voor: strak gereguleerde en afgeschermd participatievormen in Duitsland versus vrijwel geen beleidsparticipatie in Polen, met alle modaliteiten daartussen. Goede (vergelijkende) overzichten ontbreken echter.

- Er zijn verschillende visies op participatie en er zijn verschillende vormen van stimuleringsbeleid: In sommige landen hebben de overheden (Fr) of daartoe geëigende organisaties (bijv. de National Health Service in het VK) een expliciete visie op patiëntenparticipatie geformuleerd, of gerichte stimuleringsprogramma's ontwikkeld (FR, VK, Ned, België). Ook de Europese Commissie heeft op onderdelen geïnvesteerd in participatie en heeft daarmee het nodige bereikt. Vergelijkende overzichten en analyses hiervan bestaan echter niet en evenmin is duidelijk tot welke resultaten dit geleid heeft (zie hierna).

- Uit de gesprekken met sleutelfiguren bleek niet alleen een grote verscheidenheid in activiteiten, maar ook een aantal gemeenschappelijke aandachtspunten die zich bijna overal voordoen:

- De relatie met de empowerment van de patiëntenbeweging: participatie vraagt een patiëntenbeweging die daartoe goed is uitgerust, zowel materieel als qua kennispositie. In veel landen kampen de patiëntenorganisaties met structurele problemen (financiering, menskracht, kennis, etc.) die goede participatie in de weg staan. Dat is niet alleen te wijten aan het gebrek aan overheidsstimulering, maar ook vaak aan de verscheidenheid binnen de

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<sup>13</sup> Een project van EGAN, the alliance of both national genetic alliances and European disease specific patient organisations, zie Annex chapter 1

<sup>14</sup> European organization for rare diseases, zie Annex chapter 1

<sup>15</sup> European Medicines Agency . zie Annex chapter 1

patiëntenbeweging zelf. Het stimuleren van patiëntenparticipatie kan daarom niet los gezien worden van het bestuderen van de empowerment en organisatievormen van de patiëntenbeweging; probleem is echter dat we daar weinig over weten<sup>16</sup>

- De representatievraag (met name bij participatie in beleid). Kernvraag is: wie vertegenwoordigt de patiënt/consument nu eigenlijk? Die vraag speelt zowel op nationaal niveau als ook op EU niveau. Het is een feit dat vrijwel in ieder land de patiëntenbeweging intrinsiek verdeeld is, vgl. het VK waar 14 organisaties op het terrein van borstkanker bestaan; hetzelfde geldt wat betreft de koepels/platforms (bijv. in Nederland). In Duitsland is getracht participatie via wetgeving te regelen, hetgeen ook weer de nodige weerstand oproept (zie ook hierna). Ook wat betreft de beleidsparticipatie op EU niveau speelt dit punt. Vertegenwoordiging van patiënten binnen EU-gremia vindt plaats door het EPF<sup>17</sup> en een aantal grote categoriale internationale organisaties. Zoals eerder is geconstateerd<sup>18</sup> ontbreekt vaak de verbinding tussen nationale (koepel) organisaties en het Europese niveau. Er is echter op nationaal niveau bij patiëntenorganisaties vaak erg weinig belangstelling voor het internationale werk (of de capaciteit ontbreekt om daarin te investeren), behalve dan bij de grote categoriale organisaties (of juist bij de zeldzame aandoeningen, die vanwege die zeldzaamheid een noodzaak hebben om internationaal samen te werken). Zeker gelet op het toenemende belang van EU-beleid voor de nationale gezondheidszorgsystemen, kan de vraag gesteld worden of de nationale patiëntenorganisaties in voldoende mate bij EU beleidsvorming (kunnen) participeren.
- Met het voorgaande samenhangend speelt in veel landen een discussie over de rol van de farmaceutische Industrie ten opzichte van patiëntenorganisaties: in veel landen, en ook op EU niveau worden deze organisaties in niet geringe mate door de farmaceutische industrie gefinancierd. Dat geldt met name het verlenen van subsidies voor deelname aan onderzoeken, het organiseren van bijeenkomsten, deelname aan internationale activiteiten, etc. De mate waarin patiëntenorganisaties geld accepteren van de farmaceutische industrie lijkt omgekeerd evenredig te zijn aan de mate waarin overheden financiële steun verlenen aan patiëntenorganisaties. Deze organisaties geven vaak aan dat ze in feite weinig keus hebben. Toch kan dit vragen oproepen rond de onpartijdigheid en representatie van de patiëntenorganisaties in het participatie-proces, zowel participatie in beleid als in onderzoek en kwaliteitsontwikkeling. In een aantal landen heft dit geleid tot een hooglopend conflict, zoals bijv in Duitsland, waar het volgens zegslieden “oorlog” is tussen de Farma industrie en de koepels van patiëntenorganisaties<sup>19 20</sup>. Ook in Nederland speelt dit punt; om deze reden is het NPCF uit het EPF gestapt<sup>21</sup>. De meningen hierover zijn, zowel binnen de patiëntenbeweging als in de politiek verdeeld. Sommigen zijn radicaal tegen, anderen (ook binnen de patiëntenbeweging zelf) zien juist geen been in (mede) financiering door de farma-industrie, zeker niet als overheden geen of onvoldoende financiële steun verlenen.
- Opvallend was dat veel betrokkenen signaleren dat de “traditionele” rollen van de patiëntenbeweging aan het veranderen zijn. Zo hebben Internet en de sociale media steeds meer invloed op de kennispositie van patiënten/consumenten waardoor deze zelfstandiger worden en de behoefte om lid te worden van een patiëntenorganisatie afneemt. Een andere tendens is dat steeds meer patiëntenorganisaties zich rechtstreeks richten op fundraising ten behoeve van onderzoek (zie o.a. de publicaties van Cees Smit). Ook vinden veel gesprekspartners dat veranderingen in de nationale gezondheidsstelsels (bezuinigingen<sup>22</sup>,

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<sup>16</sup> Zie Pilot study 2011 on the position of HCPOs in seven Eu countries (2010), ZonMw

<sup>17</sup> European Patient Forum, see Annex chapter 1

<sup>18</sup> Zie rapport Internationaal pgo-beleid (2009), ZonMw

<sup>19</sup> Zie het Prognos-rapport en

[http://www.bundestag.de/bundestag/ausschuesse17/a14/anhoerungen/Archiv/m\\_Versorgungsstrukturgesetz/Stellungnahmen/Ae17\\_14\\_0188\\_69\\_Dierks\\_Prof\\_Dr\\_Dr\\_Christian.pdf](http://www.bundestag.de/bundestag/ausschuesse17/a14/anhoerungen/Archiv/m_Versorgungsstrukturgesetz/Stellungnahmen/Ae17_14_0188_69_Dierks_Prof_Dr_Dr_Christian.pdf)

<sup>20</sup> De farma industrie is van mening dat iedereen in het G-BA moet kunnen participeren, niet alleen de in de wet vastgelegde reguliere koepels, zie hoofdstuk Germany. Zegslieden geven overigens aan dat de koepels weliswaar strijd voeren met de farma industrie, maar dat veel leden van die koepels tegelijkertijd wel gefinancierd worden door diezelfde farma industrie.

<sup>21</sup> Trouw 13-7-11, zie ook de recente commotie nav een publicatie in NRC 27-11-2011 over het financieren door de farma industrie van patiëntenorganisaties

<sup>22</sup> Zie bijvoorbeeld: [http://blogs.bmj.com/bmj/2011/12/30/albert-jovell-challenges-for-the-spanish-healthcare-system/?utm\\_source=feedburner&utm\\_medium=feed&utm\\_campaign=Feed%3A+bmj%2Fblogs+%28Latest+BMJ+blogs%29&a=w\\_blogs\\_bmj-com](http://blogs.bmj.com/bmj/2011/12/30/albert-jovell-challenges-for-the-spanish-healthcare-system/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+bmj%2Fblogs+%28Latest+BMJ+blogs%29&a=w_blogs_bmj-com)

commercialisering, grotere rol voor verzekeraars<sup>23</sup>, etc.) consequenties hebben voor de rol van patiëntenorganisaties en de functie van het hele fenomeen van “participatie”. Betrokkenen signaleren dat er te weinig dynamiek zit in de discussie en beleidsvorming over dit soort zaken.

- Met voorgaande punten hangt samen dat veel sleutelfiguren aangeven dat er met name bij beleidsmakers en andere betrokkenen vragen bestaan over het nut van patiëntenparticipatie. Zoals ook hierna zal blijken, is er eigenlijk heel weinig evidence dat patiëntenparticipatie een meerwaarde of andere voordelen oplevert. In sommige landen wordt expliciet door beleidsmakers gesuggereerd dat patiëntenparticipatie alleen maar kostenopdrijvend werkt, hetgeen kan verklaren dat het aantal stimuleringsmaatregelen beperkt blijft. Veelgehoorde opmerking is: “het blijft bij fraaie woorden”<sup>24</sup>. Een probleem dat hier meespeelt is dat de benodigde kennis hierover vaak ontbreekt of moeilijk toegankelijk is (zie hierna), zodat de discussie hierover moeilijk te voeren is (of zelfs vermeden wordt), dan wel vaak neerkomt op een strijd tussen “gelovigen” en “sceptici”.  
Meer in algemene zin zijn veel gesprekspartners van mening dat een onderliggend probleem is dat de verbinding tussen wetenschap, praktijk en beleid hier tekort schiet. Wetenschappelijke publicaties zijn vaak erg “academisch” en bieden te weinig concrete aanknopingspunten, iets dat met name de patiëntenorganisaties nodig hebben. Patiëntenorganisaties zelf kampen met allerlei capaciteits- en kwaliteitsproblemen en kunnen daardoor hun behoeften en problemen niet altijd goed over het voetlicht brengen, en mede hierdoor zijn beleidsmakers en politici niet goed op de hoogte van de problematiek (en van de goede zaken die juist wel dankzij participatie bereikt zijn!). En dit kan weer verklaren waarom er vrijwel nergens door overheden een lange termijn visie en – beleid ontwikkeld wordt op dit terrein<sup>25</sup>.  
Gelet echter op de toenemende belangstelling van de zijde van de farmaceutische industrie om te investeren in vormen van patiëntenparticipatie, lijkt het er op dat men daar wél inziet tot welke voordelen goede patiëntenparticipatie kan leiden.

## **b. Welke kennis is over patiëntenparticipatie beschikbaar en in welke vorm(en)?**

- Zoals hiervoor is aangegeven gebeurt er veel, en er zijn in een aantal gevallen overzichten, literatuur, etc. beschikbaar. De informatie betreft vaak een deelgebied, is meestal eenmalig verzameld/ geanalyseerd en bestemd voor een specifiek doel, er is geen sprake van continuïteit. Veel kennis berust bij een beperkt aantal deskundigen, die allemaal druk zijn op hun eigen terrein, en ook vaak zelf niet weten wat elders gebeurt.
- Mede daarom is de informatie moeilijk te vinden door “outsiders”. Het overzicht over het geheel van beschikbare kennis ontbreekt. Dat is vaak het geval op nationaal niveau, maar zeker op internationaal niveau. Daardoor wordt te weinig gebruik gemaakt van de ervaringen die elders zijn opgedaan.
- Veel informatie wordt uitgewisseld in een aantal denktanks (EFPIA, EPPOSI, EGAN-Roche<sup>26</sup>), met name de vertegenwoordigers van patiëntenorganisaties en van de farmaceutische industrie komen daar bijeen, en bespreken allerlei ontwikkelingen en ervaringen, maar in deze denktanks participeren weer weinig onderzoekers en beleidsmensen.
- Het merendeel van de beschikbare informatie betreft kennis inzake participatie in medisch onderzoek, met name clinical trials; zie Patient Partner, Eurordis, EPF. De plannen voor EUPATI<sup>27</sup> geven aan dat met betrekking tot dit onderwerp een groot informatiecentrum opgezet gaat worden (budget: 10 mln. euro voor vijf jaar), waardoor de verwachting gerechtvaardigd is dat internationale

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<sup>23</sup> Zo is er veel belangstelling voor de projecten die in NL in het kader van Zekere Zorg gehouden zijn.

<sup>24</sup> Zelfs in Fr en het VK werden dit soort opmerkingen vaak gehoord.

<sup>25</sup> Zie Findings in de Pilot Study Zie Pilot study 2011 on the position of HCPOs in seven Eu countries (2010), ZonMw

<sup>26</sup> EFPIA: European Federation of Pharmaceutical Industries and Associations; Epposi is een onafhankelijke, niet commerciële multi-stakeholder think tank in Brussel; EGAN-Roche workshop: een jaarlijkse bijeenkomst in Basel, waar informatie wordt gedeeld en discussies worden gehouden tussen Roche and patiënten organisaties. Zie Annex chapter 1.

<sup>27</sup> European Patients' Academy on Therapeutic Innovation, zie Annex chapter 1

kennisverzameling en -distributie inzake participatie bij medicijnontwikkeling de komende jaren verder op professionele wijze uitgebouwd gaat worden. Echter ook hier speelt dat dit informatiecentrum voor de helft door de farmaceutische industrie gefinancierd wordt, hetgeen bij sommigen principiële bezwaren kan oproepen.

- Er zijn daarentegen weinig overzichten bekend van patiëntenparticipatie in beleid en participatie in kwaliteitsontwikkeling. Ook wat betreft andere onderdelen zoals overzicht van overheidsbeleid t.a.v. patiëntenorganisaties, stimuleringsprogramma's, de empowerment van de patiëntenbeweging, etc. ontbreekt het overzicht.

- Voor het merendeel van de beschikbare informatie geldt dat die vrijwel altijd beschrijvend is en in veel mindere mate analyserend/evaluerend, en dus geen antwoord geeft op bovengenoemde vragen inzake het nut of meerwaarde van participatie en de resultaten van het gevoerde beleid.

- Er is een beperkt aantal organisaties actief die verantwoordelijk zijn voor het bevorderen van participatie (op onderdelen of in "brede zin") en daarover kennis in huis hebben: organisaties als ZonMw, INSERM, NICE, INVOLVE, KBS, ViBIS, FAS<sup>28</sup>. Voorts is kennis voorhanden bij patiëntenorganisaties of organisaties die aan de patiëntenbeweging gelieerd zijn, zoals le Ciss, NAKOS, PGO-support, HSO, Spanish Patients Forum<sup>29</sup>; voorts bij (universitaire) onderzoeksgroepen, etc. Er wordt echter heel weinig kennis tussen deze actoren uitgewisseld, zeker niet internationaal.

- Verder zijn op Europees niveau een tweetal organisaties actief in gegevensverzameling: Patient View (werkt op commerciële basis), en Health Consumer Powerhouse (die vergelijkende informatie inzake de rechten van individuele patiënten/consumenten in gezondheidszorgsystemen verzamelt)<sup>30</sup>. Geen van beide voorziet in overzichtsinformatie op het terrein van patiëntenparticipatie.

- Samenvattend kan gesteld worden dat er wel veel gebeurt en dat daarover de nodige informatie en kennis beschikbaar is, maar dan wel op onderdelen, of op "kenniseilandjes", en dan bovendien vaak moeilijk toegankelijk voor buitenstaanders. Het algemene overzicht ontbreekt en kennisuitwisseling is er heel weinig. De gevolgen hiervan zijn dat veel kennis, good practices, samenwerkingsmogelijkheden verloren gaan en waarschijnlijk vele wielen regelmatig worden heruitgevonden. Bovendien lijkt de observatie gerechtvaardigd dat er inderdaad te weinig communicatie en interactie is tussen wetenschap, praktijk en beleid.

### **c. Is er belangstelling voor het internationaal uitwisselen van kennis?**

- Belangstelling?

Uit de gevoerde gesprekken/ correspondentie blijkt duidelijk dat er een grote behoefte is aan verbetering van kennisuitwisseling. Dat geldt in mindere mate voor diegenen die betrokken zijn bij participatie in klinisch onderzoek en medische innovatie (want daar vindt al veel kennisuitwisseling plaats), maar ook daar heeft men behoefte aan overzicht en kennisuitwisseling ter zake van andere aspecten (bijv. de empowerment van de patiëntenbeweging, overheidsbeleid, good practices, etc).

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<sup>28</sup> en

<sup>29</sup> : INSERM: Frans onderzoeksinstituut, zie Annex chapter 3

NICE: het UK National Institute for Health and Clinical Excellence, zie Annex chapter 9

INVOLVE: deze organisatie stimuleert publieksparticipatie in de National Health Service, UK. zie Annex chapter 9

KBS: Koning Boudewijn Stichting, België. zie Annex chapter 2

FAS: Swedish Council for Working Life and Social Research, zie Annex chapter 8

ViBIS: National knowledge centre of user involvement, Denemarken, zie Annex chapter 10

Le Ciss: Franse koepelorganisatie van HCPOs, zie Annex chapter 3,

NAKOS: National Contact and Information Service for self help groups, Duitsland. zie Annex chapter 4

PGO-support, steunorganisatie voor HCPOs, Nederland, zie Annex chapter 5

HSO: Swedish Disability Federation, zie Annex chapter 8

Spanish Patients Forum, Spaanse Koepelorganisatie, zie Annex chapter 7

<sup>30</sup> Zie Annex chapter 1

- Waarom?

Deze brede belangstelling is verklaarbaar omdat vrijwel iedereen kampt met bovengenoemde onoverzichtelijkheid en van mening is dat kennisuitwisseling kan bijdragen aan de doelmatigheid van het participatiebeleid, dan wel kan bijdragen aan het overbruggen van de kloof tussen wetenschap, praktijk en beleid zoals hierboven is geschetst.

- Welke kennis?

De eerste kennisbehoefte betreft overzicht: wie doet wat op het terrein van participatie in beleid, onderzoek, kwaliteit? Zijn er overzichten, analyses, databanken, etc. beschikbaar?

Daarnaast is behoefte aan het uitwisselen van meer specifieke informatie: hoe wordt participatie vorm gegeven, hoe gestimuleerd (zijn er bijvoorbeeld in andere landen projecten zoals thans door ZonMw zijn uitgezet?), hoe worden die geëvalueerd, bestaat er zoiets als een (overheids)beleid, wat is de rol van patiëntenorganisaties daarbij, etc.?

De derde behoefte waarin voorzien zou kunnen worden is het verkennen van vormen van structurele kennisuitwisseling, en samenwerkingsmogelijkheden zoals het ontwikkelen van een gezamenlijke onderzoeksagenda, of het gezamenlijk aanvragen van subsidies (richting EU) .

- Kennisuitwisseling: met wie?

Vanuit de positie van ZonMw bezien ligt het voor de hand kennisuitwisseling te entameren met organisaties die vergelijkbare taken vervullen als ZonMw, zoals NICE, Involve, HAS, INSERM, KBS, FAS, ViBIS (Denemarken), met vertegenwoordigers of ondersteuners van patiëntenorganisaties (Le Ciss, UPD, HSO, Spanish Patients' Forum<sup>31</sup>, etc , en met buitenlandse onderzoekscentra die actief zijn op dit terrein (bijv Paris Mines-Tech, Joseph Laporte Foundation , Patiënten universiteit Hannover, etc<sup>32</sup> ). Ook is het van belang contact te zoeken met organisaties als EPF en EUPATI, teneinde de wederzijdse initiatieven goed af te stemmen.

Hierbij moet wel bedacht worden dat slechts in een beperkt aantal landen gekeken is naar de behoefte aan kennisuitwisseling, het is goed mogelijk dat ook in andere landen deze behoefte bestaat (Italië, Oostenrijk, Noorwegen, Ierland, etc.)

### 2.3. Aanbeveling

Deze beperkte voorstudie heeft slechts ten doel gehad de belangstelling voor en de mogelijkheden van internationale kennisuitwisseling in kaart te brengen. Die belangstelling blijkt er te zijn en de mogelijkheden daartoe zijn er ook. Er is echter ook gebleken dat het een lastig terrein is en dat het leggen van contacten, uitzoekwerk, etc. erg arbeidsintensief is. Daarom is het belangrijk dat ZonMw ten principale besluit of men inderdaad verder wil met deze kennisuitwisseling en bereid is daarin te investeren (go/no go)

Het is niet verstandig direct te denken in termen van een "netwerk", maar te beginnen met het beleggen van een eenmalige bijeenkomst met beperkt aantal (ca 10) buitenlandse stakeholders<sup>33</sup>, om te bespreken of men bovenstaande observaties deelt en bereid is samen na te denken over de meest doelmatige manier van kennisuitwisseling.

Om de kennisuitwisseling direct gestalte te geven, kan overwogen worden een dergelijke bijeenkomst te combineren met een van de bijeenkomsten die ZonMw regelmatig organiseert van personen die in Nederland bij lopende ZonMw projecten betrokken zijn (of wellicht ter afsluiting van het lopende programma "Participatie") . Daar kunnen dan een aantal van de lopende projecten kort toegelicht worden en aan de uit te nodigen buitenlandse personen kan gevraagd worden korte presentaties te

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<sup>31</sup> Zie noot 28 en 29, HAS: Haute Autorité de Santé, Frankrijk, zie Annex Chapter 3, UPD: Unabhängige Patientenberatung Deutschland, steun organisatie , zie Annex chapter 4.

<sup>32</sup> Paris Mines-Tech, Frans onderzoeksinstituut, zie Annex chapter 3; Joseph Laporte Foundation: Spaanse onderzoeksinstelling, Annex chapter 7; Patiënten universiteit Hannover : geeft grootschalig cursussen aan patiënten/consumenten , zie Annex chapter 4

<sup>33</sup> Het is daarbij belangrijk personen uit te nodigen die kennis van zaken hebben én enthousiast zijn!

geven inzake de stand van zaken in hun land en deel te nemen aan een plenaire discussie over succes- en faalfactoren van het fenomeen participatie. De dag (middag/avond?) kan afgesloten worden met een gelegenheid om informeel contacten te leggen (vgl. het concept van de "Rode Hoed" bijeenkomst).

Het tweede deel van deze internationale bijeenkomst kan (bijv. de volgende ochtend) besteed worden aan een (besloten) discussie over de mogelijkheden om internationale kennisuitwisseling concreet gestalte te geven.

Het is belangrijk dat deze bijeenkomst goed wordt voorbereid en dat de uit te nodigen personen weten wat de bedoeling is en zich inhoudelijk bij de voorbereiding betrokken voelen. Daartoe is nog het nodige verdere zoekwerk nodig (wie zouden er nog meer geïnteresseerd kunnen zijn?, wat gaat er bijvoorbeeld in het kader van EUPATI en EATRIS<sup>34</sup> gebeuren, welke congressen, bijeenkomsten, e.d. staan er op stapel<sup>35</sup>, etc.?) en is het belangrijk dat er een goede Engelstalige gespreksnotitie wordt opgesteld waarin e.e.a. wordt toegelicht, waarbij betrokkenen de gelegenheid moeten krijgen hun eigen ideeën in te kunnen brengen. De indruk moet vermeden worden dat het hier om de zoveelste bijeenkomst op dit terrein gaat, dan wel dat ZonMw het allemaal zelf wil bepalen.

BK 10 april 2012

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<sup>34</sup> The European Advanced Translational Research Infrastructure in Medicine, zie Annex chapter 1

<sup>35</sup> Voorbeeld: Le Ciss is bezig met een subsidieaanvraag bij DG SANCO om volgend jaar een conferentie over informatievoorziening door patiëntenorganisaties inzake cross-border health care te kunnen organiseren, met als expliciete bedoeling dit uit te willen bouwen tot verbeterde (internationale) samenwerking tussen patiëntenorganisaties wat betreft informatievoorziening aan het publiek en de eigen achterban.

### 3. Literature, interviewed stakeholders, people who have provided information

- Abma, Tineke, Broerse, Jaqueline (2007): Zeggenschap in Wetenschap. Lemma.
- Abma, Tineke, Broerse, Jaqueline (2010) Patient participation as dialogue: setting research agendas, Health Expectations, 13, pp 160-173
- Advisory Council on Health Research (2007): Patient participation in health research. Publ. No 56.
- Advisory Council on Health Research (2007): Translational research in The Netherlands. Publ. No 55.
- Blume , Daniel (2001): Engaging citizens in the Danish health care sector, Citizens as partners, OECD
- Bovenkamp , H vd. e.a. (2008), Inventarisatie patiëntenparticipatie in onderzoek, IBMG, Rotterdam 2008
- Bovenkamp, Hester vd (2010): The limits of patient power, Examining active citizenship in Dutch health care, Dissertation Erasmus University Rotterdam
- CG-Raad, LPGGz, NPCF, Platvorm VG (2010), Patiënten- en consumentenbeweging in beeld Brancherapport 2010
- EGAN-Roche Workshop (12-13 Febr. 2012): Data sharing & therapy development: possibilities and pitfalls.
- EMA (2011): Fourth report on the progress of the interaction with patients' and consumers' organisations.
- EPF (2009) , The Value of Patient Involvement in EU Health Related Projects and Policy (conf report)
- EPF, Annual Work plans 2011, 2012 (draft)
- EPF, The Value + Handbook (2009)
- EUPATI: presentation in EFPIA Think Tank 29 November 2011
- Eurordis (2009) : Charter on Clinical Trials for Rare Diseases
- Eurordis (2011) : Patients' priorities and needs for rare disease research
- Eurordis: The role of patients groups in research and their priorities for the future, presentation by Fabrizia Bignami, rare Disease Day Workshop 1 March 2010
- Health Action International (2010) : The patient & consumer voice and pharmaceutical industry sponsorship
- Health Action International (Europe) (2009) : Patients organisations and medicine policy
- Health Consumer Powerhouse (2009): The Empowerment of the European Patient
- Health Council of the Netherlands (2011) . Medical products: new and needed! , publication no 2011/01
- Institut de recherche et débat sur la gouvernance (2010), Rapport de synthèse La place de la concertation dans la gouvernance de la politique de santé publique en France
- Keizer, Bob (2009): Internationaal pgo-beleid. ZonMw
- Keizer, Bob and Bless, Ruud (2010), Pilot study on the position of health consumer and patients' organisations in seven EU countries. ZonMw
- Koning Boudewijn Stichting: Litterature study patients' participation 2007, Patients as partners in health policy 2008, The Financial situation of patients' organizations in Belgium 2009, Hefbomen voor een betere patiëntenparticipatie, 2011
- Nierse, C.J. , Abma, T.(2011) Developing voice and empowerment: the first step
- Opedal, Ståle ; Rommetvedt, Hilmar and Vrangbæk, Karsten (2012): Organised Interests, Authority Structures and Political Influence: Danish and Norwegian Patient Groups Compared. Scandinavian Political Studies, Vol. 35 – No.1, 2012
- Patient Partner (2009): An overview of the literature
- Patient Partner (2011): Patient involvement in clinical research, A guide for patient organisations and patient representatives
- Patient View (2010): European Patient Group Directory
- PROGNOSE, 2011, Patienten- und Bürgerbeteiligung in Gesundheitssystemen
- Schipper, Karen , Abma, Tineke (2011): Coping, family and mastery: top priorities for social science research by patients with chronic kidney disease. Nephrol Dial Transplant 0: 1-7
- Schoneveld van der Linde, Maryze MA , From Empowerment for Patient Organisations to Empowered Patient Organisations, European Neuro Muscular Centre
- Smit, Cees (2011), De patiënt aan het roer , Drukkerij De Adelaar



- Smit, Cees (2012) : Een nieuwe horizon, de toekomst van de patiëntenbeweging in Nederland. Kirja Boek, Hoogwoud.
- Smit, Cees : Negen verhalen over patientenparticipatie in geneesmiddelenonderzoek (2009) . Drukkerij De Adelaar
- Smit, Cees, Valk, Tessa van der, Wever, Kim (2011) : Fundamenteel onderzoek en patientenorganisaties: een verrassende combinatie. Drukkerij De Adelaar
- Staley K. (2009) Exploring Impact: Public involvement in NHS, public health and social care research. INVOLVE
- Teunissen, G.J., Abma, T.A. 2010, Derde Partij: tussen droom en daad, TSG jaargang 88, p. 182 e.v.
- The Meeting (24 March 2011) : Optimal role of patient organisations in drug development, Conference presentations
- Towards a broad consultation in research agenda setting, Journal of Intellectual Disability Research no. 55.
- Trefpunt Zelfhulp, 2010, Morfologie 2009. Zelfhulpgroepen in Vlaanderen
- Valk, Tessa vd, Smit, Cees (2011). Patienten spelen doorslaggevende rol bij biobanken. Ned. Tijdschrift Geneeskunde 155.
- ZonMw (2006), Handboek Patiëntenparticipatie in wetenschappelijk onderzoek

**Persons who have provided information** (interviews, info by e-mail, etc):

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 Buijs, Goof, MoH, The Netherlands  
 Chanrion, Mady, Le Ciss, France  
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Wijnhout, Maaïke, MoH, The Netherlands  
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Zeijden, Albert vd (amongst others) IAPO  
Zon, Frans van, CSO, The Netherlands

## **ANNEX:**

### **Participation of health consumers and patients at EU level and in eight EU countries**

|                           |             |
|---------------------------|-------------|
| <b>1. EU</b>              | <b>p 19</b> |
| <b>2. Belgium</b>         | <b>p 28</b> |
| <b>3. France</b>          | <b>p 31</b> |
| <b>4. Germany</b>         | <b>p 36</b> |
| <b>5. The Netherlands</b> | <b>p 43</b> |
| <b>6. Poland</b>          | <b>p 50</b> |
| <b>7. Spain</b>           | <b>p 53</b> |
| <b>8. Sweden</b>          | <b>p 57</b> |
| <b>9. UK</b>              | <b>p 60</b> |
| <b>10. Denmark</b>        | <b>p 67</b> |

# 1. European Union

## 1. Health Consumer and Patients' Organizations (HCPO's)<sup>36</sup>

### 1.1. Inventories:

As regards the way consumers/patients have organised themselves, there are hundreds of organisations active at EU level, mostly (federations of) categorical organisations but also general platforms. Overviews are available on:

- **Patient View directory** <http://burson-marsteller.be/2010/11/european-patient-group-directory-3rd-edition>

- **European Patients Forum (EPF) directory** [http://www.eu-patient.org/pos/pos\\_list.php](http://www.eu-patient.org/pos/pos_list.php)

- **European Medicines Agency (EMA) list of patients' organisations:** <http://www.ema.europa.eu/see:partnersandnetworks> (see hyperlinks for more info)

### 1.2. General patients' organisations at EU level

**European Patients Forum (EPF)** <http://www.eu-patient.eu>

EPF is the umbrella organisation of pan-European patient organisations active in the field of European public health and health advocacy.

EPF was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represent [51 patients organisations](#) – which are chronic disease specific patient organisations operating at EU level and national coalitions of patients organisations.

**International Alliance of Patients' Organisations (IAPO)** <http://www.patientsorganizations.org>

Is a unique global alliance representing patients of all nationalities across all disease areas and promoting patient-centred healthcare around the world.

Members are patients' organizations working at the international, regional, national and local levels to represent and support patients, their families and carers. A "patient" is for IAPO a person with any chronic disease, illness, syndrome, impairment or disability.

**EDF:** <http://www.edf-feph.org/> The **European Disability Forum** is an independent NGO that represents the interests of 80 million Europeans with disabilities. EDF is the only European platform run by persons with disabilities and their families.

**AGE:** <http://www.age-platform.eu/> AGE Platform Europe is a European network of [around 165 organisations](#) of and for people aged 50+ which aims to voice and promote the interests of the 150 million senior citizens in the European Union and to raise awareness on the issues that concern them most.

**BEUC:** <http://www.beuc.org> the European Consumers' Organisation has a membership of 42 independent national consumer organisations from 31 European countries (EU, EEA and applicant countries). BEUC acts as the umbrella group in Brussels for these organisations and its main task is to represent its members and defend the interests of all Europe's consumers.

**Division of roles:** EPF and IAPO have a Memorandum of Understanding regarding their respective geographic remit and very strong collaboration. EDF represents disabled people from a human rights perspective, EPF represents patients with chronic diseases in their healthcare and social care environment. BEUC represents the "consumer" aspects. AGE represents older people in all aspects of ageing policy and does not represent older patients per se.

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<sup>36</sup> The terminology "HCPOs" is also used in the previous Pilot study, as being the compromise in the ongoing discussion about terminology and definitions ("patients", "consumers", "users", "clients", etc) in this area. However also the term "Patients' organisations" will be used in this report, because in the area of participation the "patient aspects" are very often prevailing.

### **1.3 Categorical organizations:**

There are more than 170 organisations, platforms, coalitions etc. of patients' organisations active.  
(Most) relevant organisations :

**Alzheimer Europe (AE)**  
**DEBRA International**  
**European AIDS Treatment Group (EATG)**  
**European Cancer Patient Coalition (ECPC)**  
**European Federation of Allergy and Airways Diseases Patients' Associations (EFA)**  
**European Federation of Neurological Associations (EFNA)**  
**European Genetic Alliances' Network (EGAN)**  
**European Headache Alliance (EHA)**  
**European Heart Network (EHN)**  
**European Institute of Women's Health (EIWH)**  
**European Liver Patient Association (ELPA)**  
**European Multiple Sclerosis Platform (EMSP)**  
**European Myeloma Platform (EMP)**  
**European Network of Fibromyalgia Associations (ENFA)**  
**European Organisation for Rare Diseases (EURORDIS)**  
**European Parkinson's Disease Association (EPDA)**  
**European Prostate Cancer Coalition (EUomo)**  
**Fabry International Network (FIN)**  
**Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)**  
**Insulin Dependent Diabetes Trust (IDDT)**  
**International Bureau of Epilepsy (IBE)**  
**International Confederation of Childhood Cancer Parents Organisations (ICCCPO)**  
**International Diabetes Federation (IDF)**  
**International Patient Organisation for Primary Immunodeficiencies (IPOPI)**  
**Myeloma Euronet (ME)**  
**Rett Syndrome Europe (RSE)**  
**Thalassaemia International Federation (TIF)**

NB: the above mentioned organisations are selected from the register of EMA:

<http://www.ema.europa.eu/> (see: partners and networks; see the hyperlinks for more information about these organisations). These organisations are screened according to a set of strict selection criteria (see hereafter: EMA)

However there are a lot more categorical organisations active at EU level.

## **2. Patients' participation at EU level**

### **2.1. Stimulating role of the European Commission on patients' participation:**

In the last 10 years several Directorates General of the European Commission have stimulated Patients' organisations (EPF, EDF, AGE, etc) and patients' participation by providing financial support for these organisations and their projects and by creating other forms of patients' participation (participation in EMA, involving them in policy developments, etc.) DG Sanco is the Directorate General that plays an active role here, but also for instance DG Research and Innovation, DG Enterprise and Industry and DG Employment, Social Affairs and Inclusion are active in this area.

[http://ec.europa.eu/dgs/health\\_consumer/index\\_en.htm](http://ec.europa.eu/dgs/health_consumer/index_en.htm)

<http://ec.europa.eu/research/home.cfm>

<http://www.imi.europa.eu/content/mission>

<http://ec.europa.eu/social/home.jsp>

[http://ec.europa.eu/enterprise/index\\_en.htm](http://ec.europa.eu/enterprise/index_en.htm)

## 2.2. Participation of patients' organizations in EMA:

- **The European Medicines Agency (EMA)** , is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.  
<http://www.ema.europa.eu>

Participation of patients and consumers:

The European Medicines Agency has been engaging in dialogue with European patients and consumers since it was founded in 1995.

As users of the medicines that the Agency evaluates, patients and consumers are key stakeholders in the Agency's work and have specific knowledge and expertise to offer. The Agency is committed to maintaining a strong working relationship with these groups.

Patients and consumers are involved in a range of activities at the Agency, including participation in :

- the Management Board: 2 representatives of patients' organisations
- the Committee for Orphan Medicinal Products (COMP): 2 representatives of patients' organisations and 2 observers
- the Paediatric Committee (PDCO): 3 representatives of patients' organisations
- the Committee for Advanced Therapy (CAT): 2 representatives
- the EMA Patients' and Consumers' Working Party (PCWP)

The Agency engages with patients and consumers via a network of over 30 European patients' and consumers' organisations. This ensures that the Agency has direct contact with a wide range of patients and consumers representing the needs and concerns of patients and consumers across Europe.

How does EMA select the patients' organisations?

The patients' organisations are supposed to meet the "Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency (EMA) activities":

These are amongst others: legitimacy, mission/objectives, activities, representation, structure, accountability and consultation modalities, transparency.

What are the experiences? EMA publishes yearly Annual Progress Reports on the participation of Patients' and consumer organisations.

### - **Future development: patients' participation in EATRIS, The European Advanced Translational Research Infrastructure in Medicine**

(See <http://www.eatris.eu>)

EATRIS is a relatively new organisation (2011), that aims to provide infrastructure to stimulate translational research. EATRIS is one of the infrastructure projects prioritized in the first roadmap of the European Strategy Forum on Research Infrastructure (ESFRI) and funded by the 7<sup>th</sup> Framework programme (FP7) of the EU.

Currently eight European countries are partners in the EATRIS consortium: Czech Republic, Denmark, Finland, Germany, Italy, Norway, The Netherlands and Spain.

Patients ' participation:

EATRIS wants to involve (amongst others) patients' organisations on a structural basis in the functioning of EATRIS, at the European level and at the level of participating countries.

EATRIS is still in the developing stage; It is expected that EATRIS will publish this year more specific information on how patients' organisations will be involved.

## 2.3. Examples of (projects of) patients' organisations focusing on participation

### - EPF: The Value + project

The Value+ project was launched in 2008 with the aim of exchanging information, experiences and good practices among key stakeholders in relation to meaningful Patient involvement in EU-funded health-related projects at both EU and national level. In this respect, Value+ represents the first effort ever made to achieve an overarching EU-wide overview and analysis of current practices and trends regarding meaningful patient involvement and raise awareness about this issue.

What was achieved?

A **literature overview** on patients' participation

A **Toolkit** for patients and patient organisations providing information on how to become involved as equal partners in EU funded health-related projects

A **Handbook** for project leaders and coordinators providing specific information on how to involve patient organisations in EU supported projects

A set of **Policy Recommendations** for policy makers on effective strategies for involving patient organisations in EU-supported programmes and projects. In addition to these three key tools, Value+ produced a **Database** containing the results of the research on EU-supported health projects and the organisations that implemented them, developed a model for meaningful patient involvement in healthcare and a directory of patients' organisations in EU Member States.

These tools and resources can support cooperation with patient organisations in developing a project proposal, implementing a project and evaluating it.

You can access the resources at:

<http://www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/Resources/Value-Resources/>

**Participatory activities of EPF:** EPF is participating in a large number of activities and projects,<sup>37</sup> like:

### - Patient Safety and Quality of Care

EPF has been involved in the EUNetPaS (European Union Network for Patient Safety: <http://eunetpas.eu/>), a project funded and supported by the European Commission within the 2007 Public Health Program. EPF also will participate in the follow-up, the European Union Network for Patient Safety and Quality of Care (PaSQ), which main objective is to strengthen cooperation between EU member states and EU stakeholders on issues related to quality management systems in healthcare, including patient safety and patient involvement.

This project is coordinated by HAS (French National Authority for Health). Its purpose is to implement the Joint Action on Patient safety and Quality of health Care, by establishing an umbrella network of all 27 EU Member States and EU stakeholders to encourage and enhance their collaboration and exchange of information (culture, reporting and learning systems, medication safety and education).

Within this project a range of activities are currently being developed (co-funded – 6 mln euro- by DG SANCO), bundled in Work Packages. In almost all of these Packages patients' organisations will be involved. The European Patients Forum plays an active role in this project.

- **EUPATI:** EPF co-ordinates this very important project, see hereafter

### - Other examples of participation of patients (EPF) in EU health policy issues:

- Clinical trials
- Medical devices
- Innovation and personalised medicine
- Improving access to medicines
- eHealth and telehealth
- Health Technology Assessment (HTA)

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<sup>37</sup> See also EPF work plan 2011, 2012 (draft)

## - EGAN / Patient Partner

<http://www.egan.eu/>

**EGAN** is an alliance of both National Genetic Alliances and European disease specific patient organisations with a special interest in genetics, genomics and biotechnology. Especially, but not only, genetic disorders are represented within EGAN.

EGAN is working for a voice in research and health policy and seeks a world in which genetic and other serious diseases are understood, effectively treated, prevented and the people affected supported.

**Patient Partner:** [www.patientpartner-europe.eu](http://www.patientpartner-europe.eu)

Patient Partner was a three year project within the 7th Framework programme funded by the European Commission. The Patient Partner Project drew to a close in the summer of 2011. The project had set out to promote the role of patient organisations in the clinical trials context.

There were four partners involved in the Patient Partner Project:

[Dutch Genetic Alliance \(VSOP\)](#) (co-ordinator)

[European Forum for Good Clinical Practice \(EFGCP\)](#)

[European Genetic Alliances Network \(EGAN\)](#)

[Genetic Alliance UK \(formerly Genetic Interest Group\)](#)

Patient Partner was based on the belief that involving patient organisations as equal partners at all stages of clinical trials contributes to research that is better adjusted to the real needs of patients. The study looked closely at the part that patient organisations play and are willing to play in clinical trials and also focussed its attention on clinical trials with children, the use of bio banks and ethical issues.

The aim of this project was to identify the patients' needs for partnership in the clinical trials context. Moreover, the project leads to a well-organised and sustainable communication platform and guidelines, to enable the mutual beneficial interactions between patients and clinical trial professionals.

Patient Partner has yielded a great number of products ( relevant for a possible information network) :

**An inventory of the existing views, needs, practices and experiences of patients**, formed the basis of the Patient Partner project. This inventory consisted of literature reviews, interviews with patient organisations, opinion leaders and other clinical trial stakeholders as well as a European survey on patient involvement in clinical trials to identify good practices.

The results of this inventory formed the basis of the subsequent **workshop** series. These workshops were the venue for dialogue between patient organisations, pharmaceutical companies and researchers, on patient involvement in the clinical trials' context. As a result of this dialogue, Patient Partner formed **recommendations** as to how patient organisations can proceed to become more equal partners in clinical trials and clinical research.

As a means towards patient partnerships with the stakeholders, the project gave rise to a facilitating structure that empowers, enables and mobilises European patient organisations to interact with the other European and international stakeholders in clinical trials. This virtual network called the **European Network of Patients Partnering in Clinical Research (ENPCR)** aimed to empower patient organisations in their role as partners in clinical trials and was a one shop stop for other stakeholders to get in touch with European patient organisations for advice on, or participation in, clinical research.

The results of the project were widely disseminated during the last year of the project. A **patient information guide and a guide for sponsors and researchers** were also developed to help give rise to more effective partnerships in clinical trials and clinical research. In addition, recommendations that were made by the joined stakeholders during the workshops were collated in a document circulated to policy makers (and the broader public via the media, conferences etc.)



## - EUPATI: European Patients' Academy on Therapeutic Innovation<sup>38</sup>

<http://www.patientsacademy.eu>

The Innovative Medicines Initiative (IMI), a public private partnership between the European Commission and EFPIA, will fund a patient-led consortium to develop the 'European Patients' Academy on Therapeutic Innovation' (EUPATI). It is an EU "Patients Academy", and a consortium of 29 partners, both patient's organisations and pharma companies. Patients' organisations that participate are the **European Patients' Forum (EPF)**, **European AIDS Treatment Group (EATG)**, **European Organisation For Rare Diseases (EURORDIS)** and **European Genetic Alliance Network (EGAN)**. The European Patients' Forum acts as the consortium leader of the project. The project has a considerable budget (10 mln euro for five years) and is expected to start in the first quarter of 2012.

Aims:

- To develop and disseminate accessible, well-structured and user-friendly information and education resources on therapeutic innovation,
- To build competencies among well informed patients and the public about pharmaceutical R&D, build expert capacity in patient advocates
- To create the leading public library on patient information in six most common languages, to establish a widely used, sustainable infrastructure for objective, credible, correct and up-to-date knowledge,
- To facilitate patient involvement in R&D to support industry, academia, authorities and ethics committees

From 2012, the academy will educate patient representatives and the lay public on personalised and predictive medicine, design and conduct of clinical trials, drug safety and risk/benefit assessment, pharmaco-economics as well as patient involvement in drug development. EUPATI will provide educational material in six European languages targeting eleven European countries.

To improve the availability of both patient-centric information as well as educated patient experts, EUPATI will develop scientifically reliable, objective, comprehensive information on therapeutic innovation by establishing certificate training courses to create 'expert advocates' on therapeutic innovation, developing a "tool kit" of educational multi-media material to be re-used by patient organisations for educational purposes, and developing an Internet-based library of up-to-date, unbiased information on medicinal development for patients and the public.

A Regulatory Advisory Panel led by regulatory authorities as well as a Project Advisory Board composed of high level experts with long standing credibility in patient involvement and pharmaceutical R&D will ensure objectivity, transparency and independence of EUPATI's educational content, adhering to the highest quality standards on information to patients.

## - Eurordis

<http://www.eurordis.org/>

EURORDIS is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe. It was founded in 1997; it is supported by its members and by the French Muscular Dystrophy Association (AFM), the European Commission, corporate foundations and the health industry.

EURORDIS represents more than 479 rare disease organisations in 45 different countries (of which 25 are EU Member States), covering more than 4,000 rare diseases. It is therefore the voice of the 30 million patients affected by rare diseases throughout Europe.

EURORDIS is a not-for-profit organisation with a stringent financial transparency policy and good governance practices.

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<sup>38</sup> This could be considered as the follow-up of the Patient Partner project

A rare disease is a disease affecting less than 1 in 2,000 citizens (in Europe).

EURORDIS' mission is to build a strong pan-European community of patient organisations and people living with rare diseases, to be their voice at the European level and - directly or indirectly - to fight against the impact of rare diseases on their lives

Eurordis is very active in European advocacy, it participates amongst others in: the European Medicines Agency (EMA), [Rare Disease Task Force](#) (DG Health and Consumer Protection - European Commission), - [EU Health Policy Forum](#) (DG Health and Consumer Protection) and a number of European Platforms:

- European Patients' Forum ([EPF](#))
- European Forum for Good Clinical Practice ([EFGCP](#))
- European Platform for Patients' Organisations, Science, and Industry ([EPPOSI](#))
- International Alliance of Patients' Organizations ([IAPO](#))
- EFPIA Think Tank <http://www.efpia.eu>
- Pan-European Blood Safety Alliance (PBSA)
- Drug Information Association (DIA) in Europe
- EUCERD <http://www.eucerd.eu/>

Eurordis has deployed a great number of activities. Some examples:

- Report: **EURORDIS research priorities : Patients' Priorities and Needs for Rare Disease Research 2014-2020 (October 2011)**  
EURORDIS has identified in this document a number of strategic areas that deserve the attention of policy-makers and researchers, like
  - Supporting registries and other infrastructures
  - Understanding the underlying mechanisms of rare diseases
  - Translating research into therapies for patients <http://www.eurordis.org/publication/research-priorities-rare-diseases>
- Study: **Role of Patients Groups and Research and their priorities for the future** [http://www.eurordis.org/sites/default/files/publications/3\\_FBignami\\_RDD2010.pdf](http://www.eurordis.org/sites/default/files/publications/3_FBignami_RDD2010.pdf)  
In collaboration with the group of the « Centre de sociologie de l'innovation » (Ecole des Mines, Paris).  
Some results:
  - POs have a high commitment for research and are keen observers of all its areas (Basic, Therapeutics, Social and Human Sciences, ...)
  - POs have a strong willingness for collaboration with researchers
  - POs play an important role as catalysts of research
  - Of the POs financially supporting research a total contribution of 13 M€ was provided over the last year  
(In addition the AFM <http://www.afm-telethon.fr/> gives an average of 60 M€/year for research)
- Charter: **Eurordis : Clinical Trials for Rare Diseases 2009**, specifying the rights of patients who participate in clinical trials <http://www.eurordis.org/content/eurordis-charter-clinical-trials-rare-diseases>
- The **Summer School** is an initiative started by EURORDIS in 2008 <http://www.eurordis.org/content/eurordis-summer-school-patient-advocates>

It aims at training rare disease patients' representatives in the areas of :  
Clinical trials,  
Drug development  
Regulatory affairs.

This preparation builds participants' capacities to act as experts in regulatory processes for their disease and to further their involvement in drug development and advocacy actions. Since its inception, the EURORDIS Summer School has collaborated on this project with the Universidad Autonoma de Barcelona (UAB).

### 3. Researchers, think tanks, other information sources and communication networks :

#### Research networks/organisations:

There is a limited number of individual researchers, university centres or groups/consortia of researchers/ organisations specialized in assessing and evaluating (aspects of) patients participation. Some of these groups/networks:

- **EPOKS** (European Patient Organizations in Knowledge Society) is a collaborative research project, funded by the [European Commission within Science In Society initiative](#). It associates five partners from four countries, France, Portugal, the U.K and Ireland. [More about the partners](#). It started in February 2009 and will last three years.

EPOKS has four main objectives :

- Characterizing patient, user, and civil society organizations' modes of involvement in the production of knowledge and expertise
  - Making a Cross-national comparison between patient, user, and civil society organizations' modes of engagement in the production of knowledge
  - Mapping and analysing the network of expertise and issues to which patient, user, and civil society organizations participate
  - Describing the dynamics of the "Europeanization" of lay organizations, and its effects on the governance of knowledge and the place of knowledge in the governance of health and medicine
- It aims at deepening the understanding of similarities as well as differences between national organizations in France, Portugal, the U.K and Ireland, active in four conditions areas. These are the fields of rare and orphan diseases, childbirth issues, Alzheimer's Disease, and ADHD (Attention Deficit and Hyperactivity Disorder).

[More about objectives of the project](#)

- **European Society of Medical Sociology ESHMS** <http://www.eshms.eu/> A small group of internationally active scientists involved in socio-medical research initiated the foundation of European Society of Medical Sociology (ESMS) in the early 1980ies.

- **Patient View**. Founded in 2000, PatientView is an independent, global, research-and-publishing organisation that works closely with patients and health and social campaigning groups worldwide. Works on a commercial basis. Patient View publishes amongst others the European patient Group Directory, an overview of international patients' organisations <http://www.patient-view.com>

- **Health Consumer Powerhouse**. Since 2004, Health Consumer Powerhouse Ltd (HCP) monitors and compares healthcare systems of 35 countries, including all EU member states as well as Canada. Example: "**The Empowerment of the European Patient**", a comprehensive overview of the state of pay in EU countries regarding patients' rights, etc. See <http://www.healthpowerhouse.com> )

- **The Cochrane Collaboration** is an international, independent, not-for-profit network of over 28,000 contributors from more than a 100 countries, dedicated to making up-to-date, accurate information about the effects of healthcare readily available worldwide. Contributors are clinicians, healthcare researchers and consumers, who work together to produce, maintain and promote the accessibility of systematic reviews of healthcare interventions, known as [Cochrane Reviews](#) (over 4,600 so far) which are published online in [The Cochrane Library](#). Cochrane reviews are intended to help healthcare providers, policy-makers, practitioners, and patients make well-informed decisions about healthcare, based on the best available research evidence <http://capsmg.cochrane.org/welcome>

#### Think tanks, Information, communication networks

- **EFPIA Think Tank** <http://www.efpia.eu> **European Federation of Pharmaceutical Industries and Associations**

In autumn 1998, patients' organisations and the pharmaceutical industry as consumers and producers of pharmaceutical products decided to set up a joint Think-Tank in order to have a dialogue on EU policy issues in the area of health and innovative medical research.

Patients' organisations and the European Federation of Pharmaceutical Industries and Associations (EFPIA) [work together \(Memorandum of Understanding\)](#) within the Think-Tank

- **EGAN Roche workshop** <http://www.egan.eu/en/our-activities/collaborations/roche>

This is a yearly event in Basel, where information is shared and discussions take place between Roche and Patients' organisations on issues like medicine innovation, initiatives of PO's, policy developments, etc.

- **EU Health policy forum**

[http://ec.europa.eu/health/interest\\_groups/eu\\_health\\_forum/policy\\_forum/index\\_en.htm](http://ec.europa.eu/health/interest_groups/eu_health_forum/policy_forum/index_en.htm) The EU Health Policy Forum brings together 52 umbrella organisations representing European stakeholders in the fields of public health and healthcare.

The Forum meets regularly in Brussels.

The Forum reviews the EU's work in various areas of public health and adopts recommendations, responds to Commission consultations and assists in organising consultations, enables exchange of views and experience on a wide range of topics

Assists in implementation and follow-up of specific initiatives.

- **Epposi** <http://www.epposi.org/> Founded in 1994, Epposi is an independent, not-for-profit, partnership-based and multi-stakeholder think tank based in Brussels, Belgium.

Goal is to work at the "cutting edge" of European health policy-making, providing members and the wider public with high quality independent research, capacity-building, knowledge exchange and dissemination with the aim of bridging the gap between innovation and improved public health outcomes.

Epposi is open to members from EU-facing umbrella patients' organisations, commercial enterprises and their related trade bodies, research institutes, professional and business federations. Associate membership is open on nomination to NGOs representing a broad range of civil society interests, foundations and international organisations which support the Epposi ethos and are active in human healthcare.

- **The EUROPEAN HEALTH FORUM GASTEIN (EHFG)** <http://www.ehfg.org/> was founded in 1998 as a European health policy conference with the aim of providing a platform for discussion for the various stakeholders in the field of public health and health care. Since, the EHFG has developed into a unique annual event, bringing together, politicians, senior decision-makers, representatives of interest groups, as well as experts coming from government and administration, business and industry, civil society and science and academia. These four groups of stakeholders with their perspectives constitute the four pillars of the EHFG.

#### **Other communication networks**

- **European Public Health Alliance**

**EPHA** <http://www.ephpa.org/> is the European Platform bringing together public health organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. EPHA has a well established and transparent consultation process that enables all members to participate in policy-making.

- **European health management Association** <http://www.ehma.org/>- EHMA is a membership organisation funded through membership fees, project income, sponsorship and event income. Has 160 members across more than 30 countries in the European region. See the current list of members [here](#).

## 2. Belgium

### 1. patients' organisations, consumer organisations, platforms, support

#### Patients' organizations

It is estimated that there are about 400 patients' organizations in Belgium. The majority consists of small and medium-sized organizations, without paid staff. See for more information:

- **KBS: De financiële situatie van patientenverenigingen (2009)** (see hereafter: KBS)  
[http://www.kbs-frb.be/uploadedFiles/KBS-FRB/05\\_Pictures\\_documents\\_and\\_external\\_sites/09\\_Publications/1858\\_FinancieleSituatiePatientenverenigingen.pdf](http://www.kbs-frb.be/uploadedFiles/KBS-FRB/05_Pictures_documents_and_external_sites/09_Publications/1858_FinancieleSituatiePatientenverenigingen.pdf)

- **Trefpunt Zelfhulp, Centrum voor sociologisch onderzoek, Leuven: Morfologie 2009, Zelfhulpgroepen in Vlaanderen**  
<http://www.zelfhulp.be/pdf/Morfologie%202009.pdf>

#### Consumer organizations:

Participation in health and health related issues is not an exclusive domain of patients' organizations. Also general Consumer organizations and Family organizations are very active. Examples;

- **Test-Aankoop** . <http://www.test-aankoop.be/> ("test-purchase") Runs since the 90-ties a very comprehensive database on all kinds of comparative information on health issues. Test-aankoop is also active as a pressure-organization, for instance regarding complaints about side-effects of medication.

The latter activity has led to an agreement with the Federal Medicines Agency to exchange information about these side-effects.

- **OIVO** (the research organization of the consumer organizations) <http://www.oivo.be/> : publishes comparative consumer information on health issues

- de **Gezinsbond** <http://www.gezinsbond.be/> and the **Ligue des Familles** <https://www.citoyenparent.be/Public/ligue/>: family organisations also providing information and participating in public debates about health issues.

#### Patients' platforms and forms of support:

There are two patients' platforms in Belgium: het **Vlaams Patiëntenplatform (VPP)** (Flamish) <http://www.vlaamspatiëntenplatform.be> and the **Ligue des Usagers des Services de Santé (LUSS)** <http://www.luss.be/const.php?p=accueil> (French language).

These two platforms are financed by the Federal and Regional health authorities<sup>39</sup>, in order to create two bodies that could represent the interests of health consumers vis-a-vis the respective governments.

There are two Support Centres for patients' organizations, also financed by the respective federal and regional authorities: the **Trefpunt Zelfhulp in Vlaanderen** en **Patienten Rat & Treff** for the German speaking community.

In the French-speaking part of Belgium LUSS (see above) supports patients' organisations, in close co-operation with the **Centre d'Information sur les Groupes d'Entraide** <http://www.selfhelp.be/index.cfm> ), an initiative of a social-democratic Mutual Insurance Company.

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<sup>39</sup> VPP is financed by the federal RIZIV and the FOD Volksgezondheid, and the regional health agency 'Vlaams Agentschap Zorg en Gezondheid', the LUSS by the Service Publique de Wallonie, département de Santé, and the Ministère de la Communauté Française.

## 2. Research/ monitoring

The above mentioned platforms and support centers are the best sources of information regarding the functioning of patients' organizations in Belgium. Also the University of Leuven (Marc Leys and others) is quite active in this research area.

However the main driving force behind research on patients' organizations and promoting patients' participation in Belgium has been the **Koning Boudewijn stichting (KBS, the "King Baudouin Foundation"**. In recent years, the KBS has developed a number of activities, aiming at:

- supporting participation of patients' organisations
- improving training, information
- formal recognition of the patients' organisations
- improving the financial situation of patients' organisations.

The KBS has published a number of comprehensive studies on this issue and has invested in a number of development projects.

Examples:

### - Litterature study patient' participation 2007

The purpose of this report was to support the multistakeholder process launched by the King Baudouin Foundation in 2007 on the topic of Patient Participation in Health Care Policy. The report sets out a theoretical framework and gives an overview of international and Belgian initiatives in the area of patient participation.

### - Patiënten als partners in het gezondheidszorgbeleid ("patients as partners in health policy") 2008

This report is the product of a multi-stakeholder process launched by the King Baudouin Foundation in 2007 to examine the possibilities of improving patient participation in health-care policy. The project consisted of an inductive process in which a diverse group of stakeholders were questioned, using both individual interviews and group discussions. The results of these interviews were analysed and summarised to obtain an overview of the current debate on patient participation in Belgium. The Foundation has used the results of the project as the basis for further initiatives to improve patient participation.

- **The financiële situatie van patiëntenverenigingen** ("the financial situation of patients' organizations"), 2009. In this research report, the King Baudouin Foundation presents quantitative and qualitative data on the types of patient associations in Belgium, how they are funded and what their needs are. The report shows a wide variety of organisations with a wide variety of activities, and financial situations.

- **Funding projects:** The KBS has funded more than 30 projects in this area, for in total € 222 500. Furthermore it has funded several trainings and information activities, provided by the Trefpunt Zelfhulp and the Ligue des Usagers des Services de Santé (LUSS) (see website).

- **Hefbomen voor een betere patiëntenparticipatie, 2011** ('Levers for better patient participation'), The KBS, together with a working group of stakeholders and experts, explores in this report how the recognition and funding of patients' associations could help to increase patient participation in Belgium. The options put forward were devised by a group of five experts, based partly on research carried out by Yellow Window.

The various options which could lead to greater patient participation have been grouped into five broad action areas. The first relates to the development of a participatory culture in which patients are aware of their role in healthcare.

Another is about developing processes with greater citizen and user participation, e.g. via citizens' conferences on health-related issues, advisory committees or user groups. Patient participation could also be enhanced within care establishments by involving patients' associations in quality management, for example by means of more institutionalized user committees and councils. Within care networks, too, input from patients' associations could foster innovations. Patients could also be involved in operational policy decisions relating to, for example, the reimbursement of certain medications, the organization of care programs or the determination of priorities for medical research.

In addition, they could pass on all healthcare-related information to citizens and act as observers, which would in itself foster greater transparency in the decision-making process. A mix of direct and indirect, structural and project funding offers the most appropriate response to the heterogeneous and varied nature of the patients' association landscape in Belgium. The creation of a neutral fund could be considered. The publication concludes with 10 key ideas for encouraging targeted forms of dialogue with stakeholders.

See for more information about the activities of KBS:  
<http://www.kbs-frb.be/otheractivity.aspx?id=215676&LangType=2067>

### **3. Patients' participation**

According to the above mentioned reports of the KBS, the patient movement in Belgium has barely grown - if at all - into an institutionalised consultation partner. In the Belgian consultation model, insured persons are represented by the mutual insurance companies within the various policymaking bodies. There is no separate place for patient associations within those consultative bodies. As they are so deeply embedded in the consultative bodies, the mutual insurance companies are sometimes criticised for paying too little attention to the interests and problems of specific groups of pathologies.

The realization of the patients' platforms and support centers has given a positive impulse to the participation of patients' organizations. However the platforms LUSS and VPP are still not formally recognized and their financial basis is unstable. Nevertheless these two platforms are working closely together and are participating in a number of important policy-making bodies like the Federal Committee on Patients' Rights, The Federal Medicines Agency (FAGG), the Strategic Advisory Council for Welfare and Health.

Recent developments show a positive trend. In a growing number of co-operation structures in Belgium health care, patients' organizations are invited to participate, like the Samenwerkingsinitiatieven in de Eerstelijnsgezondheidszorg (SEL's) in Flanders, and the Observatory for Chronical Illnesses of the RIZIV, the National Health Institute. <http://www.riziv.be/homenl.htm>



## 3. France

### 1. Organisations

#### Diversity of organisations:

The total number of HCPOs in France is unknown. Estimates differ widely. The majority of HCPOs are very small and operating at local or regional level. There are about 30-40 big organisations/federations and a few hundred middle sized organisations.

Patients' organisations in France can get a special status by the Ministry of Health that gives them access to participation in policy processes (see below). The register of the MoH mentions 144 of these organisations (see <http://www.sante-sports.gouv.fr/l-agrement-des-associations-de-malades-et-d-usagers-du-systeme-de-sante.html>).

Two other main sources of information about HCPOs are the list of organisations published in L'Annuaire des Associations de Santé (AAS) and the register of INSERM.

- The AAS list <http://www.sante.gouv.fr/htm/sante/annuaire.htm> gives a very comprehensive overview of the organisations of patients and families of patients and other organisations providing help and care in the field of health (<http://www.annuaire-aas.com>). The list is updated once a year and contains today about 14000 organisations of which some 4000 are HCPO's. This register is facilitated by Celtipharm, a marketing and communication service of the pharmaceutical industry..
- Another source is the register of INSERM (see below) <http://extranet.inserm.fr/associations-de-malades>. This register mentions almost 400 organisations

Compared to other HCPOs in the EU some organisations are very big. Examples are:

- **AFM: Association française contre les myopathies** <http://www.afm-telethon.fr> (French Muscular Dystrophy Association)
- **AFD, Association française des Diabétiques** <http://www.afd.asso.fr/>
- **APF, Association des Paralysés de France** <http://www.apf.asso.fr/>
- **AIDES** <http://www.aides.org/> AIDES was set up in 1984 and was state-approved in 1990. It is the leading HIV/Aids organisation in France.
- **FNAIR Fédération Nationale d'Aide aux Insuffisants Rénaux** <http://fnair2.pagesperso-orange.fr/present.htm>
- **Alliance Maladies Rares** <http://www.alliance-maladies-rares.org/>
- **UNAPEI** (Union Nationale des Associations de Parents d'Enfants Inadaptés) <http://www.unapei.org/> : was formed at the same period as APF (Association des Paralysés de France). It is an umbrella organization, grouping local associations of parents of children with mental retardation and mental disability.
- **UNAFAM** (Union Nationale des Amis et Familles de Malades Mentaux) <http://www.unafam.org/> : was created in 1963. It is an umbrella organization, grouping local associations of families concerned with psychiatric disorders.

#### Umbrella:

- A number of organisations have created the **Collectif Inter associatif Sur la Santé (CISS)** <http://www.leciss.org>. The CISS, created in 1996, brings together more than 30 association of health care consumers (patients, disabled persons, relatives), and two big general coalitions (Organisation Générale des Consommateurs and UNAF). This represents in total more than 100.000 persons, divided over 22 regions. The Ciss is a very important counterpart for the government and other stakeholders in health care policy. Furthermore it gives support to member organisations and gives information to the public. In some cases it speaks on behalf of its members, in other cases the member organisations can speak for themselves when it comes down to formulating their own view. Main activities of the CISS are:
  - Informing consumers about their rights. A special help-line is an important instrument in implementing this function
  - Monitoring the (quality of) the health care system



- Organising opinion polls and publishing papers and other forms of information on specific subjects

Currently, the Ciss is considering to organize an international conference in fall 2013 (see hereafter: international activities)

### Financing, professionalization

The organisations of the disabled traditionally receive public funding partly because they also provide medical and social services. Patients' organisations are very rarely financed by the government and their financial basis is mainly dependent on private funds, membership fees, fund-raising activities, and corporate funding.

Nevertheless, the larger patients' organisations usually have a substantial budget and professional staff. For example the AFM has a staff of about 600 fte's and an annual budget of 100 mln euros. AFM organizes since 1987 every year in December the Telethon, combining a 30-hour TV show and tens of thousands of local events across France to collect funds but also raise public awareness of neuromuscular diseases. The Telethon provides most of the donations of the AFM and operates as an important vehicle for information, communication and education. Thanks to Téléthon the AFM is able to finance a number of different therapeutic activities and research projects.

The CISS is mainly financed by the Ministry of Health (about 75% of the budget of about 2 mln euro in total). The staff number is about 15 fte's. This is relatively modest compared to the size of its member organisations.

### 2. Monitoring/Research:

- **Monitoring:** There is no formal comprehensive monitor on HCPOs in France, but there are some very extensive sources of information on patients' organisations (MoH, AAS, INSERM, see above) which give together a reliable overview of the most important HCPOs in France.
- **Research:** There is no specific research programme on the functioning of patients' organisations but several individual researchers have been very active in the field of HCPO's<sup>40</sup>

A major research institute in this area is:

**INSERM** (<http://www.inserm.fr>). See below for the participation of HCPOs in the work of INSERM.

### 3. Participation of HCPOs

#### Participation in policy processes:

The role of HCPOs and users of the health care system has changed considerably over the past two decades. In 1998 and 1999 the MoH organised the Etats Généraux de la Santé, consisting of a large number of meetings (over 1000). Important input was delivered by the report "La place des usagers dans le système de santé" (Secrétariat d'Etat à la santé et aux handicapés, 2000). The law of 4 March 2002 has taken over almost all the recommendations, thus recognizing the role of HCPOs.

The Etats Généraux yielded an important step forwards in the recognition of patients' rights. The concept of "démocratie sanitaire" was introduced, and a number of rights was recognised in subsequent laws. 2002: "Droits des malades et qualité du système de Santé". Important elements of this legislation were: recognition of fundamental patients' rights, like dignity and non-discrimination, access to medical files, compensation for medical errors etc. Since then a number of other Acts was introduced, further reinforcing the position of patients: 2004: "Loi sur l'assurance maladie"; 2005: "Loi: Droits des malades et fin de vie"; 2006: "Charte de la personne hospitalisée"; 2009: "Loi Hôpital, patients, santé, territoires".

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<sup>40</sup> Madeleine Akrich, Vololona Rabeharisoa, Ecole des Mines. Examples of their international research activities: ITEMS (2003-2005), <http://www.csi.ensmp.fr/WebCSI/ITEMS/>, MEDUSE, EPOKS: <http://www.csi.ensmp.fr/WebCSI/EPOKSWebSite/>. Other active French researchers are Janine Barbot (EHES), Nicolas Dodier (GSPM, EHES)

## Policy structures

The legislation above introduced a number of formal structures relevant for patients' organisations, differentiating between structures on expertise, policy making, co-ordination and programming. The main structures are:

### **CNS, Conférence nationale de Santé and the Conférences régionales de Santé**

The CNS is consulted by the government in the preparation of policy measures in the field of public health. The CNS also helps to organise the public discourse on health issues.

The CNS produces among others every year a report about the rights of consumers of the health system.

Parallel to the CNS there are also Conférences Régionale de Santé (CRS) that are consulted by the regional authorities in the context of the (implementation of) their regional public health plans ([Plan Régionale de Santé Publique](#)).

As a consequence of restructuring health care legislation the HCPOs are participating now in almost all important bodies in health care. Not only in the organisations as mentioned above, but in many other big and small committees, boards, etc, both at national and at regional level. An inventory of the CISSs showed about 30 different kinds of bodies, in which consumers/patients are supposed to participate.

HCPOs are asking for better financial compensation for their representatives to do all this work. So far only Le Ciss receives some compensation. Le Ciss estimates that at least 15 mln euro are needed to meet the financial needs of HCPOs and their representatives.<sup>41</sup>

Some institutes like HAS cover the expenses of HCPOs participating in the work of this organisation.

### **Involvement in research activities:**

**INSERM:** Created in 1964, the INSERM is a public institution with a scientific and technical vocation under the dual auspices of the Ministry of Health and the Ministry of Research. It was created as a successor of the French National Institute of Health. INSERM consists of 339 research units, run by 6500 permanent staff members. Eighty percent of INSERM research units are embedded in research hospitals of French universities. There are also 10 specialised research institutes associated with INSERM. The INSERM has recently been put under a new umbrella structure called AVIESAN. In 2004, INSERM decided to set up a policy of dialogue and partnership with patients' organisations which was organized around four priorities:

- the participation of HCPOs in the management of research programs,
- the collaboration of HCPOs in clinical research,
- training, aiming at reinforcing the capacity of HCPOs to participate
- the creation of a network of HCPOs in order to stimulate the interaction between HCPOs and the scientific community:

Examples of activities:

- The GRAM (Le groupe de réflexion avec les associations de maladies), the “think tank” with HCPOs. Has 20 members, of which 10 are representing HCPO's. Task is to advise INSERM on the strategic orientation, to make proposals for actions and to ensure the follow-up of it.
- The network of HCPOs: Inserm is in contact with more than 380 HCPOs. Practically all the main categories of diseases and handicaps are represented.
- ScienSAs (Science, Seniors, Associations) : a network of about 400 experienced (retired) scientists that are able to advice HCPOs on involvement in scientific research, to follow developments in scientific litterature, or to help HCPOs otherwise.
- Organising seminars, trainings for HCPOs
- Organising inquiries amongst scientists about their relationships with HCPOs

The “Mission Inserm Associations” implements and coordinates the activities. It also acts as a point of contact for HCPOs. 4 fte's. (co-ordinator: Dominique Donnet-Kamel)

<http://www.inserm.fr/partenaires/les-associations-de-malades/la-mission-inserm-associations>

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<sup>41</sup>

[http://www.leciss.org/uploads/tx\\_cissdocuments/100412\\_RegardsCroisesSante\\_n2\\_FinancementDemocratieSanitaire.pdf](http://www.leciss.org/uploads/tx_cissdocuments/100412_RegardsCroisesSante_n2_FinancementDemocratieSanitaire.pdf)

### **HAS: Haute Autorité de santé (French National Authority for Health)**

Was set up by the French government in August 2004 in order to bring together under a single roof a number of activities designed to improve the quality of patient care and to guarantee equity within the healthcare system. HAS activities range from assessment of drugs, medical devices, and procedures to publication of guidelines to accreditation of healthcare organisations and certification of doctors. All are based on rigorously acquired scientific evidence. Training in quality issues and information provision are also key components of its work programme.

HAS is not a government body. It is an independent public body with financial autonomy. It is mandated by law to carry out specific missions on which it reports to Government and Parliament. It liaises closely with government health agencies, national health insurance funds, research organisms, unions of healthcare professionals, and patients' representatives.

The annual budget is 60 million euros. HAS has 350 permanent staff members but can call upon over 3000 experts. HAS is comparable with NICE in the UK, and the Institute for Quality and Efficiency (IQWiG) in Germany.

One of the main objectives of the HAS is transparency. This also concerns the relationship between HAS and HCPOs which is based on a cooperation framework (see: [http://www.has-sante.fr/portail/jcms/c\\_660855/has-patients-association-framework](http://www.has-sante.fr/portail/jcms/c_660855/has-patients-association-framework)) that aims to describe working rules between HCPOs and HAS, to facilitate the HCPOs involvement in the work of HAS and to guarantee optimal conditions for cooperation.

The framework is based on strong values which create rights and duties for consumers/patients' representatives:

- To recognize and to increase the value of patients' expertise whether it is based on personal experience of disease or family or people in contact with someone affected.
- Consequently, to consider patients' representatives as experts by providing them the same rights and duties as medical or scientific experts, which means a right to be paid for their time, and reimbursed of their costs of participation; prior to participation, they have an obligation to complete a declaration of potential conflicts of interests and an obligation to respect confidentiality of documents until publication by HAS.

### **Haut Conseil de la Santé Publique (HCSP) (High Council of Public Health):**

Created also by the law on public health policy of August 9, 2004, the HCPH is a body of expertise that incorporates and expands the tasks of the former Higher Council of Public Hygiene of France established in 1848 and the High Committee Public Health established in 1991. The task of the HCSP is to:

- Contribute to the definition of the multi-annual public health plan, assessing the achievement of national public health plan and contribute to annual monitoring;
- Provide government, in conjunction with health agencies, with the expertise needed to manage health risks and the design and evaluation of policies and strategies for prevention and safety;
- Provide government with advice on planning and public health issues.

HCSP can be consulted by the ministers concerned, by the chairmen of relevant committees and the President of the Parliamentary Office for evaluation of health policies on any matter concerning prevention, safety or performance of the health system.

The HCSP has paid in the past particularly attention to the integration of users in the functioning of the health care system and involvement in the policy-making processes in health care.

### **Haut Conseil pour l'avenir de l'Assurance maladie,**

This entity consists of 58 members representing both sides of the parliament, the State, health insurance funds, medical professionals and health institutions, health consumers as well as other qualified experts. Le Ciss is participating in the work of this Council. The High Council has been assigned with four missions:

- To assess the health insurance system and its evolution;
- To describe the financial condition and prospects of health insurance schemes and assess the conditions required to ensure their sustainability;
- To ensure the cohesion of the health insurance system in terms of equal access to high quality care and a fair and equitable funding;

- To formulate, where appropriate, recommendations or proposals about meeting the objectives of financial stability and social cohesion in the health system.

#### **Mission des associations et de la représentation des usagers.**

This is a body within the Ministry of Health that facilitates the participation of patient/consumer in the various structures of the health system.

#### **4. Other issues**

##### **Relations with the pharmaceutical industry:**

This is a “sensitive subject”, according to all the interviewees; it is well known that the pharma industry gives considerable support to HCPOs. HAS has published in 2010 an overview of the contributions of the pharma industry to HCPOs (article 74 of HPST law). This can be considered as a first step towards more transparency. In the public debate the funding of HCPOs by the pharma industry is often used as an argument to raise doubts about the independence of HCPOs.

Condition for being acknowledged by MoH: not more than 30% funding by the p.i.

##### **International activities**

The CISS is a member of the European Patients Forum (EPF). Le Ciss is also active in the framework of Active Citizenship <http://www.activecitizenship.net/>. The big HCPOs in France are very active within their own categorical international structures.

Currently, the Ciss is considering to organize an international conference in fall 2013, aiming at increasing the awareness of patients’ organisations in the different EU Member States of their role in implementing the EU Directive on cross-border health care. Furthermore the conference aims to encourage involvement of patients’ organisations in the definition and dissemination of information on this issue, and to stimulate co-operation between stakeholders.

In general the problems with HCPOs in participating in international activities are: financing, knowledge, expertise, continuity, language barrier.

## 4. Germany

### 1. Organisations

Germany has many HCPOs. The total is estimated at 70.000, of which the vast majority consists of very small local groups. There are at federal level about 100 bundles of groups. The terminology "Patients' groups" is in German legislation used both for patients/consumers ("Betroffenen"), and advisors/supporters ("Berater").

Some examples:

#### Patients' organisations ("Betroffenen"):

##### Selbsthilfe-Organisations:

- **BAG Selbsthilfe** <http://www.bag-selbsthilfe.de>  
(Die Bundesarbeitsgemeinschaft Selbsthilfe von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen)

An umbrella organisation with more than 100 big HCPOs as members. BAGS is the umbrella for organisations for the disabled and patients with chronically diseases and their families. Activities: advocacy at all policy levels, information, support for member organisations.

Example of an important member-organisation: **Umbrella organization for Rare diseases: ACHSE** <http://www.achse-online.de>, which has about 90 member-organisations.

- **Forum chronisch kranker und behinderter Menschen**, <http://www.der-paritaetische.de/>

Established in 1986 as an association of 37 out of the 92 national HCPOs that are member of the Paritaetischen Gesamtverband. This forum represents the interests of chronically ill and disabled people both within the Paritaetischen and outside this organisation. The Paritaetischen Gesamtverband supports these activities at federal level and at Bundesland level.

##### Sozialverbände<sup>42</sup>

- **Sozialverband VDK** <http://www.vdk.de>

Established in 1950 under the name: "Verband der Kriegsbeschädigten, Kriegshinterbliebenen und Sozialrentner Deutschlands e. V." as an organisation of war victims. Has developed itself into a big modern union of patients, disabled, pensioners, etc. Has 1,5 mln members and is the biggest union in Germany. Is active in all kinds of social insurance issues.

- **Sozialverband SOVD** <http://www.sovd.de/>

Der SoVD represents the interests of pensioners, patients, clients of health insurance funds and the disabled. Offers its members a wide-spread network of offices or representatives (3.000) where they can get advice on all kinds of social issues, including social/health insurance questions, And gives support in legal procedures. SoVD is a big organisation with about 525.000 members.

- **Co-operation structure: Deutscher behindertenrat (DBR):** <http://www.deutscher-behindertenrat.de/>

The DBR brings the above mentioned Selbsthilfe-organisations (BAG Selbsthilfe, The Forum), the Sozialverbände (VDK and SOVD) and Behinderteverbände (a number of organisations for the disabled)<sup>43</sup> and a number of other organisations together in a co-operation structure of in total about 50 organisations, representing more than 2.5 million people affected by illness or handicaps in Germany.

The DBR sees itself as a platform for common action and exchange of experiences. It is not an umbrella organization and therefore does not possess a general mandate of representation: the

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<sup>42</sup> Some interviewees had the opinion that the Sozialverbände are actually more "Berater" than "Betroffenen"

<sup>43</sup> Also called the "Three pillars"

member associations maintain their autonomy and as a rule represent their interests themselves. The DBR represents the member organisations in the G-BA (see below)

### Supporting organisations (“Berater”):

#### – VZBV: Verbraucherzentrale

<https://www.vzbv.de/start/index.php?page=english>

The Federation of German Consumer Organisations is a non-governmental organisation acting as an umbrella of 42 German consumer associations. It represents the interests of consumers in public and vis-à-vis legislators, the private sector and civil society.

Goal is to protect and empower the consumer. Has consumer centres (Verbraucherzentralen) in all the 16 German states (“Bundesländer”, Germany has 16 states), while product testing is undertaken by the [Stiftung Warentest](#) (tests amongst others the quality/price of health insurances and products related to health)

#### – DAGSHG: Deutsche Arbeitsgemeinschaft Selbsthilfegruppen. <http://www.dag-selbsthilfegruppen.de>

DAGSHG is an organisation for support of HCPOs. Exists since 1982. Members of DAGSH are organisations that support HCPOs at local level („Selbsthilfekontaktstellen”, HCPO contact offices), and other workers/organisations in this field.

DAGSHG provides a basic support for the member organisations as well as support of individually selected self-help projects. DAGSHG represents more than 300 contact offices<sup>44</sup> of self-help organisations. The national, broader issues (“themenübergreifend”) are administered by NAKOS, see below.

#### – NAKOS <http://www.nakos.de/site/>

NAKOS is the national information, service and network organisation of DAGSHG. Supports HCPOs and gives also information about HCPOs to patients/consumers and their families. Runs a great number of information activities regarding HCPOs (see below: Monitoring), and works on general advocacy for HCPOs.

#### – BAGP <http://www.gesundheits.de/bagp/> Bundes-Arbeits-Gemeinschaft der PatientInnenstellen.

The BAGP is an association of regional independent health (advisory) services, mostly the “Gesundheitsladen”<sup>45</sup> and exists since 1989. Activities of the BAGP focus on information, consultancy, participation, general support, general advocacy at policy levels.

#### – UPD Unabhängige Patientenberatung Deutschland. <http://www.unabhaengige-patientenberatung.de/>

The UPD is an umbrella of 21 independent offices for patients’ support (Patientenunterstützung- or Patientenberatungsstellen). These offices give information and advice (medical, legal, psycho-social) only to individuals; general advocacy is not allowed. The UPD is a co-operation structure of the VdK, VZBV and the VUP (Verbund Unabhängige Patientenberatung, a coalition of amongst others BAGP and SOVD.) There is at least one UPD office in every state (except Bremen).

The budget is about 5 mln per year, financed by the health insurance funds, see below). Currently the UPD is commissioned by the umbrella of the health insurance funds (GKV Spitzenverband) to create a nationwide infrastructure to support HCPOs.

### Financing of HCPOs

- Some supporting organisations like VZBV get federal government funding;
- In general there is no (direct) federal government funding of HCPOs or the Sozialverbände but all Bundesländer fund HCPOs; in 2007 in total 11,5 mln euro<sup>46</sup>

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<sup>44</sup> These offices function independent from VZBV, UPD and BAGP (see below).

<sup>45</sup> “Health shops”, all though they don’t sell anything (they give advice, consultancy, etc)



- Under German legislation the health insurance funds must give support to self-help groups/organisations and their contact offices. Since 2000 health insurance funds are obliged to finance self-help groups with 0,55 euro per year for every insured person, which means that the self-help groups are funded by the health insurance funds which in 2008 amounted in total to about 40 mln euro yearly<sup>47</sup>. (§ 20 SGB V, fünftes Sozialgesetzbuch: [http://www.gesetze-im-internet.de/sgb\\_5/\\_20c.html](http://www.gesetze-im-internet.de/sgb_5/_20c.html)).
- Also in 2000 the health insurance funds were obliged to invest 5 mln euro yearly (for a period of four years) in independent offices for patients' support (unabhängiger Informations und Beratungsstellen, § 65b SGB V: [http://www.gesetze-im-internet.de/sgb\\_5/\\_65b.html](http://www.gesetze-im-internet.de/sgb_5/_65b.html)) see above: UPD Unabhängigen Patientenberatung Deutschland
- In general the HCPOs are financed by membership fees, donations, contributions and by corporate funding, mainly the pharma industry, etc.

## 2. Monitoring and research on HCPOs, information for patients:

- **NAKOS** <http://www.nakos.de/site/datenbanken/> publishes on a regular basis information about HCPOs: The "Red", "Green", "Blue", "Orange", "Yellow" addresses: information about all kinds of German HCPOs, both at local and national level, supporting offices, HCPOs and supporting organisations at international level, etc. Furthermore NAKOS publishes comprehensive reports on **the functioning of HCPOs (financing, activities etc), and a wide range of other reports and materials**. See also: <http://www.nakos.de/site/materialien/fachinformationen/studien/>
- **The white List** <http://www.weisse-liste.de/>, a project of the Bertelsmann Foundation and HCPOs, provides information to the public and HCPOs about the quality of hospitals and other care providers
- **Patient University** : The first university for **patients** in Germany was founded in Hannover in October 2006 ([www.patientenuniversitaet.de](http://www.patientenuniversitaet.de)). The university's goal is to offer health education and empowerment to citizens and patients. The university aims to address both experts and the general population. Specific educational provisions, which are oriented toward citizens, patients and their representatives, are designed to impart knowledge about responsibilities when treating illnesses, as well as knowledge of the structures of the health care system and methodological background for the assessment of study outcomes. Driving force behind the Patients University is Prof. Marie-Luise Dierks, Institut für Epidemiologie, Sozialmedizin und Gesundheitssystemforschung, Medizinische Hochschule Hannover.

## Other German research institutes on health issues (possibly relevant for an information network on patient participation)

- **Zentral Institut** <http://www.zi-mannheim.de>  
The Central Institute of Mental Health (CIMH) is a globally recognised centre of modern psychiatry delivering outstanding science, research and teaching in partnership with institutions at home and abroad. The researchers at the CIMH, which was founded in 1975, examine the ways in which mental illness occurs, develops and is medically treated.
- **Ärztliches Zentrum für Qualität AZQ** <http://www.aeqz.de>  
The German Agency for Quality in Medicine (AQuMed/ÄZQ) is the German Physicians' Centre of Excellence for Evidence based Medicine, Knowledge Management and Patient Safety.

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<sup>46</sup> NAKOS: Selbsthilfeförderung durch die Bundesländer in Deutschland im Jahr 2007, also indicates that gradually the total amount of funding is decreasing in the last years (14 mln euro in 1993).

<sup>47</sup> Welcome speech at the expert meeting 'Networking in Europe – Chances, Challenges and Demands' by Mrs Helga Kühn-Mengel, Patient Commissioner, 20 August 2009

Established in 1995 and located in Berlin, co-ordinates healthcare quality programmes with special focus on evidence-based medicine, medical guidelines, patient empowerment, patient safety programs, and quality management.

- **Bundeszentrale für gesundheitliche Aufklärung (Health Education)**  
<http://www.bzga.de/>  
This is the Federal Centre for Health Education, established in 1967, and has the following tasks, in particular:  
Elaboration of principles and guidelines related to the content and methods of practical health education, vocational training and continuing education of persons working in the field of health education, coordination and intensification of health education in Germany, international collaboration.
- **The Robert Koch Institute** <http://www.rki.de>  
The Robert Koch Institute (RKI) is the central federal institution responsible for disease control and prevention and is therefore the central federal reference institution for both applied and response-orientated research as well as for the Public Health Sector.
- **WINEG**  
[www.wineg.de](http://www.wineg.de)  
WINEG ist the scientific institute of the Techniker Krankenkasse (TK) (Health Insurance Fund of the technical professionals); addresses political and scientific issues relevant for the insured members.
- **WIdO** <http://www.wido.de> – Scientific Institute of the AOK <http://www.aok.de/bundesweit/>, the largest German health insurance fund (24 mln clients); WIdO organises regularly surveys amongst health care consumers
- **Gesellschaft für Versicherungswissenschaft und –gestaltung (GVG)** <http://www.gvg.org/>  
A very broad discussion platform for social policy issues. Runs a number of projects that offer all kinds of support both at national and at international level.  
One of the projects is **gesundheitsziele.de** (“Health Targets”), originally the implementation of the WHO Health for All targets.

### 3. Forms of patients’ participation in Germany

- An important measure of the government was introducing the right of patient/consumer groups to participate in the **Federal Joint Committee. (G-BA, Gemeinsame Bundesausschuss** <http://www.g-ba.de/institution/sys/english/>) which was created in 2004 to replace several sectoral committees. Within the legal framework, the G-BA has wide-ranging regulatory power to formulate and implement in detail what services will be provided by the insurance funds. One of its most important responsibilities is to assess new methods of medical diagnosis and treatment, which must receive a positive evaluation vis-à-vis benefits and efficiency before they can be reimbursed by the insurance funds. Since 2004 national groups representing patients were given the right to file applications and to participate in the consultations of the G-BA. Groups that are allowed to participate are: Deutscher Behindertenrat, BAGP, DAGSHG, and VZBV<sup>48</sup>. Although the groups are allowed to participate, they do not have voting rights.  
It is estimated that around 100 technical experts are involved as permanent patient representatives in the work of the Federal Joint Committee, and about 100 experts on a ad hoc basis. By law of 1 January 2007 the position of these representatives has been strengthened, amongst other by allowing them a reimbursement for participation activities (more than just travelling expenses). The G-BA has established a special department for support for patients’ representatives (Stabstelle Patientenbeteiligung, 2 fte).
- **Participation in health insurance funds (Die Krankenkassen)**  
There are about 160 Health insurance funds, that cover the insurance of almost 90 % of the population. (umbrella: Der GKV-Spitzenverband <http://www.gkv-spitzenverband.de>). As regards health insurance, the G-BA is the most important policy –making body, but some powers have

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<sup>48</sup> Articles 140 f and 140 g Sozialgesetzbuchs Fünftes Buch (SGB V), See for the text of the regulations



been given directly to the individual health insurance funds, e.g. the license to contract providers directly, to negotiate rebates with pharmaceutical companies and to negotiate contracts with manufacturers.

Representatives of the insured are allowed to participate in the management boards of the insurance funds. However there is criticism on the way these representatives are nominated (there is no open democratic procedure)<sup>49</sup>.

- **Participation at Bundesland- level:** HCPOs participate in (a limited number of decisions of) commissions that decide whether care providers, like medical doctors or psychotherapists are allowed to work in certain areas or institutions (“Zulassungsausschüsse” <http://de.wikipedia.org/wiki/Zulassungsausschuss>). They also participate in “Berufungsausschüsse”, bodies that decide on appeals against decisions of the Zulassungsausschüsse, and in the “Landesausschüsse für Berufsbildung”, commissions that advise the Bundesland governments on the planning of the number of professionals needed in health care.

#### **Participation in quality development, research institutes, etc**

- **IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen** (Institute for Quality and Efficiency in Health Care, <http://www.iqwig.de/>), an independent scientific institute that investigates the benefits and harms of medical interventions for patients. IQWiG regularly provides information about the potential advantages and disadvantages of different diagnostic and therapeutic interventions. A representative of HCPOs has an advisory function in this institute. Via its department of “Health., Information”, the IQWiG develops overviews of current medical knowledge to provide comprehensible information on quality and efficacy of health services also for laypersons.
- **Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)** <http://www.bfarm.de>  
The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) is an independent higher federal authority within the portfolio of the Federal Ministry of Health. The authority's seat was transferred to Bonn in the course of the Government's move to the capital. The BfArM is the successor to the Institute for Drugs (Institut für Arzneimittel) founded on 1 July 1975 as part of the now dissolved Federal Health Office (Bundesgesundheitsamt, BGA). Patients' organisations participate in several activities of this institute.
- The **AQUA-Institut** <http://www.aqua-institut.de/>, Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen (development of quality indicators). This institute, which was founded in Göttingen in 1995, is one of the most experienced and successful providers of concepts and innovative problem solutions in the area of quality improvement in health care in Germany. AQUA is one of Germany's pioneers in peer-review groups (quality circles) in medicine, of the evaluation of new care models, the development and implementation of quality indicators, of patient surveys and data-based quality management. AQUA maintains intensive co-operation with a large number of external experts as well as patient representatives.

#### **Other examples of organisations in which HCPOs participate:**

- **The German Agency for Health Technology Assessment (DAHTA)** <http://www.dimdi.de>
- **Gematik** (electronic health card) <http://www.gematik.de/cms/de/startseite/index.jsp>

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<sup>49</sup> Die neue Patientenbeteiligung in Deutschland, Christoph Kranich, Verbraucherzentrale Hamburg, 2004

- **Aktionsbündnis Patientensicherheit** (APS) <http://www.aktionsbuendnis-patientensicherheit.de/>, a platform of care providers, HCPOs and others aiming at improving patients' safety in health care by collecting information on mistakes/accidents and trying to develop prevention strategies.

#### 4. Patients' policy of the Government

##### Patients' policy:

The main characteristic of German health care policy is that the German government provides the legal framework and delegates further regulation to a large extent to the self-governing corporatist bodies of both the health insurance funds (Krankenkassen) and the medical providers' associations. These bodies formulate and implement in detail which and under which conditions services will be provided.

Since the 70s there has been a growing number of initiatives aiming at strengthening the position of health care consumers/patients in Germany like the establishment *Patientenstellen* (patients' offices) and *Gesundheitsläden* (health' "shops"), that gave legal advice to patients. Another development was the growing number of self-help groups (*Selbsthilfegruppen*).

A very important development was end of the 80s the involvement of the national consumer organisations (*Verbraucherzentralen*) in the health consumer field, in reaction to a medicine-scandal. As regards the federal Government, for a long time little attention was paid to the issue of health consumers/patients' policy. A major change took place in 1998 when the Green party participated in the government and several measures were taken to strengthen the position of health care consumers/patients. Since then the federal government has continued this policy.<sup>50</sup>

Some examples:

- The obligation for the *Krankenkassen* to invest on a yearly basis 5 mln euro in the UPD, and the obligation to finance 0,55 euro per insured person for self-help groups (see above)
- An important measure of the government was introducing the right of patient/consumer groups to participate in the **Federal Joint Committee. (G-BA, Gemeinsame Bundesausschuss** <http://www.g-ba.de/institution/sys/english/>, see above.
- In the recent health reform of 2003 the position of a **Patient Commissioner** (a member of parliament) at federal level was created (*Beauftragter der Bundesregierung für die Belange der Patientinnen und Patienten* <http://www.patientenbeauftragter.de/><sup>51</sup>)  
There is also one regional Patient Commissioner in Berlin.<sup>52</sup>
- **Patients' rights:** Some rights in the relation between the insurance funds and the insured are regulated in social legislation, but individual patients' rights are mainly formulated in jurisprudence on constitutional rights. In 1999, the Conference of German Health Ministers adopted the document "Patient rights in Germany today". In this document it is explicitly stipulated that patients have amongst others the right to clear, expert and satisfactory education and counselling in order to explain the usage and risks of diagnostics, advantages and risks of the treatment or non-treatment options.

Patients' organisations, but also other stakeholders like the Advisory Council on the Assessment of Developments in the Health Care System (*Sachverständigenrat für das Gesundheitswesen*) have asked repeatedly for codification of these patients' right in legislation. The current government is now working on this issue (responsibility of the Patient Commissioner).

#### 5. Relations with the pharmaceutical industry:

Currently there is a rather polarized debate going on between the pharma industry and the HCPOs about the right to participate in the G-BA and other policy-making bodies. The pharma industry has objections against the existing "closed" system (see above). On initiative of the pharma industry a report on the good practices in patients' participation in health systems has been published and even a draft proposal to amend the current legislation has been written.<sup>53</sup>

<sup>50</sup> There is no comprehensive policy document on patients' policy, neither is there a special department for patients' policy in the Ministry. There is a *Referatsleiterin des Referates 317; Gesundheitsrecht, Patientenrechte*: Mrs Bettina Godschalk.

<sup>51</sup> Mr. Wolfgang Zöller

<sup>52</sup> Mrs. Karin Stötzner

<sup>53</sup> Prognos: *Patienten- und Bürgerbeteiligung in Gesundheitssystemen*, [http://www.prognos.com/Publications.520+M58d097a3b7d.0.html?&tx\\_atwpubdb\\_pi1%5BshowUId%5D=289](http://www.prognos.com/Publications.520+M58d097a3b7d.0.html?&tx_atwpubdb_pi1%5BshowUId%5D=289) and Dierks und Bohle:

It is unknown how much the industry contributes to HCPOs (although there is a growing number of pharmaceutical companies that publish information about these contributions). Some interviewees also expressed their concern about the phenomenon that the pharmaceutical industry gives support to experts (often care professionals) that are active within HCPOs (as medical advisors or otherwise). An interesting initiative is taken by BAG Selbsthilfe and the Forum im Paritaetischen to start a monitor-procedure in case of suspicions that HCPOs receive too much corporate funding (often by the pi) <http://rehanews24.de/archives/585>

## **6. International activities**

The big German HCPOs are active at international level. The DBR is a member of the European Disability Forum, NAKOS is active in the European Expert network on self-help support (organised the Tenth European Expert Meeting on Self-Help Support, Berlin September 2009). The big categorical HCPOs are participating in their own international networks. See the "Orange" and "Yellow" addresses of NAKOS. The VZBV participates in BEUC (International umbrella of consumer organisations) and Consumers International.

There is no comprehensive overview or analysis of the international activities of German HCPOs. According to the interviewees most HCPOs are confronted with a lack of resources and continuity of expertise as well as a general lack of information about the international policy developments.

## 5. The Netherlands

### 1 Organisations

#### Organisations, umbrella's

It is estimated that there are 200-250 consumers/patients' organisations in The Netherlands. The majority consists of categorical organisations that represent the interests of people with specific disorders like genetic diseases, muscular diseases, rare diseases, diabetes, cancer, rheumatism, etc. There are five general umbrella organisations which incorporate the categorical organisations or represent (partly) their interests.

1. The Federation of Patients' and Consumers' Organisations in the Netherlands (**NPCF**) ([www.npcf.nl](http://www.npcf.nl)), aims to strengthen the position of patients and consumers of health care by promoting their common interests.
2. The Dutch Council of the Chronically ill and the Disabled (**CG-Raad**) represents the interests of organisations of chronically ill and disabled people, with a special focus on full participation in society (education, labour, income, mobility and care) ([www.cg-raad.nl](http://www.cg-raad.nl)).
3. The federation of organisations for elderly people: **CSO**. Members are the Unie KBO, PCOB, NOOM en NVOG ([www.ouderenorganisaties.nl](http://www.ouderenorganisaties.nl)).
4. The federation of organisations of people with psychiatric disorders: **Landelijk Platform GGZ** ([www.platformggz.nl](http://www.platformggz.nl)).
5. The federation of (organisations of) of mentally disabled people, their parents and other relatives: **Platform VG** ([www.platformvg.nl](http://www.platformvg.nl)).

#### Disease specific organizations /umbrella's of specific organizations:

There are hundreds of categorical patients' organizations The most important are:

- Nederlandse Federatie van Kankerpatiëntenverenigingen (NFK), a federation of 27 cancer patients organisations [www.nfk.nl](http://www.nfk.nl);
- Diabetes: de Diabetes Vereniging Nederland (DVN) , [www.dvn.nl](http://www.dvn.nl)
- Rheumatism: de Reumapatiëntenbond [www.reumabond.nl](http://www.reumabond.nl) ;
- Cardiovascular diseases: de Hart- en Vaatgroep voor mensen met hart- en vaatziekten <http://www.hartenvaatgroep.nl/>
- Astma: Het Astma Fonds patiëntenvereniging <http://www.astmafonds.nl/>
- Muscular Diseases: Vereniging Spierziekten Nederland (VSN) <http://www.vsn.nl/>.
- Rare and Genetic diseases: VSOP, an alliance of 70 patients' organisations [www.vsop.nl](http://www.vsop.nl)

#### Funds of Patients Organisations (who very often fund scientific research and other projects):

KWF Kankerbestrijding ( Dutch Cancer Society) <http://www.kwfkankerbestrijding.nl/Pages/Home.aspx>  
Hartstichting (Netherlands Heart Foundation) <http://www.hartstichting.nl/>  
Diabetesfonds (Dutch Diabetes Foundation) <http://www.diabetesfonds.nl>  
Nierstichting (Dutch Kidney Foundation) <http://www.nierstichting.nl/>  
Reumafonds (Rheumatism) <http://www.reumafonds.nl/>  
Astmafonds (Astma) <http://www.astmafonds.nl/> name will be changed into: Longfonds = "Lung Fund")

These Funds have their own umbrella organisation: Vereniging Fondsenwervende Instellingen <http://www.gezondheidsfondsen.nl>

As a relatively new development there are some patient-driven funds, that are actively participating or investing in research activities, examples: ;

#### The Duchenne Parent Project

<http://www.duchenne.nl/>

(Raises funds and stimulates Duchenne research)

#### Stichting Alpe d'HuZes

<http://www.opgevenisgeenoptie.nl/>

(invests in Cancer research, last year a budget of 20 mln euro was raised by this Foundation)

### **Financing, professionalization:**

Main sources of income for HCPOs are funding by the government (see below) and membership fees. Other important sources are private funds (many categorical organisations have their own funds), research funds and other national welfare funds. The number and the amount of financial contributions by the pharmaceutical industry is limited, the insurance companies do not - or very seldom- support HCPOs (all though some companies compensate membership fees of HCPOs).

The financial situation of HCPOs differs widely, due to the situation that some HCPOs have their own private funds.

As regards human resources, an increasing number of HCPOs (the majority) has one or more paid staff members or pays for out-contracted functions (financial administration, membership management, trainings, etc). There is a number of commercial organisations that facilitate HCPOs (see below). The bigger umbrella organisations and categorical organisations have a considerable staff capacity at their disposition (e.g. NPCF 35 full time equivalent staff, CG-Raad 40 fte).

However, as from 2012 the rules for funding HCPOs have changed considerably (see par 4: New funding system) ; It is expected that the staff capacity of the umbrella's will almost be cut in half.

As regards the **vision of the HCPOs on their future role**, a working party of experts published a report on this issue in June 2009; "De kracht van diversiteit" (The force of diversity) (downloadable on [www.pgosupport.nl](http://www.pgosupport.nl)). This report has been made on request of the MoH, but it is the intention that this report delivers input for discussion between HCPOs

**2. Monitoring, research:** Dutch HCPOs are very well monitored. Two important monitors are:

- **Brancherapport patienten- en consumentenbeweging** (Sectorial report patients' and consumers movement): a production of CG-Raad, LPGGz, NPCF, Platvorm VG  
[PGO Monitor 2010 Organisaties van patiënten, gehandicapt en ...](#)

- **Gids Patiënteninformatie**, (Guide Patients' information), yearly publication of the NPCF, contains addresses of all national organisations representing patients, health consumers, disabled, elderly, including data on supporting organisations that operate at regional levels (Zorgbelangorganisaties, platforms, etc) ([www.npcf.nl](http://www.npcf.nl)).

### **Research:**

A lot of research is done on the functioning of Dutch HCPOs, both within the health care system and in society as a whole<sup>54</sup>. Several research institutes have published studies on patients' organisations and issues that are relevant for them, like: **VU University Medical Centre**, Amsterdam

<http://www.vumc.com/patientcare/>, the **Athena Institute of the VU University** Amsterdam.

<http://www.falw.vu.nl/nl/onderzoek/athena-institute/>, **IBMG** of the Erasmus University, Rotterdam

<http://www.bmg.eur.nl/>, the **Verweij Jonker Institute** <http://www.verweij-jonker.nl/>, **Trimbos institute**

<http://www.trimbos.nl/>, **Vilans** <http://www.vilans.nl/>, **Movisie**, <http://www.movisie.nl/>, **NIVEL**

<http://www.nivel.nl/>, **Julius Centre** (University of Utrecht) <http://www.juliuscentrum.nl/julius/>

Research on the patients' movement is mainly organised and funded by **ZonMw** <http://www.zonmw.nl/>: a national organisation that promotes quality and innovation in the field of health research and health care, initiating and fostering new developments. ZonMw also actively promotes knowledge transfer and implementation, ensuring knowledge is exchanged between all relevant stakeholders (health researchers, health professionals, patients/consumers and the general public). ZonMw runs several programs in which HCPOs play an important role. ZonMw (and the VSB fund) have started the Program: "Patients' participation in research, quality and policy" (budget 2,7 mln euro, 2009-2012). Aim of this program is to stimulate patients' participation in these fields, to analyse the experiences of patients' participation and to find out how these experienced can be applied.

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54 Recently: Stille Kennis. Patiënten- en gehandicapttenorganisaties: waardevolle bronnen van informatie. M.Berk, G. Schrijvers, e.a.. Julius Centrum, Utrecht 2008

Currently about 26 projects are funded by this program, some examples:

- Insured influence. Implementing consumer perspectives in mental health care contracting by insurers.
- Patient participation in quality improvement: evaluation and monitoring of a number of subsidized projects.'
- Patient criteria to evaluate health research, policy and quality. What patient criteria do we currently have and are these useful for patients?
- Vulnerable elderly (80+) in the hospital. A study into patient participation from a care ethical perspective
- Effectiveness of client participation at a local level the functioning of SSA (Social Support Act) councils
- Creating an information network on patients' participation in quality, policy and research
- Further development of a "Toolbox patients' participation".
- "Dialogue-model" ,a methodology for health research agenda setting on basis of a dialogue with patients.
- Evaluation of programming and implementation of research agendas
- "Tailored Encounters" : A co-operation between researchers and patients organizations, aiming to increase the sensitivity of researchers for perspectives of people with cardiovascular diseases.

See for more information about these and other projects and for summaries in English:

<http://www.zonmw.nl/nl/programmas/programma-detail/patientenparticipatie-in-onderzoek-kwaliteit-en-beleid/>, and click "Alle 26 projecten binnen dit programma")

### **Reports, literature about participation in medical research/innovation**

In the last few years quite a lot of publications on participation of patients' organizations in medical research/innovations have been published:

- **Advisory Council on Health Research (2007): Patient participation in health research. Publ. No 56.**
- **Health Council of the Netherlands (2011) : Medical products: new and needed!**

For this report, the Councils' Committee focused on the needs and wishes of those who make use of medical products: patients and care providers. On the basis of fifteen disease areas selected by the Committee, the desired products were identified with the aid of focus groups. This has yielded a long list of products, together with a wealth of information on which of these are considered to be important by users. It included surprising products such as navigation systems for the visually impaired and medications to suppress the itching suffered by burns patients.

- **several publications by Cees Smit and others:** Negen verhalen over patientenparticipatie in geneesmiddelenonderzoek (2009) (nine stories about patients' participation in medicine research), Fundamenteel onderzoek en patientenorganisaties: een verrassende combinatie (2011)(Fundamental research and patients' organisations; a surprising combination), De patient aan het roer (2011) (The patient on the helm), Een nieuwe horizon, de toekomst van de patiëntenbeweging in Nederland (2012) (A new horizon, the future of the patients' movement in The Netherlands). In these publications Cees Smit gives a comprehensive description of the position and activities of patients' organizations and points at an interesting tendency of patients' organizations gradually getting more active in the area of medicine research and innovation.

- There is quite a number of interesting publications on patients' participation in medical research by the **VU medical centre and the Athena institute of the VU University**, (Abma, Broerse, Visse and others, see literature list).



### 3. Participation of HCPOs

#### **Participation in policy processes, research programming, quality/guidelines development:**

There are numerous forms of regular communication structures between all stakeholders in health care including representatives of HCPOs. Several studies were recently done on patients' participation in research programming, development of quality standards and health care policy<sup>55</sup>. General conclusion was that participation of patients in these processes is institutionalized and professionalized; this fits in with the general Dutch culture of seeking consensus on important issues. Participation of HCPOs is considered as "self-evident". All the studies point at a number of problems: participation requires a professional attitude, capacity, knowledge and manpower of HCPOs, which they do not always have at their disposition. In some cases HCPOs are forced to join forces, at cost of their specificity.

One of these studies (The limits of patient power) argues that there are certain limits to the phenomenon of patients' participation (working load of HCPOs, confusion about roles and representativeness, etc).

#### **Participation in policy-making bodies:**

At national level there is no regulation on participation of HCPOs in the most important policy-making bodies such as the Medicines Evaluation Board. Neither are HCPOs invited to participate in Medical-Ethical Commissions. However, in some bodies like ZonMw, the Health Council, the Council for Public Health and Health Care, or the Health Insurance Board independent experts who are known to be familiar with the consumers/patients' view are invited to participate where relevant.

#### **Involvement in quality standards:**

A large number of organisations is developing quality standards in health care, in which often HCPOs are involved.

Furthermore some organisations run activities specifically focusing on quality as seen from the perspectives of patients:

- The **Stichting Klantervaring Zorg** has developed guidelines how to measure quality seen from the patients' perspective. This organisation manages the **CQ-index** (Consumer Quality Index). This is a standardised method to measure experiences of patients and consumers with care providers and Insurance companies; it consists of questionnaires, and guidelines for collecting, analysis and reporting of data. This Index is developed, in collaboration with other organisations for several treatment and care sectors.

- The NPFC and other HCPOs: **Kwaliteit in Zicht** <http://www.programmakwaliteitinzicht.nl/>

- **Miletus**: a joint venture of some health insurance companies <http://www.stichtingmiletus.nl/>

#### **Quality Institute for Health Care**

Recently the MoH announced<sup>56</sup> the establishment of a new Quality Institute for Health Care in 2013. In this institute a number of current (functions of) organisations that deal with quality issues will be bundled.<sup>57</sup> Patients' organisations are supposed to play an important role in this institution, however also here no formal position for po's in this institute is foreseen.

**Involvement in the Health Insurance System:** As part of the Governments' policy to liberalize the health insurance system (see hereafter), the government has funded in 2006-2008 a 6 mln euro development project, encouraging HCPOs to strengthen their position towards insurance companies. About 25 projects have been funded, divided in four areas: quality, negotiations and contracting, information and advice, monitoring ([www.zekerezorg.nl](http://www.zekerezorg.nl)).

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55 Zeggenschap in wetenschap, Tineke Abma en Broerse, 2007; Inventarisatie patiëntenparticipatie in onderzoek, kwaliteit en beleid. H. van de Bovenkamp e.a., IBMG, Rotterdam 2008; The limits of patient power, Hester van de Bovenkamp, Rotterdam 2010;

<sup>56</sup> policy letter 25 May 2011, TK 29214, nr 59

<sup>57</sup> The Regieraad, Coördinatieplatform Zorgstandaarden, Zichtbare Zorg, Kiesbeter, activities of the Health Insurance Board, Centrum Klantervaring Zorg.

**Involvement in the development of medical guidelines:** patients' organisations are gradually more involved in the development of medical guidelines, because this involvement is considered by almost all professionals as self-evident, and very often a prerequisite for funding. Furthermore patients' organisations are getting more experienced in this area. See:

Inventarisatie patiëntenparticipatie bij richtlijnontwikkeling, Dr. Jacqueline Broerse and others, Athena Institute 2010, VU, Amsterdam

[http://www.zonmw.nl/uploads/tx\\_vipublicaties/Inventarisatie\\_patiëntenparticipatie\\_bij\\_richtlijnontwikkeling\\_1.pdf](http://www.zonmw.nl/uploads/tx_vipublicaties/Inventarisatie_patiëntenparticipatie_bij_richtlijnontwikkeling_1.pdf)

#### **Other forms of participation:**

##### **- Participation at local level:**

At local level participation in policy is structured by the Act for Social Support that regulates participation of HCPOs at the level of municipalities; this is often facilitated by the Zorgbelang organisations (See above)

##### **- Participation in institutions:**

The Act for Clients in Care Institutions requires that all care institutions must establish a "clients council" which must be informed adequately and be able to advise on all important decisions within the institution. These councils are supported by organisations like LOC and LSR (see above)

#### **4. Patients' policy of the Government**

In the Netherlands' the government has been working for quite some time to strengthen the position of the consumer/patient in public health (Patients' policy). Responsible Ministry is the Ministry for Health, Welfare and Sports (MoH). Within this ministry the Department for Market and Consumer (Markt en Consument) plays a coordinating role on this subject; apart from that several other departments are involved in patients-related issues (elderly, disabled, chronic diseases, etc)

The government has published in the past a number of documents on patients' policy (1981, 1983, 1988, 1992, 2001, 2003). In these documents the government has developed a comprehensive vision on strengthening the position of patients/health care consumers (legislation, participation, information, organisation). Since then, a number of White Papers and "policy letters" of the ministry on specific subjects have been published.

Recently the MoH published a letter on the future funding system of HCPOs, which contains some introductory remarks on governments' vision on the role and function of HCPOs in Dutch health care (letter of 25 May 2011, TK 29214 nr 59).

A strong impulse to strengthening consumer/patients policy was given by the reform of the health care insurance system. The Health Insurance Act of 2006 was the culmination of several years of Dutch policy aimed at achieving universal health care coverage. It requires all people who live in the Netherlands or receive an income from the Netherlands to pay an income-dependent contribution and to buy a basic health insurance from a private insurance company. Insurers are required to accept each applicant at a community-rated premium regardless of pre-existing conditions.

Guiding idea behind this reform is to create a market-driven system, to be kept in balance by insurance companies, health care providers and consumers.

Individuals can choose from among 14 private insurance companies and several related subsidiaries.

The MoH has set up a web site where consumers can compare all insurers with respect to price, services, consumer satisfaction, and supplemental insurance, compare hospitals on different sets of performance indicators, and can get more information about HCPOs, etc. (**KiesBeter**)

<http://www.kiesbeter.nl/algemeen/>.

#### **Legislation/patients' rights:**

Several important Acts have now come into effect: the Medical Treatments Contracts Act (Wet Geneeskundige Behandelingsovereenkomst, Stb. 1994, 837), the Client's Right of Complaint Act in the Care Sector (Wet Klachtrecht Cliënten Zorgsector, Stb. 1995, 308); Quality Act Care Institutions (Kwaliteitswet Zorginstellingen, Stb. 1996, 80) and the Participation Act for Clients in Care Institutions (Wet Medezeggenschap Cliënten Zorginstellingen, Stb. 1996, 204). A proposal for an Act on Clients'



Rights in the Care Sector is recently submitted to Parliament. This proposal puts the previous patients' rights in one Act and ameliorates some of these rights, in summary:

- this Act is applicable in all forms of relationships in care
- clients get the rights to be informed in such a way that they can make a well informed choice between care providers
- clients get the right to be informed about accidents/mistakes ("incidents") in the care sector
- easier access to complaint-procedures, independent judgment
- clients councils in institutions (see below) get more competences and better financing

## Funding

Almost all HCPOs receive funding by the government. Recently, the MoH has indicated that it considers the HCPOs to play a crucial role in the process of strengthening the position of health care consumers towards care providers, insurance companies, governments and other stakeholders. (Policy Letter 11 dec 2009, <http://ikregeer.nl/document/kst-29214-39>). The (future) role of HCPOs is often described as "a third party" in the health care playing field

## Former Funding system

Till 2012 there were two kinds of grants: organisation grants and project grants

The organisation grants consists of two components: one was independent of the number of members of the patients' organisation (30.000 euro), and the other depended on this (max 90.000 euro). The organisation were directly given by the MoH. The project grants were also given by the MoH, but on advice of an independent body: the Program Council (Programmaraad). The MoH formulated the priorities and criteria for the project grants<sup>58</sup>.

The total budget spent by the MoH on organisation grants and project grants amounted in total more than 40 mln euro on a yearly basis. About one quarter of this was spent to project grants<sup>59</sup>.

In May 2011 the MOH has published an evaluation of this funding system and introduced some considerable changes and cuts in expenditures in this system<sup>60</sup>.

## New Funding system

As from 2012 the total budget will gradually be brought back to 25 mln in 2015. Organisations for the elderly will no longer get funding. The organisation grants (in total 8,5 mln) will have a maximum of 35.000 euro in total, independent of the number of members. The Program Council is abolished, just as the Project grants for separate organisations; instead a "voucher" system is introduced, grants for projects in which at least 7 organisations work together (total budget 4,5 mln, each organisation is entitled to a voucher of 18000 euro). The budget of the umbrella organisations will be reduced to 4 mln in total, and also here an incentive is created for co-operation between these organisations (extra 2 mln). Furthermore a budget of in Total 4 mln euro is created for organisations that are active in support, professionalization, collecting and distribution of knowledge and developing quality standards (in relation to the new Quality Institute- see below)<sup>61</sup>.

## Other forms of support (often directly or indirectly funded by the government)<sup>62</sup>

- **PGOsupport**: Task: to support patients' organisations in all possible ways (information, advice, training, assistance in completing applications for governmental grants, etc). The website [www.pgosupport.nl](http://www.pgosupport.nl) facilitates these functions and stimulates information exchange between HCPOs.
- **Organisations specialized in participation of patients/clients in institutions**: **LOC**, (participation in mental health care) <http://www.loc.nl/>, **LSR** (disabled, long term care) <http://www.hetlsr.nl/>
- **Mezzo** (support informal carers) [www.mezzo.nl](http://www.mezzo.nl)
- **Per Saldo** <http://www.pgb.nl/>. Provides information and advice on everything to do with personal budgets (for explanation see website)

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58 Beleids- en beoordelingskader [http://www.fondspgo.nl/doc/pdf/Beleids-%20en%20beoordelingskader\\_20120.pdf](http://www.fondspgo.nl/doc/pdf/Beleids-%20en%20beoordelingskader_20120.pdf)

59 (Policy Letter, TK 2009-2010, 29214 nr 24) (<https://zoek.officielebekendmakingen.nl/ah-tk-20092010-2430.html>).

<sup>60</sup> Letter of 25 May 2011, TK 29214 nr 59

<sup>61</sup> And additionally 2 mln will be spent to three other institutes active in this area: Per saldo, CKZ, CBO

<sup>62</sup> It is not yet clear what the consequences of the Governments' budget cuts will be.

- **MEE-organisations** (advice for disabled people or patients with chronic diseases)

<http://www.mee.nl/>

- Support of regional and municipal patients' organisations: **Zorgbelangorganisaties**. There are 13 of these organisations active; they support and represent where relevant the interests of regional/municipal patients' organisations, they collect complaints, etc. They are financed by the provinces. They have a national organisation: **Zorgbelang Nederland** ([www.zorgbelang-nederland.nl](http://www.zorgbelang-nederland.nl)). The municipal level has in recent years become more important for HCPOs because of new legislation, the Act for Social Support (de Wet Maatschappelijke Ondersteuning, WMO), see below.

- A number of **commercial consultancy/supporting organisations** (administration, membership management, trainings, etc.)(no government funding)

## 5. Relations with the pharma industry

Generally spoken there is a good and constructive dialogue between the pharma industry and HCPOs. The financial contribution of the pharma industry to HCPOs is very limited (only a very limited number of Dutch HCPOs receive funding from the pharma industry<sup>63</sup>). There is an EFPIA code of conduct on the relationship between the pharmaceutical industry and HCPOs, further specified by the NPCF<sup>64</sup>.

## 6. Activities of Dutch HCPOs at international level

The NIZW-IC (The Netherlands' Institute for Care and Welfare, International Centre) has published in 2003 a very comprehensive study on the needs of Dutch HCPOs for "internationalization"<sup>65</sup>. The study showed a definite ambition and need of HCPOs for deploying international activities, however the majority of organizations had structural problems with collecting relevant information on international policy developments, were lacking skills and experience and above all had insufficient financial means to play an active, structural role at international levels.

In 2009 ZonMw has funded another study on the international activities of Dutch HCPOs<sup>66</sup>.

This report underlined in general the previous findings of the NIZW and observed a growing necessity of involvement of HCPOs in policy-making at international level (mainly EU). The report concluded that a number of HCPOs play an active role in international activities<sup>67</sup>; However in general very often only a few individuals within Dutch HCPOs are actively involved and have sufficient knowledge and experience.

Also this report noticed the structural problems of HCPOs to get access to the international fora and mentioned that neither in White Papers on patients' policy nor in funding rules or otherwise any attention is paid to stimulating international activities of HCPOs.

In 2010 ZonMw has funded a comparative pilot study on the position of HCPOs in seven EU countries<sup>68</sup>. Main conclusion: In many countries the organizations are confronted with problems of funding, lack of expertise, dependency on sponsors, problems with cooperation and representation which inhibit full and effective participation in policy making processes, not only at national level but also at international level.

Although all governments today adhere to principles of active involvement of consumers/ patients in health issues, there is almost no country that has recently formulated a comprehensive policy on strengthening the patients' movement.

A common underlying problem is that in most countries there is little overview of the situation of HCPOs, especially with regard to their actual functioning, representation, participation, quality and effectiveness. Collecting this information is therefore a necessary condition for policy development, both at national and international levels.

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63. Brancherapport patienten- en consumentenbeweging

64.

<http://www.pgosupport.nl/page/Kennisbank/EFPIA%20code%20of%20practice%20on%20relationships%20between%20the%20pharmaceutical%20industry%20and%20patient%20organisations>

<sup>65</sup> NIZW-IC: Ervaring over de grenzen, 2003

<sup>66</sup> Internationaal pgo-beleid, een verkenning by Bob Keizer, ZonMw 2009

<sup>67</sup> . For instance the VSOP, The Dutch Genetic Alliance, participating in EGAN, Eurordis, Epossi, EPF, ESHG

<sup>68</sup> Pilot study on the position of HCPOs in seven EU countries, by Bob Keizer and Ruud Bless

## 6. Poland

### 1. Organisations

#### Diversity of organisations

Organisations can be categorised in three major types:

#### Associations/umbrella's

Examples are:

- **Federation of Polish Patients (FPP)**, <http://www.federacijapp.pl/>, an umbrella of 75 organisations, founded in 2006 and driven by the need of consolidating the patients' voice.
- **Federation of Dialysis and Transplant Patients with** over 20 HCPOs as members, (<http://www.federacijapacjentow.pl>)
- **Cancer Coalition** <http://koalicjaonkologiczna.pl/>
- **Rheumatological Society**

**Specific organisations.** These are foundations/categorical organisations representing a special interest or target group. They are patients' driven, private initiatives or supported by and originating from commercial organisations. Poland has thousands of HCPOs often very small and locally operating. There are some 20 organisations of substantial size or importance.

**“Traditional” organisations** that exist for a very long time and provided many services within the ancient health care system (running clinics, other care services, etc). Examples are:

- **Society for Children's Help** – since 1919, 150 000 members <http://www.tpd.org.pl>
- **Polish Association of Deaf Persons** – since 1946, 100 000 members <http://www.pzq.org.pl>
- **Polish Association of Diabetics** – since 1950, covers over 500 000 patients <http://diabetyk.org.pl>

#### Funding of HCPOs

There is no direct structural funding of HCPOs by the MoH. Both the Ombudsman (see below) and the MoH have limited possibilities to fund project activities of HCPOs; In some cases the government runs competitions for funding specific projects.

There are no standard regulations for funding HCPOs but in case of funding the government demands transparency of HCPOs about their funding sources. Some HCPOs are hesitant to disclose this but when they don't provide the information they are considered to be “lobbyists” and cannot get funding from the government.

Examples of other State funding resources for HCPOs are:

- Operational Program Fund for Citizens Initiatives – since 2005 (current time frame 2009-2013). Some HCPOs receive project grants from this program.
- State Fund for Rehabilitation of Disabled Persons (PFRON), a legal entity adopted by the Employment of Disabled Persons Act of 9th of May, 1991. The financial sources of this fund consist of payments from employers not achieving the obligatory rate of disabled persons employment, subsidies from the state budget, legacies, donations, and other payments. All the “traditional” HCPOs are financed from this source.
- Local Governments (big and small cities, districts, counties) are obliged by law to be active in areas of health promotion, diseases prevention and healthcare services. A number of programs and campaigns are run every year and some HCPOs participate in these programmes.

Examples of other financial resources are:

- International foundations active in Poland, like the Open Society and the Polish-American Freedom Foundation, also provide funding for HCPO activities.
- Commercial corporations (especially the pharmaceutical industry) very generously provide funds to support HCPOs but not very often as unrestricted grants. Usually they fund concrete projects. More in general commercial corporations are only recently starting to acknowledge corporate social

responsibility activities. And at present only some big IT, electronic and industrial corporations are active in this area but HCPOs are still rarely funded by them.

- Insurance companies do not fund HCPOs, supposedly because there are no commercial health insurance products on the market. It is expected that in the future insurance companies will get more leeway on the health care market, and consequently this could create new funding opportunities for HCPOs.
- “Tax earmarking”: in Poland citizens who pay income tax can earmark 1 % of their income tax for a specific goal, e.g. for an “organisation of social usefulness”, which can be a HCPO.

## 2. Support, monitoring, research:

- An important supporting role is played by the **Institute of Patients’ Rights and Health Education**; <http://www.prawapacjenta.pl/>. This is a private foundation that facilitates meetings, provides trainings, organizes patients’ days and plays an active role in the European Citizens Network <http://european-citizens-network.eu/network>. It has a staff of 5 fte, gets funding from the government, and other sources like the Norwegian and the Swiss government, the pharmaceutical industry, etc
- Another relevant supporting organisation is **Klon Jawor** <http://www.klon.org.pl/> which helps HCPOs with project funding, giving legal advice, etc. Klon Jawor provides a very comprehensive database about the condition of the NGO sector and civil society in Poland, based on statistical and qualitative studies of civic participation. This database contains a lot of information about HCPOs. This knowledge is collected by regular studies conducted by Klon Jawor, including a nationwide survey of a representative sample of associations and foundations ("Situation of the third sector"), the International Index of Civil Society, conducted since 1997, etc. see [www.civicpedia.ngo.pl](http://www.civicpedia.ngo.pl)
- **Primum Non Nocere** <http://www.sppnn.org.pl/index2.html>. Established in November 1998. This is a NGO of persons who became victims of medical malpractice and their families. Gives juridical information and assistance of lawyers. Informs mass media. Takes active role in consultations on legislation.
- There is no **regular monitoring** of HCPOs (except the activities of Klon Jawor, see above). More in general there is in Poland a structural lack of monitoring of the functioning of the health care system (performance of hospitals, care providers, etc.) Research on patients’ organisations is not yet developed.

## 3. Participation of HCPOs

### Participation in policy processes

Participation of HCPOs in health policy issues is still very limited in Poland, in general the HCPOs do not yet have the feeling that they are really considered as a structural discussion partner. At present there is no structural participation of HCPOs in research programming or in the development of quality standards, but the impression is that the situation is improving: There is a positive trend of the government trying to involve HCPOs more in discussions on the reform of the health care system, and there are more activities and initiatives on the governments’ side to involve HCPOs, a more organized/structured approach, more coalitions launched (cervical cancer, orphan diseases, rheumatology), higher interest in public dialogue and readiness to establish partnership with decision makers.

## 4. Patients’ policy of the Government

### Patients’ policy

The issue of patients’ participation must be seen within the perspective of the general state of play of the Polish health care system that since the nineties has been confronted with severe problems: lack of funding, need for re-structuring of the insurance system, a brain drain of medical staff to other EU-countries, etc.

The need to enforce reforms was acknowledged as a high priority by the Government. New legislation (1997) created an insurance-budgetary model of health care funding. The state budget was no longer

responsible for funding health services. Since then a number of other policy changes have taken place (like decentralization) and this process is still continuing. New government proposals are expected on the introduction of privatized health care in Poland (a rapidly growing sector), revision of the role of insurance companies, changing the policy on clinical trials, policy on medicines, etc.

In line with the above mentioned policy changes in the 90s, patients' rights were introduced in consecutive laws on mental health, medical professions and transplantations. In 1998 the Ministry of Health (MoH)'s "Charter of Patient Rights" was presented. In 2001 the ministerial Bureau for Patient Rights was established. In 2005 the directive was amended and the Bureau was obliged to fulfil two goals:

- Monitoring health care institutions with regard to observing patient rights as presented in the laws;
- Providing information, handling and analyzing suggestions and complaints addressed to the Minister of Health concerning patient rights.

The law on patients' rights came into force in May 2009. For the first time all rights previously dispersed in different acts, have been codified. One of the major guaranties is that the rights will be observed by the newly created post of the Health Ombudsman (replacing the former Commissioner) whose mission is to strengthen the patients' position.

Still Poland lacks a concrete, comprehensive policy vision of the government on the role of HCPOs in health care and health care policy. All interviewees agreed that recognition of the role and function of HCPOs is essential, especially the role of the relatively "new" organisations compared to the "traditional" ones. A re-structuring and enforcing of the role of HCPOs is needed (including improving co-operation with other HCPOs). As future policy changes can be expected the need to develop a strong, independent patient consumer movement is getting more urgent.

HCPOs complain about the structural lack of information from the Governments' side and the bureaucracy and the lack of material support and scientific backing.

## **5. Relations with other stakeholders**

The pharmaceutical industry plays an important role as facilitator, initiator and is an important source of income for HCPOs. The pharmaceutical industry helps a lot with associations getting started, financing projects etc. They have a code of ethical conduct but it is not clear whether all pharmaceutical companies adhere to these guidelines.

HCPOs have ambiguous feelings towards the pharmaceutical industry: on the one hand the pharmaceutical industry is doing very good work, especially because the role of the government is weak, on the other hand HCPOs feel uncomfortable about being dependent on the pharmaceutical industry;

This is not only a problem for the HCPOs, but for the pharmaceutical industry as well; the pharmaceutical industry is quite hesitant in supporting HCPOs in order to avoid accusations from the side of the government and health care providers of promoting cost-generation by the HCPOs (i.e. encouraging them to ask for more and more expensive medicines).

The relationship with insurance companies is not yet developed, but considering the expected changes in the health care system, this might be an issue in the near future.

## **6. International activities**

Some Polish HCPOs play an active role at international levels. FPP is since 2008 a member of the International Alliance of Patients' Organisations (IAPO, the global umbrella for patients' organisations), an active member of the European Patients' Forum (EPF) and participates also in the Euro-Asian Initiative for Patients' Safety.

The Institute of Patients' Rights and Health Education plays an active role in the European Citizens Network.

The MoH is active in the EU Patient Safety Programme.

The categorical organisations and their umbrella organisations have many contacts with sister organisations in other countries.

Many international activities of HCPOs are financed by the pharmaceutical industry.

## 7. Spain

### 1. Organisations

Spain has many thousands of consumers/patients' organisations. It is estimated that there are about 30/40 patients' organisations of substantial size/importance.

There are two umbrella organisations:

**The Spanish Patients' Forum (Foro Español de Pacientes):** <http://www.webpacientes.org/fep/>.

24 member organisations, representing about 700.000 patients. Members are both large and small HCPOs.

Examples of the larger organisations are: Spanish Association Against Cancer (AECC), Familiar Hypercholesterolemia Foundation (FHC), Federation of Spanish Diabetics (FEDE), Spanish Federation of Rare Diseases (FEDER), Spanish Rheumatologic League (LIRE), Spanish Foundation of the Heart (FEC)<sup>69</sup>

The Spanish patients' Forum is considered as one of the most relevant stakeholders of HCPOs in health care policy. The FEP participates actively in more than 40 committees and commissions at national, regional and European level. It represents the interest of patients in the development of national health strategies.

**La Coalición de Ciudadanos con Enfermedades Crónicas**<sup>70</sup>, <http://coalicion.org/somos/somos.php>.

The coalition consists of five organisations with different size/character: European League of Diabetics [www.eurodile.org](http://www.eurodile.org), Spanish Liga of Rheumatology [www.lire.es](http://www.lire.es), Democratic Union of Pensioners (UDP) [www.mayoresudp.com](http://www.mayoresudp.com), National Association of Oostomized and Incontinence (Anoia), Confederation of Consumers and Users (CECU) [www.cecuc.es](http://www.cecuc.es)

Other groups of HCPOs working closely together are for example the **Spanish Confederation of People Affected by rheumatism (CONFEPAR)**, a non-profit organisation of more than 50 associations of people with rheumatic diseases throughout the country. <http://www.confepar.es/>, or

**FEAFES** (Confederación Española de Agrupaciones de Familiares y Personas con Enfermedad Mental), a confederation of organisations of people with mental illness and their families <http://www.feafes.com/FEAFES/HOME>

### Financing, support, professionalization

Financing of HCPOs mostly depends upon membership fees, some subsidies (amount is unknown) from national and regional authorities and contributions from the pharmaceutical industry, donations and income from specific events or publications.

There is no information available on the number of professional staff of HCPOs. It is estimated that only very few have one or more paid staff members.

Practical support to HCPOs is provided among others by the Universidad de los Pacientes, a project of the Josep Laporte Foundation and the Autonomous University of Barcelona, in collaboration with the FEP ([www.universidadpacientes.org](http://www.universidadpacientes.org)).

Another supporting function is fulfilled by the Patients and Citizens Network for Patient Safety Trainer, a initiative funded and promoted by the Spanish Ministry of Health, Social Policy and Equality (see below).

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<sup>69</sup> See for more organisations the list of participants of the Spanish patients safety network [http://www.msc.es/organizacion/sns/planCalidadSNS/docs/Declaracion\\_pacientes.pdf](http://www.msc.es/organizacion/sns/planCalidadSNS/docs/Declaracion_pacientes.pdf)

<sup>70</sup> According to many respondents this Forum is not very active at this moment

## 2. Monitoring, research,

**Monitoring:** In principle, organisations who want to receive government grants must be registered, but in practice this register doesn't provide much information on HCPOs. There is no systematic monitoring of the Spanish organisations but some other sources provide information on the problems of health care consumers: Healthcare public opinion surveys, hospital patient satisfaction surveys and the reports of the Patient Ombudsmen that operate in five regions in Spain.

**Research.** There is no research program on issues like the functioning of HCPOs, the participation of HCPOs in policy processes, effectiveness of patients' policy, etc. However, some years ago various studies have been carried out that are quite informative on the functioning of HCPOs in Spain.<sup>71</sup>

**Some research organisations and researchers** active in the field of patients' participation

- Joseph Laporte Foundation (Fundació Josep Laporte) (Joana Gabriele Muñoz, patient involvement and participation and Sergi Blancafort Alias, civic literacy)
- The Patients' University ((Universidad de los Pacientes – Universidad Autónoma de Barcelona)
- The Spanish Patients' Forum (Foro Español de Pacientes)

Others (relevant for a possible information network):

- The Advanced Research Techniques in the Health Services
- The Foundation for Health, Innovation and Society (FUNDSIS)
- The Spanish Institute of Scientific Medical Studies (INESME)
- The Carlos III Institute of Health
- The Canary Islands Research & Health Foundation
- The Center for Research in Health and Economics (CRES)
- The Gaspar Foundation for Health Research and Development
- The Institute for research on health services Foundation (IISS)
- Other institutes : see note<sup>72</sup>

## 3. Participation of HCPOs

### Participation in policy processes

At national level HCPOs do not participate in the important "Advisory Committee on the National Health Service".

However the "Open Health Forum" (Foro Abierto de salud) provides an informal platform for HCPOs to participate at national level.

As regards the regional level there is the Inter-territorial Health Board (Consejo Interterritorial de Salud) consisting of representatives of the national and regional health governments (ministries). The major problem for patients is that patients are not represented in the general board of this institution.

At the level of the autonomous regions HCPOs are also involved (with wide variability among regions) in advisory councils or programs of the healthcare departments.

These gaps with regard to patients' empowerment at national -and very specifically at regional level- impelled the Spanish Patients' Forum to create the regional patients' forums. One successful example is the Catalan Patients' Forum that participates in numerous and relevant health institutions such as the Catalan Institute of Health as well as in other important bodies of health and health policy decision making.

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<sup>71</sup> Spanish Report, Public Involvement in Healthcare and Health Policy, Joana Gabriele Muniz, Foro Espanol de Pacientes, Barcelona, Spain (2005); The Patient in Spain: National map of patients' associations. Madrid: Farmindustria Foundation, 2001; García-Sempere, A, Artells, J.J.: Organisation, functioning and expectations of patient organisations, Survey of key informers. Gac Sanit. 2005; 19(2):120-6

<sup>72</sup> Other organizations that are interested on patients' involvement in Spain are the OMC (Consejo General de Colegios Oficiales de Médicos de España), some regional health departments (Catalonia, Castilla La-Mancha, Andalusia, Madrid, Basque Country...) and Spanish Society for Health Service Customer Care (SEAUS), Catalan Institute of Health, Catalan Department of health, Basque Palliative Care Society (Sociedad Vasca de cuidados Paliativos), GuiaSalud. Institution of the Spanish NHS that elaborate clinical practice guidelines and the other clinical evidence-based, etcetera.



## **Participation in patient safety, research and quality development:**

The MoH plays a very active role and develops many activities on stimulating patients' policy, mainly within the framework of "patient safety". The NHS Quality Agency of the Ministry is developing a National Strategy on Patient Safety following the recommendations of WHO, Council of Europe and the European Commission. One of the main objectives of this strategy is to promote a patient safety culture among patients and citizens<sup>73</sup>. In 2008, 25 HCPOs signed the declaration "Patients for patient safety at the National Health System" (the Coalicion did, the SPF did not). Some members of these organisations form the Patients and citizens Network for Patient Safety Trainers at national level and have received a comprehensive training program (including prevention of healthcare associated infection, medication safety and others), technically coordinated by the Andalusian School of Public Health based on a contract with the MoH. The trainers of the network train other patients at regional level in order to expand the network.

Other departments within the MoH develop activities like Action plans on Chronical Diseases, Cancer, Rare Diseases, in which patients' organisations are involved,

Although there is appreciation for the stimulating work that has recently been initiated by the MoH the Spanish HCPOs would like more recognition of their role, more funding possibilities and more research on issues that are relevant for HCPOs (for example, on quality development, etc). In particular HCPOs ask for strengthening the legal basis of patients participation.<sup>74</sup>

There is no structural involvement in research programming, no structural involvement in quality processes

## **4. Patients' policy of the Government**

### **Patients' policy**

The Spanish Constitution guarantees all citizens the "right" to health care- including equal access to prevention, cure and rehabilitation services. Health care coverage under the Spanish system is nearly universal, estimated at 98.7% of the population. Spain's national health care system operates on a highly decentralized basis, giving primary responsibility to the country's 17 regions. The federal government provides each region with a budget whereby the region decides how to use it for the regional health system.

This decentralization has consequences for the patients' policy in Spain: The Spanish Ministry of Health, Social Policy and Equality (MoH, <http://www.msc.es/en/home.htm>) plays a co-coordinating role but it has to respect the autonomy of the regions. Consequently there are many regional differences.

Since 4-5 years the MoH pays attention to the issue of patients' policy.

Although there is no comprehensive paper on patients' policy in Spain, the main patients' rights have been settled in legislation. The MoH plays a very active role and develops many activities on stimulating patients' policy, mainly within the framework of "patient safety" (see above).

Other departments within the MoH develop activities like Action plans on Chronical Diseases, Cancer, Rare Diseases, in which patients' organisations are involved,

There is no formal co-ordination mechanism for patients' policy within the Ministry.

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<sup>73</sup> "Patients'safety" encompasses de facto many elements of patients'policy: information, research, participation, etc <http://90plan.ovh.net/~extranetr/>

<sup>74</sup> See also the Barcelona Declaration of patients' organisations (2003), the "political agenda" as formulated in 2006 by the SPF,



## **Funding/support**

The MoH provides funds to HCPOs albeit in limited amounts, but there is no comprehensive overview of the available budgets, neither are there regulations on state funding of HCPOs other than the requirement that the organisations must be registered.

## **5. Relations with other stakeholders**

Although there are no structural relations between the medical sector and the patients' movement (for instance no regular meetings, etc) many HCPOs have a very good relationship with medical professional groups and some associations are created and run by doctors. However, HCPOs are still often considered as 'the opposition' but they try to improve the climate by "building bridges" and conveying the notion that they can contribute to the effectiveness of the health care system.

All interviewees mention that the pharmaceutical industry has a very strong relation with patients' organisations. Almost all HCPOs get financial support for their work but it is not clear how much the pharmacy industry is funding.

There are ambivalent feelings about the relations with the pharmaceutical industry, on the one hand HCPOs are grateful for the support, on the other hand they feel uncomfortable being dependent on the pharmaceutical industry.

## **6. International activities**

Many organisations have contacts with sister organisations in other countries; The Spanish Patients' Forum is an active member of EPF. International activities are usually financed by the pharmaceutical industry. Nevertheless, the average Spanish HCPO faces major obstacles for participating at international level like a lack of financial resources, language barriers, lack of information, etc.

The MoH was an active partner in EUNetPaS (European Union Network for Patient Safety: <http://eunetpas.eu/>), a project funded and supported by the European Commission within the 2007 Public Health Program. Follow-up of this project is the European Union Network for Patient Safety and Quality of Care (PaSQ), with main objective is to strengthen cooperation between EU member states and EU stakeholders on issues related to quality management systems in healthcare, including patient safety and patient involvement. The Spanish MoH will lead the of the activities entitled: "Quality improvement systems exchange mechanism". See for more information: chapter EU, participatory activities of EPF.

## 8. Sweden

### 1. Organisations

#### Diversity of organisations

Compared to other countries Sweden has a limited number of HCPOs. The total number is estimated at 50-100. A major umbrella organisation is **HSO**, the Swedish Disability Federation (<http://www.handikappforbunden.se>), a federation of 39 patients' organisations, with in total 450.000 members. This is a typical "bottom up" organisation (democratic structure, strong influence of members). HSO is an important communication partner for the government and other stakeholders. A few organisations outside the HSO are also of a substantial size (for instance the organisations for the hard of hearing and for the visually impaired). Some have recently left the HSO and formed another association (Lika Unik, translation: "As Unique").

Professionalization: the majority of the HCPOs has one or two staff members; only a few have a staff of more than 5. HSO has 10 employees on a long term contract and 30 on a short term contract.

#### Financing, support and professionalization

Financing: almost all HCPOs receive structural funding by the Ministry of Health and Social Affairs. In 2008 the annual budget was 184 million SKR (=20 million euro), but the government gives de facto a lot of support to HCPOs via the activities of other government agencies like Socialstyrelsen and SALAR.

Main criteria for funding HCPOs are: more than 500 members and representation in more than 10 regions.

Other sources of income are membership fees, grants from EU, private donations and project funding by several organisations, like:

#### Arvsfonden (The Swedish Inheritance Fund).

[http://www.arvsfonden.se/Pages/SectionSubPage\\_15359.aspx](http://www.arvsfonden.se/Pages/SectionSubPage_15359.aspx). This fund supports non-profit and voluntary organisations wishing to test new ideas for developing activities for children, young people and the disabled. Many HCPOs get project financing from this fund.

### 2. Research, monitoring, support

#### FAS, Swedish Council for Working Life and Social Research <http://www.fas.se/>

This council was established in 2001 through a merger of the Swedish Council for Social Research and the Swedish Council for Work Life Research.

Mission and objectives:

- to promote the accumulation of knowledge in matters relating to working life and the understanding of social conditions and processes through
- promotion and support of basic and applied research.
- identification of important research needs.
- dialogue, dissemination of information and transfer of knowledge.
- promotion of cooperation between researchers both nationally and internationally, particularly in EU programmes.
- research funding

**Vinnova** <http://www.vinnova.se/en/>, (The Swedish Governmental Agency for Innovation Systems), a State authority that aims to stimulate needs-driven research and innovations required by a competitive business and industrial sector and society, and to strengthen the networks that are a necessary part of this work.

**Support:** Swedish HCPOs can get various forms of support from the **National Board for Health and Welfare (Socialstyrelsen)**, <http://www.socialstyrelsen.se/english/aboutus>) and **The Swedish Association of Local Authorities and Regions (SALAR)**, <http://english.skl.se/web/english.aspx>).

The National Board of Health and Welfare is a government agency under the Ministry of Health and Social Affairs with a very wide range of activities and duties in the fields of social services, health and

medical services, environmental health, communicable disease prevention and epidemiology. The majority of the activities focus on staff, managers and decision-makers in these areas. The organisation operates by collecting and providing information, developing standards on patient safety and supervising that the standards are observed, and by running health data registers and official statistics.

Socialstyrelsen supports HCPOs in many different ways by involving them in the development of quality standards, data collection and by funding projects. Socialstyrelsen, also sees to it that patients' organisations follow the rules that entitles them to get governmental grants.

SALAR represents the governmental, professional and employer-related interests of Sweden's municipalities and county councils. As the health care system in Sweden is highly decentralized (see below), it is an important supporting organisation for HCPOs at decentralised level.

### **Monitoring**

SALAR organizes regular health care consumer surveys but otherwise there is no special monitoring or research program on the effectiveness of patients' policy or on the functioning of HCPOs. However there are some interesting projects running that aim at involving patients' organisations in research programming (see below)

## **3. Participation of HCPOs**

### **Participation in policy**

HSO and other HCPOs are frequently consulted by the national government. HSO has a place in the Disability Advisory Board of the government and Lika Unik will be included in the near future. In general many important policy decisions of the government are prepared in the form of Inquiries. Such an inquiry has to examine an issue according to the guidelines given by the government and involvement of stakeholders is always one of the guidelines. The conclusions of the inquiries provide the basis for many of the proposals of the government.

The National Action Plan (adopted in 2000 and running till the end of 2010) of the Swedish disability policy is based on the principle "from patient to citizen". Its goal is the full participation in society of all people with disabilities, addressing also issues like the labour market, education, etc. The Swedish Agency for Disability Policy Coordination (Handisam) of the Ministry of Health and Social Affairs has the task of coordinating the National Action Plan and the cooperation with government-appointed agencies.

Other examples of the participation of HCPOs can be found in the work of Socialstyrelsen where HCPOs are structurally involved (see above). At decentral level, every regional council and municipality has a patients' committee that, based on patients' views and complaints, supports and helps individual patients and contributes to quality development in the health care system.

Another example of involvement of HCPOs in policy processes is the participation of HCPOs in the **Dental and Pharmaceutical Benefits Agency TLV**: <http://www.tlv.se/in-english/>. This is a central government agency whose remit is to determine whether a pharmaceutical product or dental care procedure shall be subsidized by the state. It has also the responsibility for monitoring profitability on the pharmacy market.

### **Participation in research**

HCPOs are gradually more involved in the processes of programming and prioritizing health related research.

Two examples: the project **From Research Object to Research Partner** of HSO which aims to include more people with disabilities in the research process (2008-2011, funded by the Swedish Inheritance Fund)

The project **Patient participation in research** (cooperation between The Swedish Rheumatism Association, the Swedish Asthma and Allergy Association, the Swedish Heart and Lung Association and the Swedish Psoriasis Association) which aims to find models for patient participation and influence in research. <http://www.forskningspartner.se/start.asp?sida=5590>

#### **4 . Patients' policy of the Government**

##### **Patients' policy**

Swedish health care and health policy is very patient/consumer oriented, although specific attention for patients' policy is relatively new. The health legislation is in line with the policy principles of "good care", that is: health care should be safe, patient centred, effective, equal, timely and efficient. Also some patients' rights are settled in this legislation: right to second opinion, right on free choice of a health care provider, right on information.

In the Swedish health-care system, responsibility for health care is shared by the central government, county councils and municipalities. The Health and Medical Service Act (Hälso- och sjukvårdslagen, HSL) regulates the responsibilities of the county councils and municipalities. The central government defines principles and guidelines for care and sets the political agenda for health and medical care by enforcing laws and ordinances or by reaching agreements with the regional and local authorities (SALAR)

There is no special department within the Ministry of Health and Social Affairs responsible for patients' policy<sup>75</sup> and there is no comprehensive policy on the role of HCPOs in strengthening the position of the health care consumers

##### **5. Relations with the pharma industry**

HSL only works with the umbrella organisation of the Pharma Industry: LIF <http://www.lif.se>. Other HCPOs work a lot with pharmaceutical companies and get funding from them for project activities. In order to guarantee transparency, there is a database with all relationships between HCPOs and the pharmaceutical industry. Furthermore LIF developed a set of "Ethical Rules for the Pharmaceutical Industry".

In general the relationship between HCPOs and the pharmaceutical industry, but also with other stakeholders like health care providers, etc. is constructive and positive. Involvement of HCPOs is considered by all stakeholders as an intrinsic element of health care.

##### **6. International activities**

HSL is an active member of EDF. Also other categorical Swedish HCPOs are active at international levels, mostly with sister organisations (some also as member of the EPF). In general stakeholders (HCPOs, government, health care providers) would like to get more information on international developments, including information on the functioning of HCPOs and patients' policy in other countries.

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<sup>75</sup> The Ministries in general are very small in Sweden, almost all the work is delegated to institutions like Socialstyrelsen, Vinnova, Fas, etc.

## 9. United Kingdom

### 1. Organisations:

There are thousands of HCPOs in the UK. The databank of Patient UK mentions more than 1900 HCPOs, the databank of Self Help UK mentions over 1000 organizations (see below).

There are the “usual” big categorical organizations (cancer, diabetes, etc), very often bundled in big federations or alliances. Even though, as regards some diseases the field is sometimes very fragmented (for example 14 different organizations working in the field of Breast Cancer)

An “national umbrella-type” organisation (representing all HCPOs interests) is **National Voices** <http://www.nationalvoices.org.uk/>. Formed in 2008, National Voices is a coalition of national health and social care organisations, coming together to ensure a stronger voice for all those who come into contact with the NHS and care services and for the voluntary organisations that help them. This organisation is funded by the government and by membership subscriptions, however it functions (according to its website) independently of the Government.

There are two other ‘umbrella’ type organisations: **Shaping our Lives** and the **Association of Medical Research Charities (AMRC)**. Shaping our Lives is an independent user controlled organisation that supports a network of service users and other user controlled organisations ([www.shapingourlives.org.uk/](http://www.shapingourlives.org.uk/)), whereas the AMRC is a membership organisation of leading medical and health research charities in the UK ([www.amrc.org.uk](http://www.amrc.org.uk/)).

**Support, advice:** there are several organizations that provide support and advice to HCPOs and individuals and that are active in advocacy. Examples:

– **The Patients’ Association** [www.patients-association.org.uk](http://www.patients-association.org.uk)

The Patients’ Association provides an advice service and is a collective voice for patients. It is independent of the government and medical profession.

- It provides help and advice to individuals and cross-refers to the most relevant organisation.
- It publishes patient information literature on a range of topics, for example, some medical conditions, self-help groups, access to records, access to services.

Is sponsored by amongst others the pharma industry

– **Counsel & Care**, [www.counselandcare.org.uk](http://www.counselandcare.org.uk)

Counsel and Care’s gives every year information and support to around 250,000 older people, their families and carers. Advises on a range of community care issues, including finding and paying for care, welfare benefits, and hospital discharge. Is active in policy influencing and general advocacy towards the media and other stakeholders to get the best care and support for older people. Is independent from the government.

– **Consumer Focus/The National Consumer Council** <http://www.ncc.org.uk/>

Is the national consumer organization of the UK. Operates across the whole of the economy, persuading businesses, public services and policy makers to put consumers at the heart of what they do. Consumer Focus has the right to investigate any consumer complaint if they are of wider interest, the right to open up information from providers, the power to conduct research and the ability to make an official super-complaint about failing services. This organization will be abolished in the near future (see Review of Arms Length Bodies

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4086081](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086081))

– **Self Help UK** <http://www.self-help.org.uk/welcome/>

Is a free service provided by Intuition Communication Ltd, specialists in health care publishing on the Internet. Provides a [searchable database](#) of over 1,000 self help organisations, patient support groups and charities across the UK that provide support, guidance and advice to patients, carers and their relatives. The groups and organisations that are covered, embrace many medical conditions, diseases and treatments. Self Help UK is a free and non profit making site.

– **Patient UK** <http://www.patient.co.uk/selfhelp.asp>

Provides a databank with more than 1900 patient support organisations, self help groups, health and disease information providers, etc. Each entry is cross referenced and details are checked annually. Was first launched in 1997, and re-launched as a joint venture between PiP and EMIS (Egton Medical Information Systems).

Patient UK has a number of related, 'sister' websites, like [Patient UK Experience](#), an interactive forum which enables users to read and contribute to online discussion on experience of medical conditions and treatments. The site contains links to and from related information in Patient UK.

[Patient UK Newspaper](#)

This is an online newspaper displaying selected daily stories relating to medical subjects from the world's media. The site contains links to and from related information in Patient UK.

### **Financing/Staffing of HCPOs:**

The latest available figures were collected in the De Montfort study of the Leicester University in 1999/2003, on 123 HCPOs, and published in a comprehensive study "Speaking for patients and carers" (Baggott, Allsop, Jones, 2005). Although somewhat outdated the figures still can be considered as representative for the situation of UK HCPOs.

**Financing:** According to the De Montfort study only 6% of the HCPOs had an income of £10 mln or over per annum, while 16 % had an income of 10.000 GBP or less. Most groups (87 %) had an income of £1 mln or less per annum. Sources of income: Grants from the Government (see below), memberships contributions, public donations, charitable trusts, legacies, etc

**Staffing:** The De Montfort study showed that 76 % of the HCPOs had paid staff at headquarters. Of these organisations 38% employed two or less fte members of staff. Only 20% employed more than 10 people and 40 % had between 2 and 10 members of staff

**Financing by the Central government:** The Secretary of State for Health, through the Section 64 General Scheme of Grants (S64 of the Health Services and Public Health Act 1968), has the power to make grants to voluntary organizations in England whose activities support the Department of Health's policy priorities. There are three types of grants: core funding, capital grants and project grants. Section 64 grants represent the greatest single source of financial support that the Department provides to the voluntary sector.

The grants are discretionary and terms and conditions agreed by Ministers and HM Treasury apply. Competition for the available funds is always very strong, and priority is given to applications with innovative proposals of national significance that will complement statutory services and so help secure provision of high quality health and social care and promote the nation's health. The system was revised in 2008. The new programme has two strands: a strategic partner programme and an innovation, excellence and service development fund. In 2008, the Department of Health awarded £24m in Section 64 grants to charities that deliver services on its behalf.

**Charities:** With regard to donations it is advantageous for HCPOs to become recognised as a "charity" (donations are then tax deductible). Most charities with an annual income of over £5,000 have to register with the **Charity Commission** <http://www.charity-commission.gov.uk>.

## **2. Monitoring, research:**

**Monitoring:** there is no regular monitoring of HCPOs in the UK, other than through their relationship with the Charity Commission.

**Research:** a lot of research has been done on public involvement in the UK, including on public involvement in health care. However less on the functioning of HCPOs and the effects of involvement of HCPOs in health policy. The above mentioned study "Speaking for patients and carers" can still be considered as the most comprehensive and recent study on this subject, and the Health Policy Research Unit of the De Montfort University at Leicester as an important research centre in this area. But also in other universities individual researchers are active in this area.

Finally here the recent study of PatientView <http://www.patient-view.com/> should be mentioned, based on a survey of about 900 HCPOs, profiling of the activities of 287 UK patient groups.



### 3. Patients' participation, information for patients':

#### Participation in the National Health Service:

Since 1948 the (NHS) covers almost all health care services in the UK; The NHS accounts for 87 percent of total health expenditure. It is funded by general taxation (76%), national insurance contributions (18%), user charges (3%), and other sources of income (3%). Responsibility for health legislation and general policy matters rests with Parliament. The NHS is administered through 10 regional strategic health authorities who are accountable to the Department of Health. Locally, services are provided through a series of contracts between the 152 Primary Care Trusts (PCT) and service providers (hospital trusts, GPs, independent providers). PCTs control around 80 percent of the NHS budget.<sup>76</sup> All health and social care providers must be registered by the **Care Quality Commission (CQC)**. This is the health and social care regulator for England ([www.cqc.org.uk](http://www.cqc.org.uk)). This Commission collects and compares information on performance and quality from a wide range of perspectives. Furthermore, the organisation carries out systematic inspections and also puts a significant amount of energy into presenting that information to the public. The website of this organisation can show which care units are close to the patient's home along with their addresses, visiting hours and phone numbers. Thereafter, it is possible to find the health care provider clients are searching for, based on speciality and geographic location, and they can see detailed data on the quality of the provider. The visitor can tabulate and compare different care givers with one another.

**Monitor** <http://www.monitor-nhsft.gov.uk/>

was established in January 2004 to authorise and regulate NHS foundation trusts. Monitor is independent of central government and directly accountable to the UK Parliament.

There are three main strands to their work:

- determining whether NHS trusts are ready to become NHS foundation trusts;
- ensuring that NHS foundation trusts comply with the conditions they signed up to – that they are well-led and financially robust; and
- supporting NHS foundation trust development.

It is important to notice here that there are differences in the implementation of the NHS in the UK countries (England, Scotland, Wales, Northern Ireland), for instance as regards the policy on privatized health care, financing of elderly care, compensation for medication, etc.<sup>77</sup> The consequence of this is that HCPOs who want to influence this policy have to lobby on four government levels.

Since the start of NHS not much attention was paid to patients'-consumers issues. However since the 70s there has been a growing concern about the "democratic deficit" of the NHS. In the same period the number of HCPO's and self-help groups increased and many of them developed roles in advocacy, campaigning and providing support for people who wished to complain.

In 1974 Community Health Councils were introduced in each local area to represent the interest of local people. The CHCs had the right to be consulted on substantial service changes and provided advice and information for the local population.

During the 1980s under conservative governments the focus on "patients" was shifted to a focus on "consumers". Various new mechanisms to involve these "consumers" were introduced, however with little effect, not in the least because the CHCs were under resourced and lacked experience. Nevertheless the political plans for reforms had an unintended effect on health consumer groups. The pressure on HCPOs to respond to the proposed health care reforms has led to strengthening the informal networks between these groups and to formation of new alliances.

In the 90s and specifically under "New Labour" a great number of initiatives have been taken in the United Kingdom to strengthen the position of the patients. In 1997, the government announced the introduction of a new NHS, a plan to modernize, develop and rebuild its services. The accent shifted to "partnership", "involvement" and "the expert patient". A number of important policy documents were published, amongst others "Patient Partnership: building a Collaborative Strategy" (NHSE, 1996), "In the public interest" (1998) and the NHS Plan of 2000.

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<sup>76</sup> This again will be subject to change which proposes an abolition of the PCTs and a move to commissioning from 'general practice consortia'

<sup>77</sup> see R. Baggott (2007) Understanding Health Policy (Bristol Policy Press), chapter 9

Since then, a number of initiatives have been taken, mainly focusing on patients' information, participation, and protection of patients' rights. Some Examples:

- **NHS direct** <http://www.nhsdirect.nhs.uk><sup>78</sup>  
This is a 24 hour telephone advice line that is staffed by nurses. Provides expert health advice, information and reassurance, using telephone service and website, and is the NHS' provider of choice for telephone and digitally delivered health services.  
Also offers services like: out of hours support for GPs and dental services, telephone support for patients with long-term conditions, pre and post operative support for patients, 24 hour response to health scares, and remote clinics via telephone.
- **Patient Advice and Liaison Services “ (PALS)** <http://www.pals.nhs.uk/>  
The Patient Advice and Liaison Services operate at decentralised level and have been introduced to ensure that the NHS listens to patients, their relatives, carers and friends, and answers their questions and resolves their concerns as quickly as possible.  
PALS also helps the NHS to improve services by listening to what matters to patients and their loved ones and making changes, when appropriate.  
PALS provide the customers with information about the NHS and help with any other health-related enquiry, helps to resolve concerns or problems of customers using the NHS; provides information about the NHS complaints procedure, information on agencies and support groups outside the NHS, etc  
Provide an early warning system for NHS Trusts and monitoring bodies by identifying problems or gaps in services and reporting them.
- **Independent Complaints and Advocacy Services“ (ICAS).**<http://www.carersfederation.co.uk/what-we-do/icas/>  
ICAS provides advocacy support to people who wish to make a complaint about the service - or lack of it - that they have received from the NHS.  
Everyone has a right to complain if they feel something has gone wrong, and for this reason the NHS has a Complaints Procedure. All services provided by the NHS are covered including GPs, hospitals, pharmacies, opticians and dentists.  
ICAS advocates give support guiding clients through the NHS complaints process.  
The ICAS service is free, independent and confidential.
- the „**Expert Patient Programme**“ <http://www.expertpatients.co.uk/>, example of a project aiming at strengthening self-management and self-responsibility of patients.  
Runs free courses for people living with long-term health conditions. Main aim is to improve the quality of life for these people. The courses are designed to give them the tools, techniques and confidence to manage their condition better on a daily basis.  
Is established in April 2007, the government's commitment is to increase EPP capacity from 12,000 course places a year to over 100,000 by 2012.  
A recent development in the NHS is the introduction of personal budgets in health care in England. Patients in England will be given cash payments to buy physiotherapy, home nursing and other healthcare services<sup>79</sup>. Also here training courses for patients will be developed.
- **Patient- and population surveys**  
The NHS patient survey programme, led by the Picker Institute, was initiated in 2002. The centre is assigned to coordinate surveys that are conducted in emergency and primary health care in the United Kingdom, commissioned by the Care Quality Commission. The centre compiles and publishes results from different patient surveys on a continuous basis.
- **NHS Constitution**  
<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx>  
For the first time in the history of the NHS, the constitution brings together in one place details of what staff, patients and the public can expect from the National Health Service. The Constitution sets out the rights of the NHS patient. These rights cover how patients access health services, the quality of care, the treatments and programs available, confidentiality, information and the right to complain if things go wrong. The NHS Constitution is now part of a legislative framework so these rights and responsibilities have a legal weight.
- **NHS Choices** [www.nhs.uk](http://www.nhs.uk) the biggest health website in the UK and is the 'front door' to the NHS giving people information about health and wellness issues and about available NHS services. Its

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<sup>78</sup> The future of NHS Direct is still under discussion

<sup>79</sup> A similar system exists already for several years in The Netherlands



information is accredited by the Information Standard which is a benchmark of quality patient information.

- **Recently announced policy changes:** recently the government has issued a white paper on NHS reforms<sup>80</sup>. Also in these plans the emphasis is on shifting responsibilities from state to private/local management and on giving more responsibilities to patients/consumers.<sup>81</sup> The Health and Social Care Bill is currently making its way through Parliament and, if passed, will make significant changes to how the NHS is structured

#### **Other forms of participation:**

- **In national policy developments:** there are standard procedures in the UK for consultation of stakeholders in case of proposed policy measures (see <http://www.cabinetoffice.gov.uk>). This means that HCPOs are consulted in case of important policy changes<sup>82</sup>.

#### **Participation at decentral levels:**

##### – **Patient and Public Involvement-Forums**

- PPI Forums were established on 1 December 2003, with one forum in every NHS trust, NHS Foundation trust and PCT in England. to help improve the quality of NHS services by bringing to trusts and PCTs the views and experiences of patients, their carers and families. The forums replaced the Community Health Councils (see above) .

Each forum identified its priorities, but their primary expectations were to:

- Monitor and review NHS delivery
- Seek the views of the public about those services
- Make recommendations to the NHS accordingly

These Forums were set up and supported by the Commission for Patient and Public Involvement in Health (CPPIH), now abolished. After a public consultation (“A stronger local voice”) a decision was taken to abolish PPI Forums, as part of the Local Government and Public Involvement in Health Act 2007. The Forums were abolished on 31st March 2008 and replaced by **Local Involvement Networks (LINKs)**, that aim to give citizens a stronger voice in how their health and social care services are delivered. Run by local individuals and groups and independently supported - the role of LINKs is to find out what people want, monitor local services and to use their powers to hold them to account.

However also these LINKs will be replaced by **Local Health Watch organizations**. As a new element, a national **Health Watch** will be established, within the organizational structure of the Care Quality Commission.<sup>83</sup>

- In all 39 Counties „ **Health Overview and Scrutiny Committees**“ function, consisting of local politicians; task of these committees is look at the work of the primary care trusts and National Health Service (NHS) trusts.

#### **Participation in research programming, in development of quality standards:**

##### – **NICE** <http://www.nice.org.uk/>

The National Institute for Health and Clinical Excellence (NICE) provides guidance, sets quality standards and manages a national database (NHS Evidence) to improve people's health and prevent and treat ill health.

NICE makes recommendations to the NHS and other stakeholders on new and existing medicines, treatments and procedures, treating and caring for people with specific diseases and conditions, how to improve people's health and prevent illness and disease.

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<sup>80</sup> [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/@ps/documents/digitalasset/dh\\_117794.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf).

<sup>81</sup> This is part of the “Big Society”- plan which is bigger than health care. It covers all aspects of community responsibility.

<sup>82</sup> Some recent examples of consultations by the Department of Health on proposed policy changes on information and choices:

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_120598.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_120598.pdf).

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_120613.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_120613.pdf)

<sup>83</sup> This initiative is dependent on the passage of the Health and Social Care Bill through Parliament.

Health consumers groups submit evidence for appraisals and may appeal against any draft guidance. They also comment extensively on all forms of draft guidance. Members and staff of health consumers groups have the opportunity to sit on various NICE committees and working groups, alongside individual patients and carers. These 'lay members' of groups are not representative of organisations, but have a place on these groups as individuals. Since 2001 NICE has a Patient and Public Involvement Programme (PPIP), that provides NICE with advice on involving patients, carers and members of the public. If necessary NICE provides training courses for HCPOs. NICE compensates individual patients, carers and members of the public who are members of their groups and committees with £150 per full day meeting attended, plus travel and subsistence expenses.

- **Involve**<sup>84</sup> <http://www.invo.org.uk/> : INVOLVE was established in 1996 and is part of, and funded by, the [National Institute for Health Research](#), to support active public involvement in NHS, public health and social care research. It is one of the few Government funded programmes of its kind in the world. As a national advisory group the role of INVOLVE is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of advancing it as an essential part of the process by which research is identified, prioritised, designed, conducted and disseminated. The strategy of INVOLVE is specified in Strategic Plans ( last plan : [INVOLVE Strategic Plan 2007-2011](#), currently the Strategic Plan 2012-2015 is being developed). On basis of these Strategic Plans, yearly Operational Plans are developed, see for instance [Operational Plan 2011-12](#) .

The main strategy areas of INVOLVE:

- Lead on public involvement across the National Institute for Health Research
- Build and share the evidence base
- Develop capacity and capability for public involvement in research
- Influencing research policy and practice :

See for the current activities of INVOLVE: <http://www.invo.org.uk/about-involve/current-work/>

- **James Lind Alliance** <http://www.lindalliance.org/Introduction.asp>  
The James Lind Alliance aims to identify the most important gaps in knowledge about the effects of treatments, and has been established to bring patients and clinicians together in 'Priority Setting Partnerships' to identify and prioritise the unanswered questions that they agree are most important. This information will help ensure that those who fund health research are aware of what matters to patients and clinicians. The James Lind Alliance is a non-profit making initiative, being developed under the direction of a broadly-based Strategy and Development Group. Its Secretariat is funded by the Medical Research Council and the Department of Health.

#### 4. Relation with pharma industry: <http://www.pmcpa.org.uk/?q=patientorganisationsandcode>

Many HCPOs get funding by the Pharma Industry. A recent study<sup>85</sup> showed that only 26 per cent of consumer groups known to be in receipt of industry financial or in-kind support openly acknowledged this. The study argues that while claims of organisational capture are over-stated, the shallow approach to transparency adopted by the majority of companies and groups strengthens critiques of undue influence. This may ultimately reduce policy makers' willingness to see consumer groups as the legitimate voice of patients, users and carers in the policy process.

The Association of the British Pharmaceutical Industry's (ABPI) has established the Prescription Medicines Code of Practice Authority (PMCPA), that administers a Code of Practice. This ABPI Code covers the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines. Pharmaceutical companies are permitted to interact with HCPOs and organizations of carers or relatives as long as all

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<sup>84</sup> NB: there are two "Involves" active in the UK. The other one is : <http://www.involve.org.uk>, operating in the broader area of citizens' participation

<sup>85</sup> Jones, K. (2008) 'In whose interest? Relationships between health consumer groups and the pharmaceutical industry in the UK' *Sociology of Health and Illness*. 30 (6) 929-944.

involvement is declared and transparent and in accordance with the Code. Relationships with HCPOs were first included in the 2006 edition of the Code.

**5. International activities of UK HCPOs:**

Like many other countries, the big categorical HCPOs are participating in their own international networks, some are members of IAPO, EPF, EDF, etc.

It is difficult to get an impression of the participation of the average UK HCPO in international activities. As one interviewee put it: “most UK organisations don’t think outside the UK” which is quite comparable to the situation in other countries. Most likely working at international level is also hindered by the lack of resources and continuity of expertise as well as a general lack of information about the many relevant policy areas, consultation networks, international patients’ organisations, etc.

## 10. Denmark:

*(Note BK: all though not similar to the previous reports about the situation at EU level and in a number of EU countries, the reader might be interested in the following information, provided by Danske Patienter ("Danish Patients"), on my request for information about patients' participation in Denmark, and the interest in exchanging experiences. Danske Patienter is an umbrella organization for 16 patient associations in Denmark, representing 850.000 members)<sup>86</sup>.*

Summary:

### **What are the most important developments in Denmark regarding health consumers/patients' participation in policy, research and quality development?**

**The Danish Health Act** defines the following regarding consumer/patient participation:

§ 4. Danish counties and municipalities must – in interaction with state authorities and in dialogue with consumers/patients – continuously work to improve the quality of national health services as well as assure the efficiency and effectiveness by means of education, research, coordination, cooperation etc.

**The NSS**, a national assembly of health research, has developed a strategy of involving patients in health research. NSS is a public-private partnership, and it aims both at reinforcing cooperation and coordination between private and public actors in the health sector, promoting the use of research and, finally, strengthen the competitiveness of Danish health research.

**ViBIS** <http://vibis.dk/english> is a newly established national knowledge centre of user involvement. The knowledge center is established to expand the knowledge based involvement of patients and their relatives in the development of the health care system in Denmark. Denmark has no formal tradition for involving patients and their relatives in the development of the health care system. The existing projects in relation to user involvement are scattered and lack systematic evaluation. ViBIS will gather, share and develop knowledge, methods and experiences on user involvement from both Denmark and abroad, at the advantage of all actors in the Danish health care system.

The **Danish Healthcare Quality Programme** (DDKM) provides accreditation standards of good quality – along with methods to measure and control this quality. It has just launched two new standards of patient involvement.

A general tendency (not systematic): Different actors at all levels of the health services (state, regional, local hospitals etc.) are engaged in developing policies and strategies of patient involvement. The Ministry of Health is presently working on a strategy of patient participation.

### **Who are the main stakeholders in the area of patients' participation?**

- National Board of Health
- Danish Knowledge Center for User Involvement in Health Care (ViBIS) <http://vibis.dk/english>
- Various patient organizations like The Danish Cancer Society, Danish Diabetes association, Rare Disorders Denmark.
- Various medical societies and professional organization like Danish Nurses' Organization (DNO), Danish medical association, Danish Physiotherapist.
- Danish Regions: the organization representing the five regions in Denmark
- IKAS, The Danish Institute for Quality and Accreditation in Healthcare
- Universities and other research institutions like university of Southern Denmark, The Danish Institute for Health Services Research, The National Institute of Public Health.

### **Already available information/existing networks:**

- Danish Knowledge Center for User Involvement in Health Care (ViBIS) (see above)
- Vidensforum for Brugerinddragelse

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<sup>86</sup> Information provided by Mrs Annette Wandel

- Unit of Patient-Perceived Quality, The Capital Region of Denmark Patient satisfaction
- Danish Institute for Health Services Research
- Danish society of patient safety

**Is Danske Patienter interested in exchanging knowledge?**

Yes, there is a need for exchanging knowledge regarding patient and consumer participation. ViBIS will be happy to engage in the work. Presently, there is an increasing focus in Denmark on patient participation, by patients' organizations, national authorities on health, health care organizations and politicians.

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