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Patients' Rights

THALASSAEMIA INTERNATIONAL FEDERATION 1996
"In official relation with the W.H.O."
EDUCATIONAL PROGRAMME

By **Dr. Androulla Eleftheriou**

This booklet is dedicated to all members of the Board of the Thalassaemia International Federation, who have shown unlimited devotion and incredible persistence in promoting the right of every thalassaemia patient, everywhere in the world to receive quality medical care.

The Author
Dr. Androulla Eleftheriou

Message from the President of the Republic of Cyprus
Mr. Tassos Papadopoulos

This manual prepared by the Thalassaemia International Federation (TIF) offers a comprehensive overview of patients' rights, drawing on the work of leading international health organisations, particularly the World Health Organisation, the European Union and the Council of Europe, as well as patients' groups and other non-governmental organisations.

As a result of work by such organisations, it is now an internationally established principle that people everywhere are entitled to access to the highest possible quality medical services, via health systems showing dignity to the individual without discrimination on the grounds of race, religion, social or financial status, educational level or political conviction.

Nonetheless, members of the medical profession the world over remain unconvinced, resisting patients' demands that their rights be respected. And it is here that patients' organisations play a pivotal role in securing and promoting implementation of the legal framework protecting the rights of patients, as well as providing a strong platform from which to lobby for greater action.

Human rights, democracy and justice are fundamental principles of the European Union. I emphatically assure the people that I personally, as well as the government of the Republic of Cyprus, will be closely monitoring implementation of regulations regarding patients' rights in Cyprus. I hope that the experience, principles and knowledge gained in Europe will constitute the basis for the promotion and formulation of a legal framework protecting patients across the world.

With a membership consisting of patients' associations from more than 50 countries around the globe, TIF has shown great initiative in undertaking to produce this manual. I offer the Federation my warmest congratulations. I also congratulate Dr Androulla Eleftheriou for the diligent writing and editing of this manual. Dr Eleftheriou has made a valuable contribution to the field of hereditary haemoglobinopathies, both through her work as an author, with work translated into more than 10 languages and distributed in more than 50 countries around the globe, as well as in her capacity as a World Health Organisation (WHO) consultant, and as scientific and executive director of the Thalassaemia International Federation (TIF), collaborating closely with national ministries of health, the National Patients' Associations and various international and scientific communities.

Her contribution towards the health professionals globally, but more importantly to patients, especially honours Cyprus. I am sure that this booklet will be another valuable addition to the collection of educational books and manuals that have been published so far by the Thalassaemia International Federation.

Tassos Papadopoulos
President of the Republic of Cyprus

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A message from **Panos Englezos**

President of the Thalassaemia International Federation, Honorary President of the Pancyprian Thalassaemia Association and Chairman of the Pan European Blood Safety Alliance

The issue of patients' rights is a critical and relatively new area of concern in thalassaemia – for carers, medical practitioners and, most importantly of course, for patients themselves.

Advances in the prevention, diagnosis and treatment of thalassaemia have together made a huge impact, both on the incidence of thalassaemia and on patients' health. But, as those 'essentials' have become more firmly established, particularly in wealthier parts of the world, so has the focus rightly shifted to the less tangible, but equally important, question of quality of life.

With the advent of new treatment regimes, patients fortunate enough to afford and have access to state-of-the-art treatment can expect to live longer, and to have more productive lives. Convinced that "Unity is our strength", the Thalassaemia International Federation (TIF) is committed to improving the health and quality of life of every patient with thalassaemia, wherever he/she may live, irrespective of nationality, race, religion, social or educational status. And an important means of improving the care of patients with thalassaemia is to provide them with reliable, useful, up-to-date information on every aspect of their disease and its treatment.

This booklet is the seventh in a series of TIF educational publications, each of which has been translated into a number of languages. Details can be found at the end of this booklet. Unlike previous publications, this one addresses a subject that has to date received little attention, but which nevertheless plays a pivotal role in ensuring the safe and appropriate clinical management and care of patients with thalassaemia: "Patients' Rights", as individuals and as patients.

The focus of this publication is on best practice in the area of patients' rights, and here, it seems that Europe has much to teach us all. This booklet therefore draws greatly on the European experience, presenting

ways in which everyone involved in thalassaemia, wherever they live, can work to ensure that the rights of patients with thalassaemia are always respected, everywhere and in every way. More than that, it is hoped that this booklet will serve as a valuable guide for patients with diseases other than thalassaemia, wherever they may live and whatever their medical condition may be.

Patients are asked to do many things every day – to battle pain, to rise above despair, to comfort those who worry for them. And every day, they do just that. Asking patients to fight for their rights as well, requires something from us too: we must provide them with the accurate and useful information that will be their ammunition. This, of course, is exactly what TIF and our many partner national thalassaemia associations, across the world seek to do.

I would like to thank TIF's Executive Director and Coordinator of TIF's educational programme, Dr Androulla Eleftheriou, for all her hard work in preparing this extremely valuable publication. I would also like to thank Mrs Anastasia Neophytidou who has significantly contributed to the preparation of this long-awaited booklet, and Dr Helen Perry for her work editing it. Most important, I offer great thanks to the wider TIF family – our Board, Federation members, national associations, patients, parents, friends and collaborators in the medical, scientific and pharmaceutical communities. I feel very proud of what we have achieved so far, and I feel still greater optimism for what we will achieve in the years to come.

About the Author

Androulla Eleftheriou

Dr Eleftheriou obtained her graduate and postgraduate degrees (BSc Hons, MSc, PhD) from the University of London, in the fields of Microbiology and Virology. She has been awarded a number of scholarships by the World Health Organisation and the Fulbright Commission. Her postdoctoral fellowship was completed at the Centre for Disease Control in Atlanta, GA, USA. Dr Eleftheriou has also recently obtained a Diploma in Business Management from the University of Leicester - UK.

Since 1990 and until August 2006, Dr Eleftheriou had been the head of the Virus Reference Centre of the Cyprus Ministry of Health – a centre she was closely involved in establishing. She is now the Executive Director of the Thalassaemia International Federation (TIF) Headquarter Offices, based in Nicosia, Cyprus, and the Coordinator of its educational programme. In addition, Dr. Eleftheriou regularly acts as a World Health Organization (WHO) consultant on issues related to her field of expertise.

Through her work with TIF, Dr Eleftheriou has carried out numerous projects of local, national, regional and international scope, working closely with international experts, local physicians and thalassaemia associations worldwide. She is the author of several works published by TIF, as well as a number written in collaboration with the W.H.O. and other international bodies on a wide range of scientific topics. Dr Eleftheriou is the Chief Editor of TIF Magazine, issued quarterly and which is distributed to 3,500 subscribers, in more than 40 countries worldwide.

A Message

...from a patient and founding member of the Thalassaemia International Federation:-

According to the United Nations, 10 per cent of the world's population, or about 650 million people, suffer from various disabilities. On August 27th 2006, at the UN Headquarters in New York, UN General Assembly President Jan Eliasson declared «… we want to have a life with dignity for all and in which all human beings are equal."

This is the goal in establishing patients' rights in all the countries of the world.

I hope that this booklet will help all thalassaemics and their carers to understand their legal rights, as well as the obligations their governments have undertaken, to ensure that they are treated with dignity and respect.

Discrimination on the grounds of race, colour, social or economical background is illegal in most countries. But unless we educate ourselves on the laws and regulations that give us rights as patients, we will not be able to demand those rights.

George Constantinou
Secretary of the Board of Directors
of the Thalassaemia International Federation
Member of the Board of the UK
Thalassaemia Society

Why "Patients' Rights"?

Aren't human rights enough to cover any particular needs? Do we need a specialised legal framework for patients, or for any other particular sub-group, for that matter?

Patient rights- and patient organisations' activists must have encountered these sorts of questions frequently in their struggle to legally safeguard patient rights in their countries. Sometimes this sort of questioning emanates from genuine ignorance of developments in the legal protection of patient rights, or it is simply a means by which some stakeholders oppose such a development.

Patients' rights is nothing more and nothing less than the protection of human rights in a particular field, that of health services. The protection of these rights does not imply an antagonism with health service providers: rather, it outlines the boundaries of their relationship, thus enabling both sides to manage that relationship for the benefit of the patient. The protection of patients' rights should not (and does not) interfere with the practice of medicine, as some national medical associations claim, since no patients rights' legal framework, anywhere, interferes with the practice of medicine. This is why, in all patients rights' legislation, the issue of malpractice is treated separately, under the penal code. However, old perceptions die hard, and resistance to change persists evident.

Patients' rights started to be recognised as an entity in their own right, in the industrialised European and North American countries, in the early 1960's, developing further to cover most European countries in the early 21st century.

The thinking behind this trend came from the recognition that any citizen making use of health care services is, in reality, a "consumer" of medical services, and therefore the relationship between the "supplier" and the "consumer" needed to be regulated.

Overcoming outdated perceptions, viewing the patient–healthcare provider relationship in the light of the enabled citizen, patients' rights promises a whole new era of cooperation between the stakeholders involved, opening a new chapter of mutual respect, recognising respective rights and obligations. Civic responsibility is enacted when citizens are

enabled to understand and exercise their rights. It is not an exaggeration to claim that the legal protection of patients' rights (like the protection of any other social sub-group) is a stepping stone in the process of strengthening democracy.

On behalf of the Pancyprian Federation of Patients' Rights, I would like to congratulate the Thalassaemia International Federation for producing a publication focused on patients' rights, in the context of its 2006 educational programme - an activity reflecting the pivotal role international and European patient-parents' organisations can play in the promotion and, very importantly, the implementation of patients' rights in their individual countries.

Dr Christos Eliades
President of the Pan-Cyprian Federation
of Patients Rights

From the Author

Patients' rights are a reflection of human rights. The rights of patients as specific human rights became recognised throughout the European region only in the last two decades, triggering an international trend in their definition and promotion.

This booklet aims to bring together important information on patients' rights from around the world, including levels of public awareness, legislation governing patients' rights and the degree to which such legislation is implemented.

Patients who are well-versed in their rights and responsibilities can contribute enormously to efforts made to promote improvements in their medical care and quality of life. At a time when rights and responsibilities have, in many instances, been laid down by national legislation, patients have greater control of their destiny.

But there are also many patients who live in parts of the world where patients' rights are virtually unknown. It is hoped that for them, this booklet can provide guidance on the way forward, too.

Indeed, there is a great deal to be done even where the concept of patients' rights is most advanced. For its part, the Thalassaemia International Federation (TIF) seeks to improve the health and quality of life of patients with thalassaemia around the world by providing through this booklet, information on which patients can build, and by taking the issue of patients' rights a step further, to consider the question of the rights of patients with chronic diseases.

An important issue to emerge from research carried out for this booklet is that the many charters, declarations and laws surveyed here do not make specific reference to the rights or quality of care of chronically ill patients. Furthermore, there is a widespread assumption that if patients' rights are properly implemented, chronic conditions will be automatically and satisfactorily catered for. This is unlikely to be the case: chronic disorders have special and unique features that require additional attention in terms of patients' rights. TIF has therefore launched a new project entitled Chronic Disorders – Patients' Rights and Quality of Life, funded in collaboration with an international organisation, which aims to suggest ways in which a patients' rights framework can better serve patients with chronic disorders.

We hope that each reader will benefit from this booklet and that it will be distributed as widely as possible. TIF particularly encourages patients' associations to translate its contents for distribution, amongst friends, health professionals and policy-makers. The issue of patients' rights, after all, concerns everyone, everywhere, and efforts to promote their legislation and implementation require both unity and consistent, adequate knowledge. We are confident that this booklet will contribute to providing valuable information on this issue and that TIF, through its work and activities, will promote unity amongst its members, true to TIF's motto – "Unity is our strength".

I would like to acknowledge the contribution of Mrs Anastasia Neophytidou in the preparation of this booklet. Thanks, too, Dr. Matheos Demetriades for typing its contents, and to Dr. Helen Perry for editing it.

My deepest and most sincere appreciation go to His Excellency the President of the Cyprus Republic, Mr Tassos Papadopoulos, who showed great interest and accepted TIF's invitation to write the forward.

Androulla Eleftheriou
(B.Sc., M.Sc., Ph.D., Dipl. Management)
Executive Director,
Coordinator of Educational Programme
Thalassaemia International Federation

Preface

The father of western medicine, Hippocrates (470-360BC), advised his fellow medical professionals to ***"First, do no harm"***, and indeed until the 1970's, the health professional-patient relationship was primarily defined by the rules of medical ethics. In the modern world, the focus has shifted to legal provisions and Hippocrates' golden rule can be taken today to mean ensuring equality of access to safe, high quality health services – a goal at the heart of many western, particularly European, healthcare systems.

The idea that human beings have fundamental rights is central to organisations such as the United Nations (UN) and the World Health Organisation (WHO). And amongst those rights, the right to health features prominently.

Article 25 of the UN's Declaration of Human Rights states:

"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care ...."

The founding of the WHO in 1948 was marked with the words:

"The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, without distinction of race, religion, political being, economics or social condition."

Every country in the world is now party to at least one international treaty recognising health-related rights and opposing inequality and discrimination in healthcare delivery. But words, obviously, are not enough.

Moving Forward... and Apart

Over the last thirty years, global average life expectancy has increased by between six and seven years, on the back of social and economic development and the expansion of national health services. At the same time, however, the world has seen a widening health gap between and within countries, between rich and poor, between men and women and between different ethnic groups. **More than a billion of the world's poorest people are not benefiting from major advances in the health care.**

Infectious diseases have a massive social and economic impact, particularly in the developing world. New diseases such as SARS and avian influenza give added urgency to the need to control epidemics. At the same time there has been a shift in the balance of major causes of death and diseases in developed and also increasingly in developing countries with non-communicable diseases now representing almost 60% of the global disease burden.

These trends indicate that without a strong political commitment, integrated policies and broad participation, future progress in improving health is likely to be accompanied by still greater health inequalities. As a result, the WHO's global health agenda for 2006-2015, 'Engaging in Health', seeks to involve all stakeholders and partners. Priority areas include:

- **Investing in health to reduce poverty;**
- **Building individual and global health security;**
- **Promoting universal coverage, greater equality and health-related human rights;**
- **Strengthening health systems and equitable access;**
- **Harmonising knowledge, science and technology, and;**
- **Strengthening governments, leadership and accountability.**

Recent years have seen a dramatic increase in the number of international partnerships in health, drawing on the combined strengths of public and private organisations, civil society and patient/parent groups. Such partnerships have succeeded in scaling up response to global health needs, providing additional influence where the market fails to mobilise the resources needed to tackle health challenges. Individuals united for a particular cause, such as patient or civil society groups, are forming powerful lobbies and raising public awareness of issues such as access to appropriate treatment and international development assistance.

Promoting patients' rights in the EU

Improving health and promoting patients' rights are goals shared by the European Union and the Council of Europe, prompting Member States to draw up patient charters and enact relevant legislation at the national level. It is indeed here that patients' and parents' organisations could play a pivotal role, promoting and monitoring the implementation of such legislation.

In June 2006, European Union Ministers of Health adopted a **'Statement of common values and principles in EU health systems', underlining the importance of "protecting the values and principles that underpin health systems in the EU". The Statement aimed at "ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member state to another and enshrining these values and principles in a legal framework in order to ensure legal certainty".**

Patients' rights and citizen empowerment – Changes in the patient-doctor relationship

For centuries, the balance of power in patient/doctor relations has lain with the medical professional. Without the power of information, patients have been left ignorant and afraid of their disease and the means of its treatment. The management of patient health has been the almost exclusive preserve of health professionals.

It is only recently – and certainly not everywhere – that patients' right to information, their right to explanation and their right to be involved in decisions affecting the management of their health, begun to gain ground. This shift towards greater patient involvement in the management of their own health reflects upon the changing socio-economic realities. The emergence of growing economic elite in many parts of the world, coupled with a rise in the incidence of chronic diseases, has had the dual effect of increasing costs and demand. This, in turn, has had the effect of empowering the wealthy while forcing policy makers to ration general access to healthcare services.

In Europe, changes to the way healthcare is provided have prompted considerable alarm among patient-activist groups. A report produced by the Active Citizenship Network (ACN) ("Patients Rights in Europe: A citizens' report") following a meeting at the European Parliament in Brussels in 2005 indicates a high degree of dissatisfaction with even the basic healthcare provision. **As a result, patient action groups are pushing harder than ever for greater access to medical information, added protection from potential medical blunders and, above all, for greater patient involvement in the shaping and delivery of their own healthcare**.

Historical Background

Establishing the concept of patients' rights

The United Nations' (UN) Universal Declaration of Human Rights – particularly Article 25 with its reference to the universal right to health and medical care – **was a critical first step** in establishing the concept of **patients' rights** – rights derived from a declaration recognising that "the inherent dignity, the equal and the inalienable rights of all members of the human family are the foundations of freedom, of justice and peace in the world."

Yet it was not until after the dramatic scientific and medical achievements of the 1970s that patients' rights began to receive more serious attention, often as a result of pressure from patient organisations.

European and World Health Organisation efforts:

In Europe, the period 1977-1993 was marked by a growing interest in promoting standards in healthcare and patients' rights. In 1979, for example, the Charter of the Hospital Patient was adopted by the Hospital Committee of the European Economic Community (see Appendix A – specifically addressing the Hospital Patient).

Later, according to the Amsterdam Declaration on the Promotion of Patients' Rights (1994).

> *"Patients have the fundamental right to privacy, confidentiality, consent to, or refuse treatment and be informed about relevant risks of medical procedures"*

This convention, along with others (including the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms, the 1961 European Social Charter, and the 1966 Fundamental Convention on Civil and Political Rights and International Covenant on Economics, Social and Cultural Rights) built a firm foundationfrom which to base patients' rights, along with appropriate national legislation and charters.

The above declaration was the outcome of a meeting of the European Consultation on the Rights of Patients that was held in Amsterdam, under the auspices of the World Health Organisation Regional Office for Europe (WHO-Euro), and hosted by the government of the Netherlands. The meeting aimed at defining principles and strategies for the promotion of patients' rights, against a backdrop of wide-reaching reform in the healthcare systems of many countries at the time.

WHO–Euro used the long consultation period to encourage the promotion of patients' rights, including Pan-European surveys of the status of patients' rights across the continent. These were published in a book –

'The rights of patients in Europe'. One of the conclusions to emerge from this comprehensive series of surveys was that "patients should be aware of the significant contribution they can make to the optimal functioning of health systems". Patients' active participation in the process of diagnosis and treatment was, the researchers found, desirable and sometimes indispensable.

First Steps

The role of government:-

Although, not legally binding, the consultation process was intended to provide the moral authority that would stimulate governments to act. To that end, the final declaration was designed to serve as a powerful tool for governments and consumer groups alike, covering:

- Legislation or regulations specifying the rights and responsibilities of patients, health professionals and health care institutions;
- Medical and other professional codes, patients' charters and similar other instruments, drawn up on the basis of common understanding between representatives of citizens, patients, health professionals and policymakers;
- Networking between and among patients and healthcare provider groups;
- Government support for non-governmental organisations (NGOs) in the field of patients' rights;
- National conferences to bring the various parties in the field together;
- Involvement of the media in informing the public and creating awareness of the rights and responsibilities of patients and healthcare users;
- Better training in communication and advocacy skills, and;
- Promotion of research.

The Declaration divides patients' rights into five areas, summarised as follows (see Appendix B for the Declaration in full):

1 **Respect for human rights and values in health care**:- Particular emphasis is placed on protecting the dignity and integrity of the person and on promoting respect for the patient as an individual. It safeguards the patient's right to self-determination and to respect for moral, cultural and religious values. Patients have the right to protect their health through disease prevention and to pursue their highest attainable level of health.

2 **Information about health services and how to best use them**:-

- Patients have the right to information about their health, including medical facts, potential risks and benefits of any given procedure,

and alternatives to proposed treatment. **Information should be withheld only if it could cause serious harm without benefit, or where the patient has made an explicit request not to be informed.** Information must be communicated to patients in a way **appropriate to their capacity to understand it;**

- Patients have the right to choose who, if anyone, should be informed about their health, and should have the opportunity to seek a second opinion;
- When admitted to a healthcare establishment, patients should be informed of the identity and professional status of those responsible for their care, and of any relevant rules and routines, and;
- Patients should be able on discharge to request and receive a written summary of their diagnosis and treatment.

3 **Consent to clinical trials (see also Appendix C)**:- Patients' consent to any medical intervention or participation in clinical studies (see later for more detailed information) must be a prerequisite to any treatment.

- The patient has the right to refuse medical intervention, but must be given a careful explanation as to the implications of such a refusal;
- In the case of legal representation, patients must be involved in the **decision-making process** to the extent **they have the capacity to do so**, and;
- Where the patient is unable to give informed consent, he/she must be represented by a third party.

4 **Confidentiality and privacy**:- All information about a patient's health and any other personal information must be kept confidential, **even after their death**.

- Confidential information can only be disclosed if patients give their explicit consent;
- All identifiable data must be protected;
- Patients must have access to their medical files. There can be no intrusion into patients' private and family life, and;
- In-patients have the right to expect facilities that ensure privacy.

5 **Care and treatment**:- Everyone has the right to the healthcare appropriate to their health needs. Services should be continuously available and accessible to all.

- **Patients have the collective right to some form of representation in matters concerning the planning and evaluation of services;**
- Patients have the right to quality healthcare, characterised by high technical standards and by a **humane relationship between the patient and the healthcare provider;**
- Patients have the right to **continuity of care** and to **choose** and **change their physician**, care provider or care establishment insofar as is compatible with the functioning of the healthcare system;
- Treatment which is **limited in supply** should be provided to potential patients after **a fair selection process based on medical criteria**;
- In the case that a patient should be discharged, community services should be available, and;
- Patients have the right to be treated with dignity and to enjoy the support of their families; they have the right to **humane terminal care and the right to die with dignity.**

Under the five headings respect for human rights and values in health care; information about health services and how to best use them; consent, confidentiality and privacy; and care and treatment, the 1994 Amsterdam Declaration on the Promotion of Patients' Rights provided a comprehensive guide to promoting and safeguarding patients' rights. Despite the universality of its basic principles, however, the Declaration retained – if only in name – a European flavour.

Reforming health care for better health and quality of life for all: the European experience

Attention therefore shifted to drawing up a document with truly global appeal.

The Charter on Reforming Health Care, prepared in 1996 by the WHO, in Ljubljana, contains a series of recommendations aimed at improving healthcare services across all WHO Member States. The Charter centred on the principle that healthcare should, first and foremost, lead to better health and quality of life.

Drawing on the experience of those, predominantly European, countries that had attempted healthcare reforms, the Charter declared that the **general health of a population served as a useful indicator of social development**. European Union (EU) Ministers of Health that participated in the Ljubljana Conference urged citizens, institutions and governments alike to accept the need for healthcare reform, guided by certain key principles:

- **First, any reform process must be guided by principles of human dignity, equity, solidarity and professional ethics**. Healthcare reforms should aim at delivering continued improvements in the quality of care provided, as well as cost-effectiveness; address citizens' needs, building a service that is responsive to public demand and offers users the choice; and ensure that health services at all levels protect and promote health, improve quality of life, prevent and treat disease, rehabilitate patients and care for the suffering and terminally ill. **At the same time, citizens must share responsibility for their own health. Patients must be involved in joint decision-making with their care provider. Government should play a crucial role in regulating the financing of healthcare systems, and any major reform initiative must be accompanied by clear targets for improved health;**

- **Second, given the complexity of the issue, any major healthcare reform** must take account of national socioeconomic conditions, and must be continuously monitored and evaluated in a way that is **transparent to the public. Government must take a lead role in ensuring the equitable distribution of resources and access to health services, through legislative and regulatory levers;**

- **The Ljubljana Charter placed considerable emphasis on the rights of the citizen in shaping national health services**, stressing the importance of **open communication** and **access to information on issues of particular concern**, such as:

  - Service quality;
  - **Management of waiting lists**, and;
  - **The handling of complaints.**

The rapidly changing disease and population profiles of many countries means that new healthcare strategies are urgently needed, helping to shift working capacity from acute hospital care, to primary, community, day and home care services, for example. Regional health service networks need to be made more cost-effective, better able to respond to emergencies and better able to facilitate cooperation between hospitals and primary healthcare services. At the same time, healthcare services need to focus on developing information systems capable of guiding individual physicians, nurses and other healthcare providers.

Similarly, human resources need to be re-oriented to cope with the demands of changing healthcare systems. Managerial functions and public health infrastructures need to be devised in order to achieve the desired improvements in general health. **Perhaps most important of all is the need to promote the exchange of experiences on a national and an international level. And amidst all these changes, patients' rights must be held high.**

Europe Shows the Way

The 1996 Ljubljana Charter was followed in the same year by the 56th Conference of European Health Ministers in Warsaw, organised by the Council of Europe on the theme of Social Challenge to Health Equality and Patients Rights in the Context of Health Reforms.

Considerable focus was placed on establishing mechanisms that would address citizens' needs, give citizens a voice, ensure that choice was central to the design and delivery of health services and drive home the idea of individual as well as shared responsibility for one's own health. A Conference 'action plan' covered the following key issues:

- **Citizen and patient participation in the design, reform and functioning of national health services;**
- **Equitable access to healthcare services, and;**
- **Reassessment of the importance of health as an overall marker of social well-being.**

Close on the heels of the 56th Congress in Warsaw, the European Health Committee, composed of experts from the United Kingdom, France, Poland, Portugal and the Netherlands, held its 49TH meeting in Strasbourg, where it duly adopted terms of reference for a co-ordinated research study on the development of structures for citizen and patient participation in the decision-making process affecting healthcare (1997-1998). Those terms included:

- Reviewing and analysing **existing ways** of setting up and developing structures for citizens' and patients' participation in health care decisions;
- Identification of healthcare fields in which citizens and patients become involved in decisions relating to their health, and;
- Describing potential difficulties raised by the involvement of citizens and patients in the healthcare decision-making process.

Advancements in medicine and biotechnology – clinical trials, processes and registration - ensuring respect for human and patients' rights:

"respect for human life and human dignity"

In the meantime, dramatic developments in human biotechnology had been achieved, and continue at an often astounding pace. As the significant benefits offered by these new techniques are becoming clear, so too are the concerns they raise in terms of respect for human life and human dignity. The field of human rights has an important role to play in dealing with these issues, by providing a framework through which the rights of all interested actors can be taken into account. **The completion of the International Human Genome Project (HGP) for example had a major impact on issues of human and patients' rights. While not raising new ethical issues in medicine, the HGP does exacerbate old ones, especially with regard to equitable access to genetic services, privacy, disclosing of genetic information and freedom-of-reproduction choices. As a result, the HGP has increased public concerns about genetics despite its great promise for advances in human health.**

"guidelines on the disclosure of genetic information"

In a bid to address these concerns, particularly among individuals with genetic disorders, the Council of Europe has drawn up strict guidelines on the disclosure of genetic information. In a meeting at Oviedo in 1997, the Council of Europe Convention for the "Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human rights and Biomedicine", addressed the issue of patients' right to a private life and to access reliable, updated information on medical and biological advances – themes that have preoccupied a number of European and International authorities ever since.

In recent years, screening for genetic disorders such as thalassaemia, as well as for more common disorders such as heart disease, has become increasingly common. As a result, medical genetics have come to play a more and more prominent role in national healthcare services; and that has meant an increased role for governments in ensuring that such services are widely available, and in monitoring how genetic services protect patients' rights.

For its part, the Council of Europe has continued to take a lead in monitoring the impact of advances in medicine and biology, through the Parliamentary assembly's ad hoc Committee of Experts on Bioethics (CAHBI) – later renamed the Steering Committee on Bioethics (CDBI).

The Council of Europe prepared and issued the first legally binding international document aimed at protecting human dignity, rights and freedoms from misuse in biological and medical science.

Declaring that **"The interest of human beings must come before the interest of science or society"**, a series of principles and prohibitions were laid down, in the course of a Convention organised by the Council of Europe, concerning, among others, bioethics, medical research, consent, privacy, right to information and organ transplantation. **In brief, the Convention**:

- Bans all forms of discrimination on the grounds of a person's genetic make up, and allows the carrying of predictive genetic tests for medical purposes only;
- Prohibits the creation of human embryos for research purposes and requires the adequate protection of embryos in countries where in-vitro research is permitted;
- Stipulates that a patient's express consent must be secured before treatment, except in emergencies, and that such consent may be freely withdrawn at any time;
- Declares that patients have the right to be informed about their health – as well as the right to request not to be informed, and;
- Recognises the importance of promoting public debate and consultation on the above-mentioned issues.

Clinical Trials and Patient's Rights

Clinical trials is another important issue of concern in the context of rapid technological advancements in the area of drug development. It is also one that has for years been regarded as too complex a topic for ordinary people – something best left to specialists and academics but when, in June 2004, New York State Attorney, Elliot Spitzer sued a pharmaceutical company for allegedly concealing negative information about a drug, clinical research ceased to be an esoteric issue. Until then, industry (or indeed any person conducting a clinical trial) could legally suppress data obtained in clinical research.

Since 2004, consumer and patient organisations have joined forces with the medical professionals including the WHO to return to the process of clinical trials. A key demand is that any investigation into medical intervention should be made public right from the outset, before patients are recruited to enter trials. In the US, the 'Fair Access to Clinical Trials Act' (FACTA) was submitted to Congress in 2004, with similar moves taking place in the UK (see Appendix C for more on clinical trials and patients' participation).

EURORDIS – The European Organisation for Rare Diseases has lent its voice to those calling for change, launching the EURODIS Charter for Collaboration between Sponsors and Patient Organisations for Clinical Trials in Rare Diseases (see Appendix C). The Charter outlines a series of principles to which sponsors may publicly state their acceptance. EURODIS will then support such sponsors in identifying European patient organisations to co-operate in clinical trials. In this context, patient organizations may faithfully collaborate with sponsors in all phases and on several aspects of clinical trials such as:

- Adapting the design of the study to patients' expectations facilitates their adhesion to the trial;
- Providing early information to potential participants ensures and speeds up their inclusion in the trial;
- Supporting patients during the study reduces number of drop-outs and incomplete files;
- Taking quality of life into consideration and discussing trial results with sponsors contribute to the assessment of clinical and day-to-day benefits of the treatment.

(For more information on the Charter, sponsors and patient organisations are invited to contact **clinicaltrials@eurodis.org** .)

Challenges Ahead

"Europe's first network for patients' rights and citizen empowerment"

From this point, the intersection of healthcare systems and citizen/patient interests developed real momentum in Europe – one that easily lent itself to the more specific area of patients' rights. An early indication that the issue of patients' rights was indeed moving forward **was the establishment of Europe's first network for patients' rights and citizen empowerment**, at the **Nordic School of Public Health** in Göttenburg. This was the outcome of the Ljubljana Conference, which brought the WHO, the Nordic School of Public Health and the Nordic Council of Ministers together in consultation in Copenhagen in **April 1999**.

The Consultation provided a debating forum among parties interested in the promotion of patients' rights. **Participants discussed major concerns, including obstacles to implementing and enforcing legislation, and difficulties in monitoring the promotion of patients' rights.**

Key discussion points included:

1 How to increase patient participation in clinical decision-making

In order for patients to assume an active role in clinical decision-making, they must have the necessary time to get informed, enjoy a trustful relation with his/her health provider, and be capable of taking sound decisions concerning his/her own health or treatment. Issues such as the emotional state of the patient are possible challenges to patient participation in decision-making.

Increasing patient involvement in the process of decision-making requires that patients are perceived as knowledgeable, as individuals with fears and (dis)abilities, and as the best experts with regard to their disease. Patients must be involved in healthcare decisions as members of an 'executive board' of opinion – one in which their insight will be a major contribution.

2 How to involve patients' organisations in international work

It is commonly agreed that patients and patient groups should be closely involved where international organisations seek to promote patients' rights. In reality, however, this is very difficult to achieve, **Key challenges include**:

- Different culture and organisation;
- A large number of small patient groups making it difficult to handpick a few without creating resentment in others;
- Lack of resources;
- Different organisations have different goals;
- Language problems;
- Different interests.

At the same time, however, a number of factors make international collaboration possible, including:

- Genuine interest in learning from other countries;
- Patients' rights is a hot subject: measures aimed at strengthening civil society tend to appeal to politicians and international foundations alike;
- International involvement provides opportunities to influence the administrative and political system, and;
- Uniting forces is power, and organisations understand this.

In this context, the Consultation produced several suggestions, including:

- The WHO should issue an annual bulletin for patients' organisations, including guidelines and ways of promoting patients' rights;
- A European directory of patients' organisations should be created, organised by country and by interests disease group;
- A five-yearly European 'conversation' on patients' rights and related issues should be organised.

3 Media involvement in patients' rights:

The mass media could play an important role in informing the public about patients' rights, although it is a difficult subject to make 'newsworthy', by promoting patients' rights among the public at large and among decision-makers and running consumer satisfaction polls, interviews and hotlines.

4 Protection of children's rights and psychiatric patients

The rights of particularly vulnerable patients, such as children and those in the care of large psychiatric institutions, require the special attention of international conventions, as well as national legislation.

5 Development of information technology and its impact on confidentiality:

The rapid growth of information technology (IT) and its application to the healthcare sector carries both risks and opportunities. On the one hand, **some patients may now be able to gain more control over his/her personal data, while new technologies can provide physicians with more accurate information, at a quicker pace.**

On the other hand, challenges include security problems such as possible leaks of information and the difficulty of limiting access to only certain parts of a given database.

6 The role of healthcare providers with regard to patients' rights:

Health care workers have their own rights and obligations (see example from Hungary in Appendix D), and the best way to improve and enrich the relationship between health provider/doctor and patient is through a two-way process of education and information-sharing. Health professionals should adhere to their responsibilities and obligations, including respect for ethics and patients' rights, key areas in gaining patients' trust.

In addition, health care providers should inform citizens/patients as to what services are offered by their national healthcare system and how to access them.

Into the field

European Partnership for Patients' Rights: patient involvement in healthcare becomes a reality

Careful reflection by leading experts on the subject of patients' rights produced a useful outline of the key issues involved, along with guidelines as to how to approach the subject in the real world. The time had come to broaden discussions to include a wider audience.

In 1999, the WHO organised a meeting aimed at establishing a European patients' rights network, later renamed the 'European Partnership for Patients' Rights and Citizens' Empowerment' (EPPRCE), attended by representatives of 36 WHO Member States, non-governmental organisations (NGOs), experts from the fields of law and medicine, patients' representatives and other health professionals.

The following year, in February 2000, European Ministers of Health signed the 'Recommendation on the Development of Structures for Citizens' and Patients' Participation in the Decision-Making Process Affecting Health Care'. This document started from the premise that healthcare systems should be patient-oriented, and that citizens should be involved in all aspects of the healthcare system, at every level – national, regional and local.

The EU's Charter of Fundamental Rights

A first step towards a Charter of Patients' Rights

Later the same year, European Union Member States adopted the 'Charter of Fundamental Rights', signed in Nice on 7 December 2000, the Charter setting out the common values of EU Member States, and **drawing together rights previously laid down in national laws and international conventions, including those of the Council of Europe, the United Nations and the International Labour Organisation.**

On the issue of patients' rights, Article 35 of the Charter of Fundamental Rights states:

"Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".

In addition to Article 35, the Charter of Fundamental Rights contains many further provisions that refer either directly or indirectly to patients' rights. Examples include the inviolability of human dignity (Article 1) and the right to life (Article 2); the right to the integrity of the person (Article 3); the right to security (Article 6); the right to the protection of personal data (Article 8); the right to non-discrimination (Article 21); the right to cultural, religious and linguistic diversity (Article 22); the rights of the child (Article 24); the rights of the elderly (Article 25); the right to fair and just working conditions (Article 31); the right to social security and social assistance (Article 34); the right to environmental protection (Article 37); the right to consumer protection (Article 38); and the right to freedom of movement and of residence (Article 45).

The European Charter of Patients' Rights

The issue of patients' rights was finally given full and individual attention with the adoption of the European Charter of Patients' Rights in November 2002.

The Charter established 14 patients' rights, each of which was deemed to be at risk amidst a growing financial crisis in the welfare systems of EU Member States. The 14 rights specified were the right to: preventative medicine; access; information; consent; free choice; privacy and confidentiality; respect for patients' time; observance of quality standards; safety; innovation; avoidance of unnecessary suffering; avoidance of unnecessary pain; personalised treatment; and the right to complain and to receive compensation.

Establishing these rights in a European Charter actively served to support and promote their application at the national as well as the EU level. **The Charter also outlined a number of guiding principles relating to patients' rights:**

- Responsibility for health is shared between individual citizens and healthcare providers;
- The Charter applies to all individuals;
- The Charter cannot be assumed to have a position on ethical issues.

The Charter further stipulates that the rights defined are an embodiment of fundamental rights applicable in the contemporary European healthcare setting (see below). While defining and illustrating the rights specified, the Charter offers guiding principles rather than a handbook for all possible eventualities.

1 Right to Preventative Medicine

Every individual has the right to a proper service in order to prevent illness.

2 Right of Access

Every individual has the right to access to the health service that his or her health needs require. Health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.

3 Right of Information

Every individual has the right of access to all forms of information regarding their individual health, the health services and how to use them, and all, that scientific research and technological innovation makes available.

4 Right to Consent

Each individual has the right of access to all information that might enable them to actively participate in decisions regarding their health.

5 Right to Free Choice

Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information.

6 Right to Privacy and Confidentiality

Every individual has the right to the confidentiality of personal information,

including information regarding their state of health and potential diagnostic or therapeutic procedures, and the right to privacy during diagnostic exams, specialist visits and medical/surgical treatment in general.

7 Right to Respect Patients' Time

Each individual has the right to receive necessary treatment within a swift and predetermined period of time, at each stage of treatment.

8 Right to the Observance of Quality Standards

Each individual has the right of access to high quality health services, as specified by standard-setting authorities.

9 Right to Safety

Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards (see section on Safety).

10 Right to Innovation

Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.

11 Right to Avoid Unnecessary Suffering and Pain

Each individual has the right to secure, within the healthcare services, avoidance of as much suffering and pain as possible, in each phase of his or her illness.

12 Right to Personalised Treatment

Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.

13 Right to Complain

Each individual has the right to complain whenever he or she has suffered harm, and the right to receive a timely response or other feedback.

14 Right to Compensation

Each individual has the right to receive appropriate compensation within a reasonably short period of time whenever he or she has suffered physical, moral or psychological harm caused by a health service treatment.

The Role and Rights of citizens in promoting the Charter

In order to promote and verify the implementation of the above-stated patients' rights, some citizens' rights must be proclaimed, chiefly referring to organised groups of citizens (patients, consumers, advocacy groups, advice-givers, self-help groups, voluntary and grassroots organisations, etc.) that have the unique role of supporting and empowering individuals in the protection of their rights. These rights are pegged to the rights of civic association, contained in article 12, section 1 of the "Charter of Fundamental Rights" and include:

1 **Right to perform general interest activities:** Citizens have the right to perform general interest activities for the protection of healthcare rights. It is the duty of the relevant authorities and all relevant actors to favour and encourage such activity.

2 **Right to perform advocacy activities:** Citizens have the right to perform activities for the protection of rights in the area of healthcare, in particular (i) the right of persons and information to freely circulate in public and private health services; (ii) the right to measure the level of respect for the rights of citizens in the healthcare system; (iii) the right to prevent the violation of rights in the field of healthcare; (iv) the right to intervene in situations of violations or inadequate protection of rights; (v) the right to submit information and proposals and the obligation of the relevant authorities to consider those submissions and to reply.

3 **Right to participate in policy-making in the area of health:** Citizens have the right to participate in the definition, implementation and evaluation of public policies relating to the protection of healthcare rights. In this context, (i) the establishment of an ongoing exchange of information among citizens and institutions in the definition of the agenda is essential; (ii) citizens should be consulted on policy planning and decision-making, with the obligation on the part of the relevant institutions to consider proposals submitted by citizens' organisations and give feedback; (iii) all partners (citizens, institutions and other corporate partners) are fully responsible and operate with equal dignity; and (iv) all outcomes of civic associations be considered as tools for evaluating public policies.

The role of patients' and other non-governmental organisations

In addition to written rules and guidelines, such as legislation or the European Charter of Patients' Rights, another important tool in promoting and safeguarding patients' rights is patients' themselves, through their organisations.

In recent years, a number of international patients' organisations have focused significant attention on promoting patient-centred healthcare around the world, and on bringing into policy arenas the patient perspective on issues such as health literacy, patients' rights and adherence to therapy regimes.

Good examples include the Thalassaemia International Federation (TIF) (see section on TIF) and the International Alliance of Patients' Organization (IAPO). **The first IAPO Congress on this issue was held in London in 2005, involving 70 patient representatives gathered under banners reading "Trust us – we're patients" and "Nothing about us without us". The second IAPO Congress, held in Geneva in 2006, brought together over 120 patient representatives, to discuss issues such as access, participation in healthcare decision-making and policy impact.** The Congress closed with a Declaration on Patient-Centred Healthcare, outlining five basic principles underpinning patients' rights: (i) respect; (ii) choice and empowerment; (iii) patient involvement in health policy; and (iv) access to information. Congress participants also outlined the importance of securing the support and collaboration of policy-makers, health professionals, service providers and health-related industries.

"Trust us We are patients"

NGOs, and in particular patient-driven organisations, have an important role to play in furthering the patients' rights and citizens' empowerment agenda. In many cases, it is the work of NGOs that has put important health-related issues on the national and international policy-making agenda. NGOs that have spent years working in specific areas such as AIDS, cancer, haemophilia, thalassaemia or mental health, to name just a few, have highlighted the need for change in order to better address the concerns of individual patients and their families. The expertise such organisations have developed in shifting healthcare services to meet consumer demand, as well as in influencing national and international policy-making, serves as an important source of reference for those seeking to strengthen patients' rights.

NGOs: defining the policy-maker/ lobbyist interface

"Interaction between EU policy-makers and lobbyists"

An important activity at the EU level has been NGOs promotion of the long-awaited Green Paper, adopted in 2006, laying down clear ethical guidelines governing the interaction between EU policy-makers and the estimated 15,000 lobbyists, NGOs and other pressure groups that seek to influence them.

Publication of the Green Paper kick-started a public debate demanding greater openness of and accessibility to EU institutions. It will also, it is hoped, raise awareness of how EU funds are spent, as part of a general process of increasing the public accountability of EU institutions.

"Participatory democracy"

In the same vein, the EU has seen a surge of interest in the question of participatory democracy. Also in 2006, the Civil Society Contact Group (CSCG) organised a conference on the subject, focusing on two questions. First, what does participatory democracy mean to EU institutions and NGOs? And second, should NGOs be part of a dialogue with or in protest against EU institutions?

"Working with or against established authorities"

The question of working with or against established authorities, be it governments, corporations or international organisations, is an important one for NGOs. **For some organisations, however, NGOs are a vital link in their work chain. The World Health Organisation (WHO), for one, has had a long and successful history of working with civil society and non-governmental organisations – groups that it recognises as essential partners in fulfilling its mission to improve standards of health around the world.** WHO's work in the health sector involves not only medical specialists, but also politicians, economists, lawyers, communications specialists, social scientists and ordinary people everywhere. The success of such partnerships has in turn given rise to a new emphasis on partnerships, communication and outreach within the Organisation.

Collaboration between NGOs and the WHO

NGOs offer the WHO unique avenues for action, helping to implement health programmes at the country level, facilitating outreach to remote areas and population groups, advocating public health issues to a broad audience, addressing sensitive issues in a local context and helping the WHO raise funds more effectively. The increasing role of NGOs in the area of public health has placed new demands on the WHO. But it has also opened up new opportunities for building on the mutual benefits inherent to partnerships.

One of the most important contributions NGOs have made in the field of public health relates to human rights, pushing for national policies on the rights of health service users, as well as monitoring policy implementation at the local, national and international levels. NGOs also play a key role in supporting the WHO's work with individual governments to build up local public health capabilities. TIF, a non-governmental organisation in official relations with World Health Organisation, is an example of such productive collaboration. Indeed, in many parts of the world, the bulk of public health services are delivered by NGO, such as TIF. In the case of national emergencies, NGOs frequently play a lead role in providing access to health services and medicines. Very often, NGOs are the only route by which the WHO can secure access to local populations in need.

In short, NGOs are involved in a wide range of healthcare issues, including the delivery of services and are central to any discussion of patients' rights. The fact that many NGOs are also prominent and extremely important partners of the WHO's means that a strong network is in place through which an international effort to bolster patients' rights could feasibly be launched. And because the WHO also enjoys strong links with professional organisations, such an effort is more likely to have the simultaneous support of healthcare workers.

Finally, the important role NGOs play in balancing the political and commercial interests involved in public health only reinforces the contribution they can make to supporting patients' rights. In many parts of the world, NGOs work to promote openness and transparency in the setting of public health standards and policy, and help to ensure that private sector interests do not supersede public health priorities – functions critical to promoting and protecting patients' rights.

Patients' Safety

Safety in Health

Patient safety, a particularly important component of patients' rights, is rapidly becoming a critical area of concern in the area of public health. The EU, the Council of Europe, the WHO and patients' organisations have all focused on this issue. The second IAPO conference, for example, devoted a session to counterfeit medicine and its impact on patient safety. The 2006 WHO conference held in Rome discussed the theme of "Combating Counterfeit Drugs: Building effective international collaboration". Conference delegates proposed establishing an International Medical Products Anti-Counterfeiting Taskforce (IMPACT), with the WHO taking a lead role.

At the level of healthcare provider, improving patient safety requires carefully designed systems of care that reduce risks to patients. Complementary actions are needed to prevent adverse events, make them quickly visible when they do occur, mitigate their effects on patients and healthcare workers and reduce risks to future patients. As part of the process of improving patient safety, competent, conscientious and safety-conscious health workers in frontline services are vital.

Speaking on the subject of patient safety, the late Director-General of the WHO (2003-06), Dr Le Jong-Wook, said:

"Real leadership and commitment are required if we are to fight a problem that can affect every patient in the world and to reduce the appalling costs of unsafe care. It is needed to draw on the strengths and contributions of all parts of society through broad-based partnerships. And it is instrumental to mobilising national and international knowledge and resources on a scale far greater than we have so far."

In 2002, the Executive Board of the WHO recommended that the World Health Assembly (WHA) consider the issue of patient safety. The WHA duly adopted a resolution calling on Member States to:

- Pay the closest possible attention to patient safety;
- Strengthen patients' safety and quality of health care, for example by supporting the monitoring of drugs;

- Develop global norms and standards;
- Promote evidence-based policies and develop mechanisms to recognise excellence in patient safety internationally, and;
- Encourage research to further support other Member States.

Following the above resolution, the 57th WHA, in 2004, went further to support **the creation of an international alliance to facilitate the development of patient safety policy and practice in all Member States and to act as a major force for international improvements in patient safety.**

"*World Alliance for Patient Safety was established(2004)*"

In 2004, the World Alliance for Patient Safety, chaired by Sir Liam Donaldson, was launched. The Alliance aims to fulfil the requirements of the earlier WHA Resolution, creating an over-arching strategy, action programmes and coalition of nations, stakeholders and individuals to transform the safety of healthcare worldwide.

As the Alliance's work has progressed around the world, common challenges have emerged, including:

"*Raise Awareness*"

The need to raise awareness of the size of the patient safety problem and to build political commitment for action.

"*Repeated errors and system failures need to be addressed*"

'Solving' safety problems for which solutions already exist. The Alliance has found that the same errors and system failures are repeated not only across but also within countries. Action to address known risks is often too slow and poorly implemented.

"*Culture of blame vs culture of learning*"

Timely identification of new issues and their solutions. Despite increased efforts systems to detect risk and patient safety problems are still primitive. Even when adverse events do occur, many of them are not reported by healthcare workers. A culture of blame –

rather than a culture of learning – predominates. And blame and retribution cause harm and prevent safety flourishing. Understanding of the causes of patient safety problems is incomplete – knowledge essential to the design of effective solutions.

"The wisdom of patients is not effectively harnessed"

A lack of open partnerships with patients. Healthcare organisations are typically defensive in dealing with patients and their carers in the aftermath of a serious event. Patients and their carers are rarely asked for feedback on risks and problems. The wisdom of patients is not effectively harnessed.

The World Alliance of Patients' (WAP) Forward Programme 2006–07:

"…sets out an ambitious and comprehensive agenda for action on patient safety. Everyone working in healthcare needs to play their part. The stakes could not be higher. Safe care is not optional. It is the right of every patient who entrusts their care to our healthcare systems." (Sir Liam Donaldson, Chair, World Alliance for Patient Safety)

Through a concerted effort in key priority areas, the World Alliance for Patient Safety seeks to:

- **S**upport the efforts of Member States to promote a culture of safety within their healthcare systems and develop mechanisms to enhance patient safety;
- **P**ut patients at the heart of the international patient safety movement; Catalyse political commitment and global action in areas posing greatest risk to patient safety through the Global Patient Safety Challenge;
- **D**evelop global norms, standards and guidelines for ways of detecting and learning from patient safety problems to reduce risks for future patients;
- **M**ake safety solutions widely available to all Member States in ways that are as easy as possible to implement and relevant to their needs;
- **D**evelop and spread knowledge about evidence-based policies and best practice in patient safety;
- **B**uild a consensus on common concepts and definitions of patient safety and adverse events;

- **I**nitiate and foster research in areas that will have most impact on safety problems;
- **E**xplore ways in which new technologies such as simulation methods can be harnessed in the interest of safer care;
- **B**ring together partners to contribute towards knowledge development and social mobilisation;
- **T**arget technical work to reflect the patient safety priorities both of developed and developing countries.

Patients for **Patient Safety**

A second action area under the Global Patient Safety initiative was **'Patients for patient safety'**, which aimed at mobilising and empowering patients and patient representatives. A key approach included the **SPEAK-UP Campaign, promoting the following:**

- **S**peak up if you have questions or concerns: It's your right to know;
- **P**ay attention to the care you are receiving;
- **E**ducate yourself about your diagnosis, test and treatment;
- **A**sk a trusted family member or friend to be your advocate;
- **K**now what medications you take and why you take them;
- **U**se a healthcare provider that rigorously evaluates itself against safety standards, and;
- **P**articipate in all decisions about your care.

The Council of Europe and the European Union on **patients' safety**

The CoE has also devoted considerable attention to the question of patients' safety. In 2004, a recommendation was drafted on the management of safety and quality in healthcare, updated and revised in 2005. At the same time, the EU held a conference under the Luxembourg Presidency, in 2005, entitled '**Patient Safety – Make it happen'**, which focused on the following issues:

Challenges to patient safety at the EU level, and;
Developing a national framework for patient safety.

"Patient Safety - Make it happen"

The conference conclusions, summed up in the *'Luxembourg Declaration on Patient Safety'*, stated that access to high quality healthcare is a human right recognised by the EU, its institutions and member citizens, and the establishment of an EU forum bringing together major stakeholders was recommended.

National action on patient' Rights

Twelve years after the WHO Declaration on the promotion of patients' rights in Europe (Amsterdam 1994), 17 countries (Finland, 1992; the Netherlands, 1994; Israel, 1996; Lithuania, 1996; Iceland, 1997; Latvia, 1997; Hungary, 1997; Greece, 1997; Denmark, 1998; Norway, 1999; Georgia, 2000; France, 2002; Belgium, 2002; Switzerland, 2003; Russia, 2003; Estonia, 2002; Cyprus, 2005), have enacted laws on the rights of patients. A total of 17 countries (France, 1974 and 1975; San Marino, 1989; UK, 1991 and 1997; the Czech Republic, 1992; Spain, 1994; Ireland, 1995; Malaysia, 1995; South Africa, 1996; Portugal, 1997; Hong Kong, 1999; Germany, 1999, 2001 and 2002; Poland, 1999; Slovakia, 2000; Austria, 2001; Cyprus, 2001) have used Patients' Charters as a tool to promote patients' rights. The declaration, combined with networking and collaboration between the WHO and its Member states, has played a major role in this development and will continue to do so.

Passing legislation is not the only way to promote patients' rights. Many countries have charters that operate at the institutional level. This means that is sometimes difficult to assess patients' rights by country. Nonetheless, some broad conclusions can be drawn on a country-by-country basis. And at a still broader, regional, level, one important observation stands: while the 'hot' issues of consumer protection and citizens' empowerment are well entrenched in the countries of Western Europe, they are also gaining ground in Central and Eastern Europe and other parts of the world. It is these building blocks of a strengthened civil society that will provide the firm foundation on which patients' rights will become similarly entrenched – not just in word, but in action, too.

The efforts made in select countries towards the promotion of legislation on **Patients' Rights**, follow. The information provided is not exhaustive, and intends only to provide the reader with an overview. Information on Hunga has been included in appendix D.

1 The Nordic Model: Finland, Iceland, Denmark, Norway, Sweden

The Nordic countries are among the world leaders with regard to safeguarding patient rights. There were several factors behind increasing interest in patient rights in the Nordic countries as well as in the rest of Europe, however, the two dominant factors were medical technological advances and increasing lifespans.

Patients in these countries have the right to report any errors or shortcomings to supervisory authorities, which may lead to investigation of the care unit(s) in question. A limited number of regulations, among others those providing for the right to medical care in emergency situations and the right for patients to read their own medical records, give patients the option of turning to the courts if healthcare personnel have not fulfilled their obligations.

"Treatment 'guarantees'"

Another distinctive characteristic of Nordic health and medical care is the existence of so-called treatment **"guarantees"**. This is how the State handles existing queues of patients waiting to receive care and treatment. The extent of the guarantee varies between the Nordic countries and includes, among other things, the right to be examined by a doctor and to receive care and treatment within certain time frames. In practice, the care guarantee is an agreement between the State and the healthcare principal, a relationship to which the patient is not a party. He or she has no legal rights.

"Patients' legal rights"

Nordic countries have made increasing progress when it comes to safeguarding patients' legal rights. **Indeed, the most important provisions, in order for patients to be able to defend their legal security, is the possibility to make a complaint. The range of complaint procedures is impressive, meeting an important need among patients who, for some reason, may be dissatisfied with their care and treatment.**

However, a not too far-fetched scenario for the Nordic countries is that ageing populations and rapid technological development in the field of medicine, as mentioned above, accompanied by a growing need for health and medical care among the general public, will lead to calls for more robust prioritisation, in order to avoid the conflict between ambitions and resources that leads to patients' frustration and disappointment. These prioritisations will no doubt pose a threat to the development of patient rights.

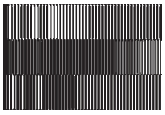
"Nordic countries play the role of model in this field"

Nordic countries are the role model, carriers of knowledge and an information bank. At a time when an increasing number of European countries are striving to strengthen patients' legal security and position within the health system, it is important to have both the models and the tools required. Nordic countries support the development of patients' rights in the rest of Europe, as well as in other parts of the world, by exporting their competence and experience in patients' rights.

Other countries with this type of legislation include: Israel, Lithuania, the Netherlands and Greece.

Israel

The Patients' Rights Law was enacted in Israel on 1 May 1996. Its objective is to regulate the relationship between people who require medical treatment and the medical staff who provide it. The law has established binding norms and codes of conduct concerning patients' rights. Medical staff and patient are partners in medical treatment. The law is based on the assumption that the patient is a cognitive person capable of demanding his right to proper medical care. The opening paragraph of the law states: "This act aims to establish the rights of every person who requests medical care or who is in receipt of medical care and to protect his dignity and privacy."



Lithuania

A Patients' Rights Law was enacted in Lithuania in 1996, intended to secure good medical practice and also to improve understanding between patients and medical staff, with the prerequisite that both were aware

of their rights. The Lithuanian law on patient's rights and compensation for damage to patient's health - now referred to as the Law on Patient's Rights - details patients' rights to: (i) accessible health care, (ii) select a physician, nursing staff member or health care institution, (iii) receive information, (iv) participate in instructional processes or scientific or medical experiments, (v) refuse treatment, (vi) file a complaint, and (vii) inviolability of personal privacy.

The results of a study conducted in 2002 demonstrated that the Lithuanian medical profession was well-informed about patients' rights but did not always respect them. It was believed that a lack of knowledge and assertiveness on the patients' side were key contributing factors. These results further suggest a need for awareness-raising among patients, which will contribute to the practical implementation of the Patient's Rights Law in Lithuania.

The Netherlands

The "Medical Treatment Contracts Act" came into force in the Netherlands in 1995, specifying the reciprocal rights and obligations of patients and care providers.

According to the results of the EuroHealth Consumer Index survey, launched in Brussels in June 2005 and involving 12 European countries, the Netherlands scored 48 points out of 60, winning first place.

Recently, the Netherlands has undergone considerable healthcare reforms, with a direct effect on patients' rights. Three developments prompted the change: the rising cost of technological advances, ageing and, very importantly, the prevailing belief that healthcare costs were a matter for the government to resolve. People tended to accept what they got from a doctor or hospital without been able or interested to judge the quality of care they received – a perception and situation that still prevails in many countries, within and outside Europe.

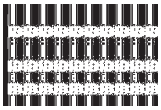
In addressing these problems the Dutch government involved all stakeholders in the provision of health care - consumers, care providers and insurers - to make them aware of its costs.

Since 1 January 2006, the country has had healthcare insurance that covers every person in the Netherlands. This transformed the field into a transparent market overnight.

In the Netherlands, everyone pays a substantial contribution, regardless of his/her income. Freedom of choice has been increased and people can now choose their insurer, and have better insight into differences between care providers.

Never before have Dutch people been so involved in their healthcare arrangements, and no other European country has a population so keenly aware of the costs of its healthcare provision.

There is a strong incentive for undertaking innovative customer-focused projects in the healthcare sector, particularly in hospitals focused on improving effectiveness and quality.



Greece

Until 1992, patients' rights were indirectly addressed through legislation focusing on the obligations of physicians: the code of Practice Medicine (1939) and the Regulation of Medical Deontology (1995), which referred to the physicians' obligations to provide all patients with equal care, to respect patients' dignity and religious freedom, and to protect medical secrecy. In addition, relevant provisions of civil, penal, administrative and disciplinary law referred to the rights of the individual. In 1992, based on the 'European Charter of Hospital Patients' Rights of 1979, legislation directly addressing the rights of patients was passed: the 'Act of Modernisation and Organisation of the Health System'.

Efforts to promote patients' rights subsequent to the 1992 legislation have focused on increasing public awareness by informing patients upon their admission to hospital, and through education of health professionals on patients' rights. Most educational institutions are introducing relevant courses in their curricula. It is expected that these efforts will be intensified and that further patients' rights legislation will give rise to health policies **increasingly empowering patients.**

Hungary: The Foundation for Patients' Rights, founded in 1994, has made significant advances in the field (see Appendix D).

Italy

Italy's National Health Service was established in 1980, with the following principal characteristics: citizens are free to choose 1) their doctor from a list of accredited GPs within the health service, 2) the ambulatory unit or out-patient service for their medical examinations, and 3) the hospital, should hospitalisation necessary. Free specialty medical services and medicines are provided to all from birth to 10 years of age, and to the over-60s, with additional support between 10-60 years of age, depending on patient diagnosis.

The Tribunal for the Rights of Patients

The Tribunal for the Rights of Patients was launched, in Italy in 1980, to protect the health and welfare rights of citizens and to help to achieve a more humane and functional health service. The Tribunal is comprised of ordinary citizens, workers from the sector and professionals, who provide their services on a voluntary basis. It involves local units throughout Italy and over 10,000 citizens working in hospitals and territorial services, a central structure to co-ordinate the network activities. Ongoing programmes and campaigns implemented by the Tribunal for Patients' Rights include:

- The "Safe Hospital Campaign";
- A programme for good practices in the health sector;
- An experimental project to reduce waiting lists;
- A programme on safety and quality in medical practices;
- A project on the "surgical path and citizens' rights";
- A campaign on pain therapy;
- A campaign to sponsor generic drugs, and;
- A campaign for compensation for damage suffered due to infections contracted from transfusions of infected blood.

The Tribunal for Patients' Rights is linked to the **Chronically Ill Associations' Coalition** and is composed of one hundred member Federations and Associations for **patients with chronic diseases.**

The Coalition seeks to leverage the actions of individual organisations through a common policy for all chronically ill patients. In 2000, it began publication of an annual report on Italian policy on chronic patients and their rights.

The Tribunal for Patients' Rights is also linked to "PIT Salute", a service created in 1996 to offer members of the general public information, advice and mediation in the protection of their rights in the welfare and health fields.

This service receives and manages reports and requests from 35 local provinces on how the health sector works and the quality of services offered.

Cittadinanzattiva is another Italian initiative, which aims to ensure that citizens assume a leading and constructive role in public policies. At the operational level, this entails a commitment to ensure that rights set forth in law are effectively implemented.

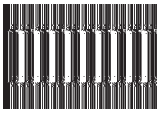
Regarding the promotion of civic space in Italy, Cittadinanzattiva has contributed to the rephrasing of paragraph no. 118 of the Constitution, which now states that the State, the Regions and local administrations must enable citizens to freely and independently carry out activities of general interest.

Germany

Until recently, patients' rights in Germany derived from Constitutional law, covered by extensive regulations. However, patients' interests received little attention from the medical professional or statutory health bodies, including insurers. As in many countries, financing health care came to be a significant problem. Important issues requiring resolution included discrimination against foreigners, the poor, children and women. Health policy needed to address cost patient responsibility, and the structure of medical care with its physician-centred approach. For these reasons, experts recommended the creation of the "Patients' Rights Charter", established in February 2003 by the German Federal Ministries of Justice and Health and Social Security.

Patients now enjoy greater participatory rights, with patient and consumer organisations participating in the decision-making process. A joint committee of patients' representatives, physicians and health insurance funds – not the State – decides on procedures that will be covered by health insurance.

In the past, representatives of the health insurance funds, doctors, dentists and hospital employees used to take important decisions on their own, without the participation of those affected. Changes in this regard have considerably improved the culture and transparency of the decision-making process. Informed patients who manage their own health are indispensable partners in a modern health care system.



Spain

In Spain, healthcare politics is a complex matter that involves 17 autonomously governed regions, with their own self-governing healthcare systems, and the national government. The 'Foro Espa•ol de Pacientes', an advocacy organisation for patients' rights whose charter is based on the Barcelona Declaration on Patients' Associations, issued in 2003 in Barcelona, aims to bridge the gap between the national and local health authorities.

France

The concept of patients' rights has been recognised in France since as far back as 1936, when the Supreme Court stated that the relationship between a doctor and a patient constituted a contract of health care. According to this, the patient had the right to expect treatment reflecting scientific progress at the time, and the physician was responsible for his/her patient. The first French text related to patients' rights as such was a ministerial circular dated 20 September 1974, introducing a Charter focused on patients admitted to hospital for in-patient treatment. However, the charter concentrated on the obligations incumbent upon healthcare establishments, rather than on the rights of patients within them. Thus, although it remains the first comprehensive text dealing with patients' rights in France, the charter has limited impact and is narrow in scope (see Appendix D for more on the rights of hospitalised patients).

The charter was later revised with the new version, issued in 1995, emphasising a patient's right to access any public hospital service and to comment on their stay in healthcare establishments. In addition, every hospitalised patient was to be provided with a copy of the Charter, informing her/him of their rights and expectations while in hospital.

France has enacted several other laws addressing patients' rights, biomedical research, and the ethical implications of medical technological advancements. In 1996, the Social and Economic Council strongly recommended that patients' rights should be given high priority in national legislation.

Patients in France today have free choice of provider and can visit any GP or specialist practising privately or in hospital outpatient departments, without referral and without any limit on the number of consultations. Patients can be hospitalised in the public or private sector service of their choice, with some limitations due to financial barriers (co-payments) or problems with geographical accessibility in rural or suburban areas. Patients can be given authorisation for treatment abroad, if the treatment is medically justified and not available in France, with the exclusion of emergency care.

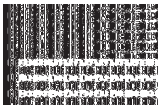
UK

In the UK, the awareness of patients' rights and related issues increased rapidly at the beginning of the 1990's. The Patients' Charter, launched by the British government in 1991, linked ideas of the individual consumer of healthcare services with the organisational reforms of the National Health Services (NHS). The Patients' Charter outlined rights and national standards, including the right to healthcare; physical security; freedom of choice; information; privacy; and the right to complain, the idea being to improve service quality and to give more value to the views of patients and carers.

Patient rights and responsibilities are set out in "Your Guide to the NHS" (http://www.nhs.uk/nhsguide/home.htm). Patients' complaints are addressed first through a local resolution, but patients can refer their complaint, if they wish to a higher level, requesting

the view of an independent panel or even higher, to the health service commissioner, or ombudsman. Under new legislation, Patient Advocacy and Liaison Services will be set up in every Trust, as well as in every locally based Independent Complaints Advocacy Service.

A stronger local voice sets out the government's plans for the future of patient and public involvement in health and social care, including the establishment of Local Involvement Networks (LINks), which will replace patients' fora. These will work with existing voluntary and community sector groups, as well as with interested individuals, to promote public and community influence in health and social care. The package of plans is designed to promote the importance of user and public involvement at all levels of the health and social care system, and to create a system that enables more people to become involved and have their voices heard (see also appendix C – DUETS).



USA

In 1997, President Bill Clinton established the **Advisory Commission on Consumer Protection and Quality in the Health Care Industry**, which focused on the preparation in 1998 of a report, **"Quality First: Better Health Care for All Americans"**. As part of its work, the Commission issued a **Consumer Bill of Rights and Responsibilities** which was intended to serve as a blueprint for how systems and procedures that aim to protect consumers and ensure quality of care could be improved. Three key goals were to:

i. Strengthen consumer confidence by ensuring that the healthcare system is fair and responsive to consumers' needs, i.e., that it provides consumers with credible and effective mechanisms to address their concerns, and encourages consumers to take an active role in improving and assuring their health;
ii. To reaffirm the importance of a strong relationship between patients and their healthcare professionals, and;
iii. To reaffirm the critical role consumers play in safeguarding their health by establishing rights and responsibilities for all participants in improving their health.

On 1 March 1999, a new bill was introduced to implement patients' rights legislation with regards to Denied Health Care. The legislation introduced by Senator Jack Reed (D-RI) would give consumers a place

to turn when they feel they have been wrongfully denied care from their managed care plans and would help them understand their rights and responsibilities within their health plans.

Consumer assistance programmes established by the Reed legislation would:

- Provide comparative information to help people select health plans most responsive to their families' needs;
- Operate 1-800 numbers to answer questions and complaints;
- Help health plan enrolees who felt they had been wrongfully denied care, with non-litigate appeals – that is, appeals conducted by health plans and administrative appeals independent of health plans;
- Make referrals, as appropriate, to health plan administrators, employers, regulators and others, and;
- Document the inquiries and complaints received so that all stakeholders in the healthcare system learn about emerging consumer concerns.

Consumer assistance programmes have already been established for Medicare and long term care patients. These programmes have helped millions of patients better understand their rights and helped them get the care they need.

In 2001, President Bush, stated that while he favoured passage of legislation creating a patient's bill of rights, he did not consider any of the Bills currently before Congress appropriate: "I want to sign a patients' bill of rights this year, but I will not sign a bad one. And I cannot sign any one that is now before the Congress," stated the President. "So enacting a patients' bill of rights this year is going to require some different thinking, a new approach, based on sound principles."

According to President Bush, existing Bills failed to provide adequate protection to healthcare plans against unnecessary and unreasonable law suits filed by patients.

The President also presented the principles he expected to see in a Federal patients' Bill of rights:

- "First, a federal patients' bill of rights must cover everyone, all patients in all private health plans. The standard should be strong enough to protect everyone, yet flexible enough to preserve the good work that has already been done in many states."
- "Second, we must guarantee all patients important rights: the right to get emergency treatment at the nearest emergency room; the right to see a specialist when they need one - say, just for an example, the right to see a cardiologist for a heart problem."
- "Third, if medical care is denied, patients should have the right to a fair and immediate review. People want health care quickly. They do not want to have to go through a legal, lengthy process to get it. I want to sign a bill that protects patients' rights with a strong, binding, independent review process. If your health plan denies you care, you should be able to appeal immediately to an independent, impartial review panel of medical doctors."
- "Fourth, a patients' bill of rights should offer patients who have been harmed a meaningful remedy, without inviting frivolous lawsuits. After independent review, if you have been harmed by your Health Maintenance Organisation's (HMO) refusal to provide care, you have a legitimate complaint, and you should have recourse in court. With a strong, independent review process, most disagreements should not wind up in court. Our federal legislation must allow the review process to work, not short-circuit it by inviting unnecessary lawsuits. With strong independent review, doctors make medical decisions, not the lawyers."

However, in May 2005, Republican John Dingell and other Democratic legislators introduced a new patients' bill of rights measure that would allow health plan members to sue their insurers in disputes over coverage of health care services. The measure, which is based on a bill passed by the Senate in 2001, would guarantee basic standards for access to care, including clinical trials, allow access to health care specialists and give patients "a fair, independent" external review process if an HMO denies care.

Belgium

Belgium has had a long history of promoting Patients' Rights. In August 2002, a new law was enacted that better protects patients' privacy rights, by giving them, for example., the right to be clearly informed about their health state, to consent to any medical interventions, and to have access to their medical files.

Malaysia

On 21 August 1995, a Memorandum of Understanding regarding the Patients' Rights Charter was signed between the Federation of Malaysian Consumers Associations, the Malaysian Medical Association, the Malaysian Dental Association and the Malaysian Pharmaceutical Society, although no information is available in the literature regarding the state of its progress and implementation.

Among other recognitions the Malaysian Patients' Charter include the following:

- The relationship between the provider of healthcare and a patient is privileged and sacrosanct;
- The highest traditions of healthcare mandate mutual trust and respect between the provider of healthcare and the patient;
- The meaningful partnership between the provider of health care and a patient requires that the patient participates actively in decisions relating to his/her health;
- A patient must assume not only rights, but also responsibilities;
- This Charter advocates universal ideals and standards of health care, which the government, the providers of healthcare and the public should strive to achieve, and;
- This Charter is an educational document embodying the Code of Medical Ethics.

Hong Kong

In accordance with contemporary trends in other industrialised countries, Hong Kong has adopted a Patients' Charter that outlines patient's rights regarding health treatment and choices. The purpose of the Patients' Charter is to explain both the rights and responsibilities when a patient uses the services of any Hong Kong's public hospitals. The patient, knowing and understanding his/hers rights and responsibilities will have the opportunity to make his/her relationship with health care providers a mutually beneficial one.

The Charter sets out the ways in which the community and the hospitals work as partners in a positive and open relationship with a view to enhancing effectiveness of the health care process.
Results of recent studies indicate that in Hong Kong not all patients are willing or wish to take part in decision making about treatment. For example, younger participants desired greater collaboration with the doctor in decision-making, while older participants preferred the doctor to have the greater input with respect to decision making.

Australia

The Australian Consumer's Council is developing a charter for all recipients of healthcare in both public and private hospitals in Australia. Several states already have laws covering various aspects of patients' rights and the Consumers' Health Forum in partnership with the Australian Consumers' Association have been involved for long in campaigns to improve the quality of the health system, including surveying the system.

Bangladesh

The Consumers Association of Bangladesh hosted a meeting on consumers and the healthcare system in 1994 which issued a series of recommendations to improve quality of service and encourage more involvement of consumers. However, no charter or legislation on the issue exists to date.

India

The Association for Consumers Action on Safety and Health (ACASH) and the Voluntary Health Association of India (VHAI) have publicised the Charter on Patients' Rights drafted by the Consumers Action Group in 1993 and have been campaigning ever since for its implementation. In mid-1995, a working group consisting of representatives from consumer groups, the Indian Medical Association and the Medical Council of India developed a citizens' charter scheme which the government intends to implement in the near future, through the Ministry of Consumer Affairs.

A recent article in "The Economic Times" of India raised some interesting facts concerning patients' rights in India:

According to the articles, "There is little protection that Indian patients and consumers get under the Indian Penal Code". The state of Maharashtra is trying to establish consumer rights in health care,. the state government prepared in 2006,.draft legislation (the 'Bombay Nursing Home Registration Act' (BMNHRA)) ,listing the rights that a patient can demand from every healthcare service provider in the state.

The only protection Indian consumers have in relation to healthcare service providers, is under the Indian Penal Code and the Consumer Act (Copra), which gives protection against criminal offences and malpractice by healthcare providers. The Indian legal system does not lay down the general level of rights and protection that a patient deserves. BMNHRA covers some of these issues, but it is only applicable in the state of Maharashtra.

The absence of central legislation for patients' rights is partly due to the exalted status given to doctors and hospitals in India. Patients do not see themselves as consumers of a service and doctors are not seen as service providers, but instead are considered **as saviours of human life, who can not be questioned and can do no go wrong.**

"The issue of patients' rights itself has not been raised in our country. I have been waiting for years for someone to ask us about patients' rights. Whether they should be there is a moot question. More important is who should implement and regulate them."

Dr Narottam Puri, Executive Director, Medical Services, Max Healthcare

The majority of Indian patients would never think to ask or to demand to know their doctors' education, professional certification or recertification, years of practice or experience in performing certain procedures - credentials that in most countries are made available even if the patient does not ask. In time patients' rights may come to be appreciated as a necessity by patients themselves in India. In the meantime, patients' organisations can contribute immensely in speeding the process.

Indonesia

A health law was adopted in Indonesia in1992, setting out provisions for patients' rights, including the right to receive information; give informed consent; enjoy medical confidentiality; have a second opinion; access to one's medical records and have the right to select one's physician and hospital. However, no further information is available in the literature regarding the extent of its implementation.

Pakistan

The Peoples' Health Movement (PHM) was formed in 2000 at Savar in Bangladesh, with the participation of 1,453 delegates from 75 countries. The Peoples' Health Charter endorsed at the event endeavours to revitalise the spirit of Alma Ata, which called for "Health for All" and a focus on "primary health care".

The Network for Consumer Protection took up the initiative, consulting with fellow organisations at a national meeting.

Dialogue between Pakistan and India professionals started in the course of this meeting. The first public health professional exchange not only supported the peace processbetween the two countries, but also mobilised people of both nations to demand their rights to health. Meetings all segments of society, including public health professionals, NGOs, academics, the media and ordinary people emphasised the shared interest promoting health for all in Pakistan.

The event provided new vigour to the PHM in Pakistan, helping to mobilise all segments of society.

Cyprus

Cyprus offers an interesting example of the important role NGOs can play in shoring up patients' rights. The Cyprus Patients' Rights Action Group (known by its Greek acronym, KIDDA), is an NGO whose ad hoc committee of 'wise men' includes a former President of the Supreme Court. Determined to raise public awareness of the issue of patients' rights, KIDDA drafted a Patients' Rights Charter, released in June 1999.

Efforts to introduce legislation were at first resisted by organisations representing the medical community. However, a bill on 'The Safeguarding and Protection of Patients' Rights' was finally passed in a unanimous vote of the House of Representatives (Parliament), and the law came into force on 7 April 2004.

Although a major step forward in recognising and protecting patients' rights in Cyprus, the law does not cover malpractice (which can be pursued under criminal law), nor does it aim to reform the country's health system. There is, however, a clause referring to the "right to high quality healthcare services", implying a government responsibility to safeguard and improve health services. A General Health Scheme, modelled on Britain's NHS, is due to be introduced, in 2008. Practitioners will have to face 'Medical Audits', including random checks, providing a further safeguard not only of patients' rights, but also of the overall quality of healthcare services provided in both the public and private sectors.

Cyprus law on The Safeguarding and Protection of Patients' Rights

- **Part 1** which lists the rights of the patient, and
- **Part 2** which addresses the mechanisms for safeguarding the rights proclaimed in part 1, and the implementation of the law.

The law provides for a Patients' Rights Officer (PRO), responsible for investigating patient complaints, to be established in each of the main public hospitals in each administrative district. PROs must respond to patient complaints within 24 hours, or the complaint will be referred to the regional 5-member Complaints Examination Committee. The PRO is also responsible for advising patients on how to safeguard their rights, and for informing and training medical, paramedical and administrative staff. Public hospitals are required to take all measures necessary to comply with a PRO's requests regarding patients' rights; complaints from patients at private institutions are investigated by the relevant regional Complaints Examination Committee.

The Ministry of Health is responsible for establishing and overseeing both the PROs and the regional committees, as well for training PROs and committee members. The establishment and monitoring of systems to follow closely and monitor the level of implementation of national charters and/or legislation on Patients' Rights in every country are essential tools.

The Rights of citizen and patients travelling abroad

Information mainly for EU citizens

Patient mobility

The right of EU citizens to seek health care in other Member States has been established by the European Court of Justice. In offering such facility, however, it is important to ensure that the well-being and safety of the patient is properly protected. At the same time, it is also important to recognise that treating patients from other countries places a considerable additional burden on national healthcare systems. In a bid to tackle these challenges, the European Commission in 2002 invited EU Ministers of Health to take part in a high level discussion on issues relating to patient mobility and healthcare developments in the European Union.

Their reflections produced 19 recommendations across areas such as:

- **1** European co-operation to enable better use of resources;
- **2** Information for patients, professionals and providers;
- **3** Access to and quality of care, and;
- **4** Reconciling national objectives with European obligations.

On the question of strengthening European co-operation to facilitate the better use of resources, one area offering particular scope for improvement is standards of care. Here it was agreed that **the goal should be to bring all systems up to the standard of the best, by structuring co-operation in particular areas, with specific objectives and regular progress reviews**.

Another important issue concerns the rights and duties of patients. **Citizens must be sure of what they can expect from health systems and care providers, but they must also understand what is expected of them**. The process of reaching a common understanding on patients' rights at a European level must begin by bringing together existing information on how the issue is addressed by the various Member and accession states. Again, the aim here is to provide a consistent framework of patients' rights across Europe – something that coordination between states could more easily address.

Citizens of the European Union are entitled to certain benefits, including a reimbursement of fees paid for medical treatment received, in the EU, outside the patient's home country, above the amount that would have been paid in that patient's home country. Key aspects of the EU's legal framework regarding medical care are as follows:

- An EU citizen may seek in any Member state any non-hospital care to which they are entitled in their own country, without prior authorisation, and may be reimbursed up to the level of reimbursement provided by the home state;
- An EU citizen may seek in any Member state any hospital care to which they are entitled in their own country, with the authorisation of health authorities in the home state, and may be reimbursed up to the level of reimbursement provided by the home state. Health authorities are required to provide such authorisation if the care required cannot be delivered within a medically acceptable time limit;
- EU health authorities must provide citizens with information on how to seek authorisation of care in another Member State, including rates of reimbursement and appeal procedures. EU citizens temporarily resident in another Member State will be reimbursed for any healthcare costs in their home country, on the basis of tariffs and fees in force in the Member State where the care was delivered.

Despite these overarching principles, however, the system remains arbitrary in some respects, for example in securing authorisation for treatment outside the home state, undermining legal certainty. **The European Commission is investigating ways to better clarify the rights of citizens seeking healthcare in other Member States.**

There's a bed over here

Although cross-border co-operation between healthcare systems is complex, it also offers a multitude of benefits to patients and to healthcare systems themselves. A report commissioned by the European Commission suggested the evaluation of existing cross-border health projects and networking to share best practice. It also suggested that the Commission explore the

possibility of introducing a framework for health purchasing, through which the health authorities of Member States could formulate agreements.

European centres of reference

On the question of treating specific diseases, the EU has proposed establishing European centres of reference, offering a concentration of resources and expertise on specific conditions, so as to facilitate the provision of high quality, cost-effective care, particularly for rare diseases. The Commission has been tasked with finding ways to foster networking and co-operation in the organisation, design and development of such centres, in partnership with Member States.

Assessing health technology

Developments in health technology have, to a large extent, spurred the sharp improvement in human health seen in recent decades. With more effective therapies and a broader scope of health interventions, previously untreatable conditions can now be tackled and even cured. However, this increasing sophistication of health technology is also responsible for large and possibly unsustainable increases in expenditure. As a result, **there is now an urgent need to evaluate new developments in health technology, including their safety and effectiveness, and their wider implications. Here, again, co-operation at the European level offers efficiencies in terms of sharing information and tasks.**

Health systems information strategy

Information is the basis for identifying best practice and comparing standards of healthcare. However, high quality, wide-ranging information on the various healthcare systems of the EU is conspicuous in its absence. In a bid to tackle

this gap, the Commission has been asked to develop an EU-level framework for the gathering and use of health information – one that would identify: the different information needs of policy-makers, patients and professionals; how that information could be provided; and the responsibilities of the different actors concerned, including those tasks already assumed by the WHO and the Organisation for Economic Cooperation and Development (OECD). The framework should also systematise data collection and strengthen areas of particular weakness, such as data on the volume and nature of patient movement, including tourism-related flows and long-term stay.

Data protection

Of particular interest is the issue of data protection, including the sharing of confidential data between Member States. The Commission was invited to address these issues, as covered by **EU Directive 95/46/EC** on the protection of personal data and the free movement of people within the Union.

The Directive's objective is to harmonise data protection legislation across Member States, in order to facilitate the free movement of personal data within the Union, while protecting the fundamental rights and freedoms of natural persons. It also provides a strong framework for the handling of personal data in cross-border health care.

Monitoring progress and implementation

A Citizen's View

The Active Citizenship Network (ACN) began life in December 2001 as the European and international branch of the Italian citizen movement - Active Citizenship, its mission being to promote and support an active European citizenship, meaning the exercise of citizens' powers and responsibilities in policy-making. This recognises, the pivotal role of national and local citizens' organisations as participants in policy-making and the need for the EU to further promote the relationship between government institutions and citizens.

Work by the Active Citizenship Network (ACN), offers excellent insight into the status of the 14 patients' rights outlined in the European Charter.

"Patients' Rights in Europe: A citizens' report" is the result of an ACN project bringing together 13 NGOs working in the healthcare field. The project aimed to monitor the implementation of patients' rights, as well as to empower citizens – changing them from being **"mere targets and users of health services, to active citizens engaged in producing information and participating in policy-making". In short, the project itself can be regarded as a further device for promoting a 'patients' rights approach' to healthcare.**

ACN began by translating the Patients' Rights Charter into a set of measurable indicators, which could be consistently and reliably assessed 'in situ'. A total of 160 different indicators were collected from each country:

- Partner organisations interviewed 70 key local stakeholders, including medical professionals, journalists, payers (insurers) of healthcare, and representatives of national Ministries of Health;
- Partner organisations visited 39 main hospitals in each of the European capital cities, noting that hospital authorities in four of these countries (Germany, Ireland, the UK and Portugal) refused to make the relevant data available.

Headline results

Taking each of the 14 patients' rights in turn, the main findings of the survey were as follows:

1. **Prevention:** With the exception of screening for female cancers, preventative medical practice is almost absent in European hospitals;

2. **Access to care:** Patients' rights of access to care have been violated. For instance, regulators in some European countries have failed to approve medicines that are readily available in others. With the exception of Portugal and Greece, physical access to hospitals is good;

3. **Right to information:** Although hospitals have created mechanisms to supply information to the public, the material actually provided is scant;

4. **Right to consent:** Forms aimed at gaining patient's consent to medical procedures are common, but only to secure patient participation in scientific research. Efforts to gain the informed consent of patients are unimpressive;

5. **Right of free choice:** The free choice of patients to select treatments and providers is restricted, because governments refuse to pay for all types of care to be made available to all people;

6. **Privacy and confidentiality:** Healthcare providers show little respect for patient privacy beyond the traditional provision of curtaining off examination rooms;

7. **Respecting patients' time:** Hospitals consistently fall short of respecting a patient's need to be cared for within a specific and limited time span - a failure that can have serious consequences for health;

8. **Quality of healthcare:** Health performance standards are set in hospitals, but with little regard to the needs of citizens;

9. **Patient safety:** All Europe's hospitals appear to or are making serious efforts to take adequate precautions against hospital-acquired infections, but, are less effective at quashing the use of outmoded diagnostic tests or treatments. Moreove, the needs of the physically disabled are often ignored;

10. **Accessing innovation:** The uptake of innovative medical practice is ad hoc throughout Europe;

11. **Avoiding unnecessary pain and suffering:** Pain management is inadequate in most of the European countries surveyed in this project;

12. **Personalised treatment:** Few, if any, hospitals surveyed gave sufficient attention to the provision of personalised services for patients. Only the needs of children appeared to be well-considered;

13. **Complaints:** Complaints procedures are faulty throughout Europe;

14. **Compensation:** With the exception of Greece, hospitals and/or doctors carry insurance to cover patient compensation. In practice, however, patients can sometimes find it hard to secure payment.

Reservations with regard to the above project, expressed in the course of an international conference in Brussels in 2005, include:

- Insufficient attention paid to some NGO specialities,such as the health needs of women, older people and children;
- A patient's right to optimum care, and the right to receive care near home, when appropriate were not included in ACN's Charter.

Dr Giovanni Moro, programme adviser to ACN, explained at the conference that the Patients' Charter (and some aspects of ACN's methodology) were under continued review.

"It will be useful to expand the Charter, make it more robust, and link it more effectively to daily situations and to a general framework of human rights", he said.

"Experience has shown that more training is required by the local civic groups involved in the monitoring process, and greater effort is needed in future to convince hospital authorities to become involved in civic audits."

"Formulating patients' rights and promoting their implementation are incremental processes."

Participants added their own ideas, which often echoed those of Dr Moro:

- European countries need to be made aware of patients' priorities and the importance that should be attributed to advocacy organisations and citizens' groups;
- Well-meaning national measures to support patients' movements should be backed up with appropriate investment;
- Concepts such as 'wellbeing', 'prevention' and 'health' have to enter common parlance—especially that of doctors, and;
- Questions about patients' rights should become an integral part of healthcare policymaking—rather than being added on later as an unimportant afterthought.

Another survey, published by the UK Patients' Association in 2005, confirms the need for further efforts to increase public awareness in the field. For example, a large proportion of those surveyed, believed they had many rights as patients, when in fact the National Health Services (NHS) gives patients few rights. A significant minority of people did not know of the existence of the few specific rights they do have within the NHS, and, even more important, the vast majority of the public remain unaware of the existence of patient organisations that are meant to represent the interests of patients within the NHS.

"The public thinks that they have more rights as patients"

Quoting the address of Bernard Merkel, Director of Health Strategy at the European Commission's DG Sanco, at a meeting organised by ACN at the European Parliament in Brussels, in 2005, constitutes the best approach to summarise the information contained in this booklet.

"Member States share a huge range of common healthcare principles. In practice, however, huge variations in the tradition, culture and operation of national healthcare systems perpetuate significant divisions between the approaches of each country. The reality is that all 25 current Member States run their own national healthcare services exactly as they please.

Although Article 35 affords citizens in Europe specific health rights, these relate to preventive practices only. Each country is free to interpret the health elements of the EU Constitution as it wishes.

Nonetheless, the EU is starting to take a bigger role in helping to frame health policy, so that Member States can be assisted in responding to new challenges (such as EU enlargement, new technology, or increases in patient mobility). The process is being accelerated because Europeans are searching for better healthcare in EU nations other than their own. We, at DG Sanco, are also looking at several new options to improve the quality of health information.

Formulating a rights-based approach to healthcare is probably premature at the moment. Member States are unlikely to sign up to the idea as yet.

It is important to remember that European bureaucrats such as myself are not democratically elected to jobs in the EU. Change, if it is to come, should be driven from the grassroots upwards. Here, I emphasise the importance of groups like Active Citizenship Network, which embraces NGOs that have come together from across Europe. Such networks, unfortunately, are under-resourced—which does not mean that the need for an articulate voice on patient matters should be muffled. In this sense, at least, the European Commission can provide logistical help."

Bernard Merkel
Director of Health Strategy,
DG Sanco, European Commission

The Thalassaemia International Federation (TIF) and patients' rights

The Thalassaemia International Federation is committed to protecting the rights and safety of patients with thalassaemia around the world. To this end, an ongoing focus is to better understand and promote the rights of chronically ill patients. In this context, TIF works closely with other national, European and international patients' organisations, health authorities, institutions and the medical community, as well as integrating patients' rights in its educational programmes.

In protecting the specific rights of patients to receive appropriate and safe blood transfusion therapy treatment, TIF has joined forces with other European patient associations, whose treatments, as in the case of thalassaemia, require blood or blood products, jointly establishing the PanEuropean Blood Safety Alliance – (PBSA), in 2005. PBSA aims to promote the implementation of European Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components; the objective being to pass on the expertise and knowledge gained to low resource countries, where thalassaemia is of high prevalence and where hundreds of thousands of patients are in need of safe and adequate blood.

George Constantinou, a leading patient advocate and founding member of TIF, has been fighting for the rights of patients with thalassaemia since long before any charter or legislation on the issue. George is a regular speaker on the subject in workshops, seminars and conferences.

Addressing the 10th International Conference on Thalassaemia and Haemoglobinopathies and 12th International TIF Conference for Thalassaemia Patients and Parents, held in parallel on 7-10 January 2006 in Dubai, George Constantinou outlined some of the lessons he has learnt – from personal experience and through his work around the world.

"I am a patient with thalassaemia major, 40 years old, born in Cyprus. I am married and I have a daughter. I have been fighting for all my life."

George Constantinou, Patients' Rights Activist

He noted in his presentation that:

- **Research shows that people living with chronic illnesses are often in the best position to know what they need to manage their condition;**
- **Provided with the necessary 'self-management' skills, they can have a tangible effect on their disease and quality of life, and;**
- **Where a treatment programme is discussed and agreed with patients, they are more likely to comply with treatment and follow clinical advice.**

He added that a great deal is within a patient's power and advised:

- **Educate yourself about your condition and all its aspects;**
- **Learn your rights;**
- **Ask or, when necessary, demand your rights;**
- **Become an 'expert patient', and;**
- **Remember that keeping yourself well is as much your job as it is your doctor's.**

The presentation also referred to the Expert Patients' Programme, a training programme run by Britain's National Health Service that helps people with long-term chronic disease to develop new skills to better manage their condition on a day-to-day basis.

In conclusion, the rights of patients are well-recognised and laws and regulations in this field exist in a great many countries. The problem now is that more co-ordinated efforts should be promoted by NGOs, patients and health professionals, who need to actively work towards: **the implementation of the Patients Rights' Charter, regulations and laws.**

In his book "Who should we treat? Rights, rationing and resources in the NHS" (Oxford University Press, 2005), Christopher Newdick explores the changing context of healthcare in Britain, touching on many of the key reasons that patients' rights have finally made it on to policymakers' agendas.

"Was there once a golden age when patients had confidence that their doctors and the system as a whole would provide them with the treatment they needed, when they needed it and to a reasonable standard?" he asks. "Perhaps; but the basis of such belief may equally have been the absence of reliable information on which to question doctors. Medicine too could provide less security, especially before the discovery of many modern treatments. And, at the same time, there was a greater sense of inevitability surrounding illness (and, indeed, death)."

"Today, things are very different. We are less deferential to professional authority and more inclined to speak up when things seem wrong and we have more effective means of measuring and comparing medical standards. The courts too are willing to subject doctors and health authorities to closer scrutiny by insisting they have good reasons for their decisions. At the same time, medical and pharmaceutical advances present us with an increasing range of interventions that promise much therapeutic benefit, but their cost will impose further strain on finite healthcare budgets and more hard choices between deserving patients."

Appendix A

Charter of the Hospital Patient
(Luxembourg, 9 May 1979)

Adopted by the Hospital Committee of the European Economic Community during its Plenary Session, on the report submitted by the Sub-Committee on Hospital Management, held in Luxembourg on 6-9 May 1979.

Preamble

1 In the conviction that the hospital patient has fundamental rights in relation to the service provided in a hospital and that these rights are closely connected with a humane service, the Hospital Committee of the E.E.C. decided, during its 18th General Assembly in Copenhagen, May 1977, to study these rights. This study has resulted in a charter of the Hospital patient, which was adopted during the 20th General Assembly in Luxembourg, May 1979. In formulating its views the Committee has taken into account the following articles:

- Art. 25 of the Universal Declaration of Human Rights (1948);
- Art. 11 and 13 of the European Social Charter (1961);
- Art. 12.1 of the International UNO-Convention on Economic, Social and Cultural Rights (1966);
- Resolution 23.41 of the World Health Organization (1970).

2 The Charter is specifically for the hospital patient. It is not meant to ignore other patients in the health care system, but the Hospital Committee of the E.E.C. wishes to stay within its role, by formulating patient rights in the hospital situation. The Committee hopes that this Charter of the Hospital Patient will contribute to the evolution of a Charter of patient Rights in a wider setting.

3 The hospital is, in the understanding of the Committee, not an absolute solution for all health problems. The Committee holds the view that everyone has a basic right of access to an organized and structures health care system, in which the hospital, along with other services, fulfils its own role.

4 The Charter of the Hospital Patient is a statement of each person's individual basic rights, within the hospital setting. It acknowledges for instance the right of self-determination, the right to information, the right to respect for his privacy, the right to religious and philosophical freedom.

5 A statement of the rights of the hospital patient however, is in itself not sufficient. In each hospital, the conditions should be created in order to respect these rights, and further, to make the patient aware that he has claim to these rights. The need to create these conditions should be reflected in the manner in which the hospital is organized, in the planning of its physical resources and the attitudes of its staff.

6 It must be pointed out that the rights set out in the Charter are accompanied by obligations on the part of the hospital patient. These obligations include reasonable behaviour at all times, respect and consideration by him for the rights of his fellow-patients, and co-operation with the hospital staff and management.

7 Subject to the legislation enacted in each country, the Charter is applicable to all hospital patients. There are some categories of patients (e.g. psychiatric patients) who require additional safeguarding of their rights. Nevertheless the Charter is intended to be an overall statement of the basic rights of all hospital patients.

The rights of the hospital patient

1 The patient has the right of access to hospital services appropriate to the nature of his illness or condition.

2 The hospital patient has the right to considerate care with respect for his human dignity. This care includes not only medical, nursing and allied services, but also appropriate counselling, accommodation, administrative and technical assistance.

3 The hospital patient has the right to consent to, or refuse the application to him of any diagnostic or treatment procedure. In the case of a patient who is fully or partially incapable (as defined by law or in reality) of

exercising this right, it shall be exercised, to the extent that the patient cannot do so himself, on his behalf by his representative or a person defined by law.

4 The hospital patient has the right to information relevant to his situation. The best interests of the patient should be paramount in the imparting of information. Subject to this, the information given must allow the patient the fullest insight into all aspects of his situation, medical and otherwise and, on an informed basis, enable him to make his own decisions or to participate in decisions which have implications for his well-being.

5 The hospital patient or his representative (as referred to in Λ 3) has the right to be fully informed in advance concerning the risks involved in the application to him of any un-established diagnostic or treatment procedure. The explicit consent to the carrying out of such procedure must be obtained and can be withdrawn at any stage. With regard to the patient's participation in clinical research or teaching, the patient must be made to feel completely free to accept or decline, to participate or to withdraw at any stage.

6 The hospital patient has, within the physical limitations or the environment in which he is accommodated, the right to the protection of his privacy. The confidentiality of information and records of a personal, particularly medical nature must be ensured.

7 The hospital patient has the right to respect for and recognition of his religious and philosophical beliefs.

8 The hospital patient has the right to complain, to have his complaint investigated and to be informed of the outcome.

Appendix B

1 HUMAN RIGHTS AND VALUES IN HEALTHCARE

The instruments cited in the Introduction should be understood to apply specifically to the healthcare setting, and it should therefore be noted that the human values expressed in these instruments shall be reflected in the healthcare system. It should also be noted that where exceptional limitations are imposed on the rights of patients, these must be in accordance with human rights instruments and have a legal basis in the law of the country concerned. It may be further observed that the rights specified below carry a matching responsibility to act with due concern for the health of others and for their same rights.

1.1 Everyone has the right to respect of his or her person as a human being;
1.2 Everyone has the right to self-determination.
1.3 Everyone has the right to physical and mental integrity and to the security of his or her person.
1.4 Everyone has the right to respect for his or her privacy.
1.5 Everyone has the right to have his or her moral and cultural values and religious and philosophical convictions respected.
1.6 Everyone has the right to such protection of health as is afforded by appropriate measures for disease prevention and health care, and to the opportunity to pursue his or her own highest attainable level of health.

2 INFORMATION

2.1 Information about health services and how best to use them is to be made available to the public in order to benefit all those concerned.
2.2 Patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment.
2.3 Information may only be withheld from patients exceptionally when there is good reason to believe that this information would without any expectation of obvious positive effects cause them serious harm.

2.4 Information must be communicated to the patient in a way appropriate to the latter's capacity for understanding, minimizing the use of unfamiliar technical terminology. If the patient does not speak the common language, some form of interpreting should be available.

2.5 Patients have the right not to be informed, at their explicit request.

2.6 Patients have the right to choose who, if any one should be informed on their behalf.

2.7 Patients should have the possibility of obtaining a second opinion.

2.8 When admitted to a health care establishment, patients should be informed of the identity and professional status of the health care providers taking care of them and of any rules and routines which would bear on their stay and care.

2.9 Patients should be able to request and be given a written summary of their diagnosis, treatment and care on discharge from a health care establishment.

3 CONSENT

3.1 The informed consent of the patient is a prerequisite for any medical intervention.

3.2 A patient has the right to refuse or to halt a medical intervention. The implications of refusing or halting such an intervention must be carefully explained to the patient.

3.3 When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared expression of will that consent would be refused in the situation.

3.4 When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain, in time, the representative's consent.

3.5 When the consent of a legal representative is required, patients (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.

3.6 If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then the decision must be referred to a court or some form of arbitration.

3.7 In all other situations where the patient is unable to give informed consent and where there is no legal representative or representative designated by the patient for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and,, to the greatest extent possible, what may be presumed about the wishes of the patient.

3.8 The consent of the patient is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances are to be used in the current course of diagnosis, treatment and care of that patient.

3.9 The informed consent of the patient is needed for participation in clinical teaching.

3.10 The informed consent of the patient is a prerequisite for participation in scientific research. All protocols must be submitted to proper ethical review procedures. Such research should not be carried out on those who are unable to express their will, unless the consent of a legal representative has been obtained and the research would likely be in the interest of the patient. As an exception to the requirement of involvement being in the interest of the patient, an incapacitated person may be involved in observational research which is not of direct benefit to his or her health provided that that person offers no objection, that the risk and for burden is minimal, that the research is of significant value and that no alternative methods and other research subjects are available.

4 CONFIDENTIALITY AND PRIVACY

4.1 All information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death.

4.2 Confidential information can only be disclosed if the patient gives explicit consent or if the law expressly provides for this.

Consent may be presumed where disclosure is to other health care providers involved in that patient's treatment.

4.3 All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of their storage. Human substances from which identifiable data can be derived must be likewise protected.

4.4 Patients have the right of access to their medical files and technical records and to any other files and records pertaining to their diagnosis, treatment and care and to receive a copy of their own files and records or parts thereof. Such access excludes data concerning third parties.

4.5 Patients have the right to require the correction, completion, deletion, clarification and/or updating of personal and medical data concerning them which are inaccurate, incomplete, ambiguous or outdated, or which are not relevant to the purposes of diagnosis, treatment and care.

4.6 There can be no intrusion into a patient's private and family life unless and only if, in addition to the patient consenting to it, it can be justified as necessary to the patient's diagnosis, treatment and care.

4.7 Medical interventions may only be carried out when there is proper respect shown for the privacy of the individual. This means that a given intervention may be carried out only in the presence of those persons who are necessary for the intervention unless the patient consents or requests otherwise.

4.8 Patients admitted to health care establishments have the right to expect physical facilities which ensure privacy, particularly when health care providers are offering them personal care or carrying out examinations and treatment.

5 CARE AND TREATMENT

5.1 Everyone has the right to receive such health care as is appropriate to his or her health needs, including preventive care and activities aimed at health promotion. Services should be continuously available and accessible to all equitably, without discrimination and according to the financial, human and material resources which can be made available in a given society.

5.2 Patients have a collective right to some form of representation at each level of the health care system in matters pertaining to the planning and evaluation of services, including the range, quality and functioning of the care provided.

5.3 Patients have the right to a quality of care which is marked both by high technical standards and by a humane relationship between the patient and health care providers.

5.4 Patients have the right to continuity of care, including cooperation between all health care providers and/or establishments which may be involved in their diagnosis, treatment and care.

5.5 In circumstances where a choice must be made by providers between potential patients for a particular treatment which is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination.

5.6 Patients have the right to choose and change their own physician or other health care provider and health care establishment, provided that it is compatible with the functioning of the health care system.

5.7 Patients for whom there are no longer medical grounds for continued stay in a health care establishment are entitled to a full explanation before they can be transferred to another establishment or sent home. Transfer can only take place after another health care establishment has agreed to accept the patient. Where the patient is discharged to home and when his or her condition so requires, community and domiciliary services should be available.

5.8 Patients have the right to be treated with dignity in relation to their diagnosis, treatment and care, which should be rendered with respect for their culture and values.

5.9 Patients have the right to enjoy support from family, relatives and friends during the course of care and treatment and to receive spiritual support and guidance at all times.

5.10 Patients have the right to relief of their suffering according to the current state of knowledge.

5.11 Patients have the right to humane terminal care and to die in dignity.

Appendix C

(from Patientview 2005)
Clinical trials: Guides for patients

- **Informed Consent,** a 300-page consumer guide describing the risks and benefits of participating in clinical trials. [K. Getz and D. Borfitz, *Informed consent: the Consumer's Guide to the Risks and Benefits of volunteering Clinical Trials,* Thomson/CentreWatch, 2002.]

- **Should I enter a Clinical Trial?**, a patients' reference guide intended to make the subject of clinical trials understandable to the lay public. [A report by the emergency Care Research Institute (ECRI), written for the American association of Health Plans (AAHP), and funded by an unrestricted educational grant from Pfizer, *should I enter a Clinical Trial?* A Patient reference Guide for adults with a Serious or Life-Threatening Illness, February 2002; downloadable at http://www.ecri.org/Patient Information/Patient Reference Guide/prg.pdf.]

- **Questions to ask about a Clinical Trials Web Site** helps patients and the public determine whether the 40 or so websites detailing clinical trials are reputable, possible biases, limitations and influences that may affect the information services provided are analysed. [Summit or clinical Trials V, Questions to Ask about a Clinical trials Web site, August 2003, Nationla Cancer Institute; downloadable at http://www.cancer.gov/clinicaltrials/finding/questions-about-web-sites/allpages.]

- **Cancer Research: A guide to Clinical Trials,** an on line educational service for cancer patient and caregivers, developed by the National Cancer Cooperative Groups (NCCG) of Philadelphia. The resource can be found at http://www.cancertrialshelp.org/selfStudyGuide/Coalition.htm. According to Robert Cornis, president of the Coalition, "80%of patients use the internet for health information because they need to make quick decisions about their treatment". The NCCG is a coalition of group expert in cancer clinical trials, whose members include cooperative groups, cancer centers, academic medical centers, community hospitals, physician practices, and patient advocacy groups. Together, they represent the interests of more than 17,000 cancer investigators, hundreds of patient advocates, and thousands of patients worldwide. The coalition is largely financed by the pharmaceutical industry.

Clinical trials registration – patients' perspectives

Clinical trials have always been regarded as too "highbrow" a topic for ordinary people – something best left to bookish academics. Only a few health campaigners attempted to penetrate the subject (and then, only in order to fight for the rights of participating patients. But when, on June 2nd 2004, New York State Attorney Eliot Spitzer sued GSK for allegedly concealing negative information about its anti-depressant Paxil, clinical research ceased to be an esoteric issue, and moved into the media and political spotlights.

Since that date, consumer and patient organizations have delved into the regulatory and legislative frameworks governing the clinical trials process. Health campaigners discovered, to their surprise, that industry (or, indeed, any person conducting a clinical trial) could legally suppress data obtained in clinical research. Campaigners realized that this lack of transparency had encouraged a sub-culture of misconduct among academics, as well as industry. In the wake of escalating allegations of inappropriate conduct within the clinical research processes, patients and the public have joint forces with medical professionals to demand that any investigations into medical interventions should be made public from the outset, even before patients are recruited to trials. [Other stakeholders involved in reform of the clinical trials registration process include the UK National Health Service; the World Health Organization (WHO); and the US politicians who submitted the Fair Access to Clinical Trials Act (FACTA) to congress and Senate on October 7th 2004.]

Four different definitions of clinical trials:

- A clinical trial is research done to evaluate new treatments in people. [Source: National Library of Medicine – the world's largest medical library, based in Bethesda, USA.]
- Clinical trials are research studies designed to provide information on the safety and effectiveness of medical devices, drugs, diagnostics, and other healthcare interventions. [source: UK Cochrane Center, Oxford, UK]
- Any investigation in human subjects intended to determine the clinical, pharmacological, pharmacokinetic, and/or other

pharmacodynamic effects of an investigational agent, and/or to identify and adverse reactions to an investigational agent, to assess the agent's safety and efficacy. [Source: CenterWatch – a publishing house specializing in clinical research, based in Boston, Massachusetts]

- A type of research study that tests an investigational new drug or method, to see how well it works on people. The study is overseen by the US Food and Drug administration, the drug regulatory authority, and may be carried out in a clinic or other medical facility. There are usually four phases. [source: Phoenix 5, a prostate cancer patient group based in Ohio (http:www.phoenix5.org).]

Harris poll on patient participation in clinical trials

In America and Europe, the three factors most likely to influence the decision to participate were:

- "If I had a terminal illness"
- "If I thought a drug might cure me"
- "If there were no other medical options available to me"

In India the top three factors were:

- "If I thought a drug/treatment might help me"
- "If I knew there were no risks involved"
- "If my doctor recommended it"

The study was conducted in collaboration with Fas4wD, Eli Lilly & Company, and the Center for Information and Study on Clinical Research Participation (CISCRP).

Objectives of the World Health Organisation's International Clinical Trials registry Platform (ICTRP)

- Provide global standards for the registration and disclosure of trials and their results.

- Establish a global network of certified registries.
- Establish a state-of-the-art technical system, comprising a one-stop global search function of certified registries.
- Establish a system of unambiguous trials identification and template register.
- Advice and help build capacity of CT registration.
- Establish an ongoing business model for permanent operation by 2006.

The Consumers' Union and its campaign

The consumers' Union (CU) is a non-profit publisher of *Consumer reports,* with six million subscribers. The CU is running a campaign known a "Prescription for Change" [http://www.consumersunion.org/campaigns/prescription], which calls for the creation of a mandatory clinical trials register so that doctors and patients have access to the latest information about the side-effects of drugs.

In its submission to the Institute of Medicine's hearings on June 27th 2005, the CU stated that it was "deeply concerned that public confidence and faith in the drug approval-and-safety process has been severely damaged by a number of recent, high-profile cases. We believe that the Food and Drug Administration needs a number of additional authorities and resources to give more emphasis to safety in the process of pre- and post- market approval of pharmaceuticals".

The CU continued: "a key part of restoring public confidence in the drug safety process is to require that information about (and obtained from) clinical trials on pharmaceuticals be registered and made public. Though, in some cases, it may not be necessary to register and disclose results from phase-I and some phase-II trials, we urge the institute to err on the side of more public information, not less. For those who have volunteered to assist in these trials, often at danger to themselves, we owe it to these individuals to learn and gain from their experience. It is essentials that the goals, specifications, and endpoints of clinical trials be registered and made public. It is a scandal that, in some recent cases, only portions of clinical trials that made a drug look good were made public, and portions that revealed danger and unacceptable risk - or lack of effectiveness – were hidden".

The Consumers Union has endorsed the proposed Fair Access to Clinical Trials Act (FACTA), introduced to the Horse and senate in October 2004.

Database of uncertainties about the effects of treatments (DUETs)

The Database of Uncertainties about the Effects of treatments (DUETs) was launched in December 2005, and falls under the aegis of the UK-based James Lind Alliance, Mark Fenton, editor of DUET's, explains the concept behind the database:

"Many major uncertainties surround the effects of treatments. To ensure that the treatments do more good than harm, uncertainties must be identified and addressed in research. Yet, at the moment, research on the effects of treatments often fails to consider questions of importance to patients (or the clinicians to whom patients turn for help). DUETs have been established to identify and publish those questions about the effects of treatment that concern patients and clinicians. Some of the questions can be found by referring to up-to-date systematic reviews of existing research evidence."

Eurordis Charter for Collaboration between Sponsors and Patient Organisationsfor Clinical Trials in Rare Diseases.

General Principles

1. Patient organisations (POs) should be informed on all aspects of the clinical study protocol before committing to collaborate. This would provide legitimacy to the inclusion of patients in the study. For the same reasons, any potential amendment to the protocol should be immediately communicated to the POs.

2. POs should actively contribute to the documents aimed at patients - information document and consent form - to ensure their content and format can be understood by lay people, thus allowing truly informed consent by patients.

3 Domains and extent of collaboration should be declared in a document called "Agreement of Understanding" available for all stakeholders: patients, investigator, ethics committees and national competent authorities. The agreement, co-established on a voluntary basis by sponsors and POs for a given clinical study, describes the fields and potential limitations of the collaboration, without detailing its content.

4 Financial relationships between sponsors and POs should be made transparent.

5 Study results should be published, even in case of negative outcomes, non conclusive or abandoned clinical trials.

6 Patients participate in clinical studies to improve their knowledge of the disease and help develop adapted treatments. To fully respect patients' collective commitment, the data acquired during clinical trials should be made available to the scientific community, with a view to foster scientific progress and avoid unethical duplication of clinical trials.

7 In any case, the commitment of a PO in the design and/or development of a trial do not modify the role and responsibilities of the sponsor, even if the study is financially supported by the PO.

- What is included, or excluded, from the collaboration (e.g. study design, patient information and support, patients' inclusion in the trial, discussion of results, clinical benefit assessment, participation in independent monitoring committees etc).
- In the study design, the fields included or excluded from the collaboration (e.g. inclusion criteria, main and secondary objectives, quality of life criteria, number of patients included, duration of the study, use of control treatments…).
- POs' commitment (e.g. contribution to identification of study centres, communication on the clinical trial, support to the inclusion of patients, patient support during the trial, phone line dedicated to the trial).
- Points potentially considered confidential by the sponsor (e.g. production processes, clinical development plan…).

- Names of PO signatories of the confidentiality agreement in case of restricted dissemination of information. Similarly, any potential conflict of interest should be declared by each signing member.
- Date or event-related clause in case of temporary restriction of access to data (marketing authorisation, scientific communication…).
- Any type of financial relationship between POs and Sponsors: purpose, amount, and type of support, including in-kind donations.

In case of a multinational study including several national POs, a common agreement for all involved POs should preferably be adopted. However, if necessary, the agreement may be adapted to fit each national specific situation.

Appendix D

Rights and Obligations of Healthcare Workers (According to Act CLIV of 1997. on Health)

Care Provision Obligation of Healthcare Workers

Section 125

In emergencies, irrespective of time and place, the healthcare worker shall provide first aid to any person in need, to the extent that said healthcare worker can provide such aid under given conditions with the implements available, and/or shall immediately take necessary measures. In cases of doubt, the existence of an emergency shall be presumed.

Section 126

1 When mandated to provide in-area care, the healthcare worker shall take the measures during his working hours, as set forth in Subsections (2) and (5) and in keeping with the professional competencies and expertise of the healthcare worker, to provide care for a patient requesting it.

2 A physician, assuming that he is authorized to do so on the basis of professional competence and expertise, shall examine all patients requesting to be seen. Depending on the findings of the examination, he shall treat the patient or, in the absence of proper objective and personnel conditions, shall refer the patient to a physician or healthcare provider with the proper conditions.

3 Examination of the patient shall include investigating all complaints of which the attending physician is aware, ascertaining patient's medical his story and discovery of individual circumstances that influence patient recovery.

4 The measures set forth in Subsections (2) - (3) shall be circumvented only in cases when life-saving interventions of pressing necessity are required.

5 A healthcare worker who does not have medical qualifications shall provide such examinations for patients requesting them that are within his competency, or when they exceed the healthcare worker's scope of competency, he shall notify a physician with the authority to conduct said examinations. In this latter case, however, if made necessary by patient's condition, until arrival of the physician, he shall complete all interventions for which he is authorized on the basis of professional competency and experience.

Section 127

1 For the duration of the time a physician is absent or otherwise prevented from providing care,

a) the employer of the attending physician
b) in lieu of an employer, the attending physician himself
c) or if the attending physician is prevented from providing care, the regionally responsible health authority, at the expense of the healthcare provider,

shall have to arrange for the examination and treatment of the patient through another physician, which shall not include the situation when there is an on-duty physician handling the work of the attending physician.

2 The physician requested to attend to the patient as a substitute, or the on-duty physician, shall have to brief the regular attending physician on events related to the patient's health within an appropriate time frame and in an appropriate manner.

Section 128

1 To ensure that continuous care is available a healthcare worker obliged to provide In - area care shall, in keeping with employer rules and the provisions of separate statutes, beyond regular working hours

a) be within reach, or in stand-by in a specific place, or
b) provide on-duty services.

2 With respect to Subsection (1)

a) stand-by is defined as being prepared and ready to conduct work during out-of-the ordinary working times, at a specific place accessible or designated by the healthcare provider,

b) on-duty shall mean, if it is not necessary or possible to organize a regular work shift, availability to work at a work site during out-of-the-ordinary working time in return for an on-duty fee, as well as to conduct both on-duty tasks and tasks falling within the healthcare worker's job description.

Choice of Methods of Examination and Therapy

Section 129

1 It shall be the right of the attending physician to choose freely among the scientifically accepted methods of examination and therapy [as set forth in Paragraph b) of Subsection (3) of Section 119], within the framework of valid statutes, that are to be applied, are known to and practiced by him or the persons participating in the care and that can be carried out under available objective and personnel conditions.

2 The prerequisite for applying the method of examination and therapy chosen shall be that

a) the patient has consented to it within the rules of this Act, and

b) the risk of the intervention is lower than the risk of non-completion of the intervention, or that there be a well-founded reason for taking the risk.

3 When performing /his tasks, the attending physician shall be authorized to

a) request the participation of another physician or healthcare worker with other qualifications in the examination or treatment of the patient,

b) recommend or convene a consultation.

Section 130

1 The attending physician, in his area of responsibility, shall be authorized to issue instructions to healthcare workers participating in patient care. The instructions shall include a clear specification of the task to be completed, the place and time of completion, and, if necessary, the names and sphere of activity of additional healthcare workers to be requested to participate.

2 The healthcare worker participating in the care shall

a) Execute the instructions in accordance with the conditions set forth in them and in keeping with the code of practice of the profession,

b) Immediately notify the attending physician, or if this is impossible, another physician participating in the care of the patient, if an unforeseeable event or event leading to the deterioration in patient condition occurs during implementation,

c) Immediately make it known to the attending physician, or if this is impossible, to another physician participating in the care of the patient, if in his opinion, execution of the instructions would have an unfavourable influence on the condition of the patient, or if he has some other concern,

d) Refuse to execute the instructions, simultaneously notifying the attending physician, if, according to knowledge he is expected to possess, compliance would threaten the life of the patient or lead to permanent impairment to patient's health that would otherwise not be a necessary outcome of treatment.

3 The participating healthcare worker, if instructed to execute the instruction despite the provisions set forth in Paragraph c) of Subsection (2), shall be authorized to request that said instructions be communicated in writing.

4 Within the framework of the instructions, the healthcare worker, in keeping with his own professional competency and experience, shall make his own decisions on the manner and order of executing the tasks he is to complete.

The Right to Deny Care

Section 131

1 A physician directly involved in patient care may refuse to examine a patient seeking care

a) if prevented from doing so because of the immediate need to care for another patient or

b) because of a personal relationship with the patient

on condition that he refers the patient to another physician.

2 A physician may refuse to examine and provide further treatment for a patient if his own health or some other obstacle renders him physically unfit to do so.

3 A physician may refuse to provide care for a patient only following an examination, if in the course of the examination he determines that

a) the patient's health status does not require medical care,

b) the treatment requested by the referring physician or the patient is not justified professionally,

c) the healthcare provider does not have the personnel or objective conditions needed to provide the care and he refers the patient to a professionally responsible healthcare provider, or

d) the condition of the patient does not require immediate intervention and the physician completing the examination can order the patient to return at a later time, or the physician acts in accordance with Paragraph b).

4 If, during the course of examining the patient, it is concluded that the treatment recommended by the referring physician or the patient is in conflict with the statutes or with professional rules, the physician may deny care.

5 A physician also may refuse to treat a patient if

a) said treatment is in conflict with the physician's moral outlook, conscience, or religious convictions,

b) the patient seriously violates his obligation to cooperate [Subsection (2) of Section 26],

c) patient behaves in a manner that insults or threatens the physician, unless this behaviour can be attributed to the disorder,
d) patient behaviour puts the life or physical well-being of the physician at risk.

6 In the cases set forth under Paragraphs a) and c) of Subsection (5), the physician only may refuse care if

a) said refusal will not damage patient health, and
b) he refers patient to another physician, or recommends that the patient see another physician in his own interests.

Section 132

1 A healthcare worker who is not a qualified physician must deny care requested by a patient if

a) provision of said care conflicts with statutes or professional rules,
b) physically unfit to provide it because of his own state or health or other obstacle.

2 A healthcare worker who is not a qualified physician may refuse care within his sphere of competence for causes set forth in Subsection (5) of Section 131, when simultaneously notifying the attending physician.

Section 133

When a healthcare worker is employed by a healthcare provider with obligation to provide in-area care, the condition for exercising the right of refusal set forth in Paragraph a) of Subsection (5) of Section 131 shall be the notification of the employer in writing of this circumstance prior to commencing employment or immediately following the occurrence of the circumstance during the course of employment.

Obligation to Provide Information

Section 134

1 With the exception of cases set forth in Subsections (1) - (2) of Section 14, the attending physician shall brief the patient on his medical condition to the best of his knowledge, with the regularity justified by the condition, in keeping with the level of knowledge expected of the physician, and in accordance with the provisions set forth in Section 13.

2 If the patient's disposing capacity is severely impaired or limited, the attending physician also shall inform the persons set forth in Subsection (2) of Section 14 or Section 16.

3 Receipt of general informative leaflets prepared in bulk shall not substitute for a provision of oral information.

4 In appropriate cases the information shall include the circumstances set forth in Subsections (1) and (5) of Section 209, Paragraph e) of Subsection (1) of Section 210, and Paragraph e) of Subsection (2) of Section 219.

Section 135

1 The attending physician shall be circumspect in informing the patient, and shall do so gradually when necessary, considering the patient's condition and circumstances.

2 When informing the patient, special attention shall be given to the generally known, significant side effects of treatment, to possible consequences, and to possible outcomes of interventions including the frequency with which they occur. The physician shall ascertain that the patient has understood the information, and when necessary the physician shall see to it that the patient so informed shall have psychological care.

Obligation to Document

Section 136

1 The healthcare documentation shall contain data related to patient's examination and treatment. Clinical charting shall be conducted in a manner that reflects the true course of the healthcare process.

2 Healthcare documentation shall include

a) patient identification data,
b) if a patient is in possession of full disposing capacities, a person to be notified in case of emergency, or in the case of a minor or a person with a guardian, the name, address, and manner of accessing said patient's legal guardian,
c) patient's history, and the aetiology of the disease,
d) the results of the initial examination,
e) the results of examinations/test serving as a basis for diagnosis and therapy, and the dates on which said examinations/tests took place,
f) the name of the disease justifying care, the underlying diseases, co-morbidities, and complications,
g) the names of other illnesses not directly requiring care, and of the risk factors,
h) the time and results of interventions,
i) pharmaceutical and other therapies, and the results,
j) patient data on over-sensitivity (allergies) to medications,
k) the name of the healthcare worker recording the information on the chart, and the date on which it was charted,
l) a statement of the information provided to the patient and/or to other persons authorized to receive said information,
m) the fact of patient consent [Subsection (3) of Section 15] or denial of consent (Sections 20-23), and the date(s) on which it (they) occurred,
n) all other data and facts that can influence treatment outcome.

3 The following shall be maintained as a part of healthcare documentation:

a) findings from all laboratory tests,
b) documents written during the course of treatment and during consultations,

c) nursing care documents,
d) copies of images taken during imaging diagnostic procedures, and
e) findings of tests on tissue samples taken from the patient's body.

Section 137

1 At the conclusion of a therapeutic procedure consisting of several parts or following care in an inpatient facility, a written summary report (discharge summary) shall be prepared and, excepting the case as set forth in Subsection (1) of Section 14, this report shall be given to the patient.

Obligation to Maintain Confidentiality

Section 138

1 All healthcare workers and all persons employed by a healthcare provider shall be obliged to maintain unlimited duration confidentiality regarding the health of a patient, as well as regarding all data learned while providing healthcare services, irrespectively of whether said data was provided directly by the patient, or learned through an examination/test or through treatment, or learned indirectly through medical documentation or in any other manner.

2 The requirement for confidentiality shall not cover cases in which the patient has given a release, or for which statutes specify an obligation to provide said data.

Protection of Healthcare Workers

3 Section 139

A healthcare worker and all other workers employed by a healthcare provider qualify as persons performing a public service when performing any of the following:

a) issuing medicolegal expert report,
b) judging fitness or unfitness to work or the degree to which working ability has been impaired,
c) judging fitness to perform a job or work in a given occupation,
d) conducting examinations as part of a procedure to grant a permit linked to physical fitness,
e) conducting examinations to determine eligibility for other healthcare, health insurance or welfare services,
f)performing mandatory public health measures,
g) performing an examination or intervention at the request or on the orders of the authority,
h) providing on-duty or emergency services.

The Right and Obligation to Develop Professionally

Section 140

A healthcare worker and other person employed by a healthcare provider has both the right and the obligation to continuously develop and advance his professional knowledge, in keeping with the current state of science and its advances.

Rights and Obligations of Patients (According to Act CLIV of 1997 on Health)

Right to Health Care

Section 6

Each patient shall have a right to receive, in an emergency, life-saving care to prevent serious or permanent impairment to health, as well as to have his pain controlled and his suffering relieved.

Section 7

1 Each patient shall have a right, within the frameworks provided for by law, to appropriate and continuously accessible health care justified by his health condition, without any discrimination.

2 Healthcare shall be considered appropriate if delivered in compliance with the professional and ethical rules, and practice guidelines relating to the specific healthcare service.

3 Healthcare shall be considered to be continuously accessible if the operation of the health care delivery is such as to enable its use 24 hours a day.

4 Healthcare shall be considered free from discrimination if, in the course of delivering healthcare services, patients are not discriminated against on grounds of their social status, political views, origin, nationality, religion, gender, sexual preferences, age, marital status, physical or mental disability, qualification or on any other grounds not related to their state of health.

Section 8

1 The patient shall have a right to choose his attending physician, with the agreement of the healthcare provider of the level justified by his condition and, unless a legal rule sets forth an exception, the physician so chosen, provided it is not precluded by the professional contents of

the health service justified by his condition, by the urgency of care or the legal relationship serving as the basis for the use of the service.

2 The right to choose a physician as in Subsection (1) may be exercised in accordance with the rules of operation of the healthcare provider.

3 A patient may initiate that he be examined by a second physician in connection with any diagnosis made or therapy recommended by his attending physician, or regarding his planned discharge from an in-patient institution or referral to another healthcare provider.

Section 9

1 If a patient cannot be given the necessary care warranted by his health condition within the shortest possible period of time, the healthcare provider shall be obliged to inform him of the healthcare provider where the specific healthcare service is available.

2 The patient shall be placed on a waiting list, if

- the specific healthcare service cannot be delivered by another healthcare provider, or
- in the case defined in Subsection (1), the patient refuses to be cared for by another healthcare provider.

3 If placed on a waiting list, the patient shall be informed of the reason for, and expected duration of waiting, as well as of its possible consequences.

4 The patients' order on, and selection from the waiting list shall be based upon unified, controllable and published professional criteria, in a manner justified by the state of health of patients on the waiting list and without any discrimination. The patients' advocate shall also be entitled to verify compliance with these principles, upon written authorization by the patient.

5 The waiting list shall contain the medical and personal identification data of patients waiting to receive the specific healthcare service, as well as the circumstances justifying their selection.

The Right to Human Dignity

Section 10

1 The patient's human dignity shall be respected in the course of health care.

2 Unless otherwise provided by this Act, only the interventions necessary for the care of the patient may be performed.

3 In the course of health care, a patient may be restricted in exercising his rights only for the period of time justified by his state of health, and to the extent and in the way, as provided for by law.

4 In the course of health care, the patient's personal freedom may be restricted by physical, chemical, biological or psychological methods or procedures exclusively in case of emergency, or in the interest of protecting the life, physical safety and health of the patient or others. Restriction of the patient may not be of a punitive nature and may only last as long as the cause for which it was ordered exists.

5 The application of restrictive methods or procedures shall be ordered by the patient's attending physician, unless otherwise provided by this Act. Prior to applying such restrictive measures, or if it is not possible, within the shortest possible time after the initiation of their application, the attending physician shall enter the restrictive methods or procedures in the medical record, indicating precisely the reasons for and the duration of application. In the absence of continuous medical supervision, in exceptionally justified cases, a registered specialist nurse may also giver temporary order for the restriction. The attending physician shall be informed of the restriction without delay, and shall be required to approve it in writing within sixteen hours. In the absence of such approval, the restriction must be discontinued. If restrictive methods and measures are applied, the patient's condition and physical needs shall be observed regularly, in compliance with professional rules. The observation and the findings shall be entered into the patient's medical records.

6 A patient may only be made to wait on grounds and for a duration which are reasonable.

7 In the course of health care, for protection of his modesty, the patient's clothing may only be removed for the necessary time and to the professionally justified extent.

Right to Have Contact

Section 11

1 The rights set out in Subsections (2) to (7) may be exercised by the patient subject to the conditions existing in the in-patient institution, while respecting his fellow-patients' rights, and ensuring the undisturbed and smooth delivery of patient care. The detailed rules of the latter shall be defined in the regulations of the in-patient institution, without restricting the content of these rights. The hospital regulations may grant further rights, in addition to those set out in Subsections (2) to (7).

2 In the course of his stay in an in-patient facility, the patient shall have a right to keep contact with other persons, either in writing or verbally and to receive visitors. The patient may forbid that the fact of his treatment or any other information related to his treatment be disclosed to other persons. This may only be disregarded in the interest of his care, at the request of his next of kin or a person obliged to care for him.

3 A patient in a severe condition shall have a right to have the person designated by him stay with him. For a legally incapable patient, the above person might be designated by a person as defined in Subsections (1) and (2) of Section 16. For the purposes of this subsection, a patient in a severe condition is one who, due to his condition, is physically unable to look after himself, or whose pain cannot be controlled even with the use of medication, or who is in a state of psychological crisis.

4 A minor patient shall have a right to have his parent, legal representative, or a person designated by him or by his legal representative stay with him.

5 A woman in childbirth shall have a right to designate a person of age to stay with her continuously during labor and delivery, and after delivery, to have her new-born baby placed in the same room with her, provided it is not excluded by the mother's or the new-born baby's health condition.

6 The patient shall have a right to keep contact with a representative of the church corresponding to his religious beliefs and to freely engage in acts of worship.

7 The patient shall have a right to use his own clothes and personal belongings, unless otherwise provided by law.

The Right to Leave the Healthcare Facility

Section 12

1 The patient shall have a right to leave the healthcare facility, unless he threatens the physical safety or health of others by doing so. This right may only be restricted in the cases defined by law.

2 The patient shall inform his attending physician of his intention to leave, who shall enter this fact in the patient's medical record.

3 If the patient has left the healthcare facility without notification, the attending physician shall enter this fact in the patient's medical record, furthermore, if required by the patient's condition, he shall notify the competent authorities, or the legal representative of a legally incapable patient or a patient with restricted disposing capacity, that the patient has left the healthcare facility.

4 The patient or his next of kin shall be informed of his planned discharge from the healthcare facility in advance, possibly at least 24 hours prior to such planned discharge.

5 In the case of a legally incapable patient, the right defined in Subsection (1) may be exercised with the agreement of the legal representative.

The Right to Information

Section 13

1 The patient shall have a right to complete information provided in an individualized form.

2 The patient shall have a right to receive detailed information on:

- his state of health, including its medical evaluation,
- the recommended examinations and interventions,
- the possible benefits and risks of performing or not performing the recommended examinations and interventions,
- the planned dates for performing the examinations and interventions,
- his right to decide in respect of the recommended examination or intervention,
- the possible alternative procedures and methods,
- the course of care and the expected outcome,
- additional services, and
- the recommended lifestyle.

3 The patient has a right to pose additional questions during information and subsequently.

4 The patient shall have a right to be informed of the results or eventual failure, or unexpected outcomes and their reasons, after an examination or intervention has been performed in the course of his care.

5 The legally incapable patient or a patient with reduced disposing capacity shall also have a right to information corresponding to his age and mental state.

6 The patient shall have a right to know the identity, qualifications and professional status of those directly providing services.

7 The conditions necessary for the assertion of the rights to information shall be provided by the agency running the healthcare facility.

8 The patient shall have a right to be informed in a way which is comprehensible for him, with regard to his or her age, education, knowledge, state of mind and his wish expressed on the matter. If necessary and if possible, the services of an interpreter or a sign language interpreter shall be supplied for the provision of information.

Section 14

1. A patient with full disposing capacity may waive the right of being informed, except in cases when he must be aware of the nature of his illness in order not to endanger the health of others. If an intervention takes place at the patient's initiative and not for therapeutic purposes, such waiver of the right of being informed shall only be valid in writing.

2. The patient with full disposing capacity shall have a right to designate a person in writing or in any other credible manner who is to be informed in his stead.

3. The patient shall have a right to be informed even in cases where his consent is not otherwise a condition for initiating medical care.

The Right to Self-determination

Section 15

1. The patient shall have a right to self-determination, which may only be restricted in the cases and in the ways defined by law.

2. Within the framework of exercising the right of self-determination, the patient is free to decide whether he wishes to use healthcare services and which procedures to consent to or to refuse in the course of using such services, taking into account the restrictions set out in Section 20.

3. The patient shall have a right to be involved in the decisions concerning his examination and treatment. Apart from the exceptions defined in this Act, the performance of any health care procedure shall be subject to the patient's consent thereto granted on the basis of appropriate information, free from deceit, threats and pressure (hereinafter referred to as 'informed consent').

4. A patient may give his consent as in Subsection (3) verbally, in writing or through implied behavior, unless otherwise provided by this Act.

5 Invasive procedures shall be subject to the patient's written consent, or if the patient is not capable of this, to his declaration made verbally, or in some other way, in the joint presence of two witnesses.

6 A patient may, at any time, withdraw his consent given to the performance of a procedure. If, however, the patient withdraws his consent without good cause, he may be obliged to reimburse any justified costs that will have incurred as a result of such withdrawal.

Section 16

1 Unless otherwise provided by this Act, a person with full disposing capacity may, in a statement incorporated into a public deed, into a fully conclusive private deed, or, in the case of inability to write, a declaration made in the joint presence of two witnesses,

a) name the person with full disposing capacity who shall be entitled to exercise the right to consent and refuse in his stead, and who is to be informed in line with Section 13,

b) exclude any of the persons defined in Subsection (2) from exercising the right of consent and refusal in his lieu, or from obtaining information, as defined in Section 13, by or without naming a person as in paragraph a).

2 If a patient has no, or limited disposing capacity, and there is no person entitled to make a statement on the basis of Paragraph a) Subsection (1), the following persons, in the order indicated below, shall be entitled to exercise the right of consent and refusal within the limits set out in Subsection (4), subject to the provisions of Paragraph b) of Subsection (1):

a) the patient's legal representative, in the absence thereof

b) the following individuals with full disposing capacity and sharing household with the patient:

- the patient's spouse or common-law spouse, in the absence thereof,
- the patient's child, in the absence thereof,
- the patient's parent, in the absence thereof,
- the patient's sibling, in the absence thereof,
- the patient's grandparent, in the absence thereof,
- the patient's grandchild;

c) in the absence of a relative indicated in Paragraph b), the

following individuals with full disposing capacity and not sharing household with the patient:

- the patient's child, in the absence thereof,
- the patient's parent, in the absence thereof,
- the patient's sibling, in the absence thereof,
- the patient's grandparent, in the absence thereof
- the patient's grandchild.

3 In the event of contrary statements made by the individuals qualified in the same line to make statement, the decision that is likely to impact upon the patient's state of health most favorably shall be taken into account.

4 The statement of the persons defined in Subsection (2) shall be made exclusively following the provision of information, as in Section 13, and it may refer to giving consent to invasive procedures recommended by the attending physician. However, such a declaration – with the exception of the case defined in Subsection (3) of Section 20– apart from the intervention may not unfavorably affect the patient's state of health, and in particular may not lead to serious or lasting impairment to the health. The patient shall be informed of such statements immediately after he regains his full disposing capacity.

5 In making decisions on the health care to be provided, the opinion of a patient with no disposing capacity or with limited disposing capacity shall be taken into account to the extent professionally possible also in cases where the right of consent and refusal is exercised by the person defined in Subsection (2).

Section 17

1 The patient's consent shall be assumed to be given if the patient is unable to make a statement of consent as a result of his health condition and

a) obtaining a declaration from the person defined in Paragraph (a) of Subsection (1) of Section 16 would result in delay;

b) in the case of invasive interventions, if obtaining a declaration from the person defined in, Paragraph a) of Subsection (1) of Section 16 or Subsection (2) of Section 16 would result in delay and the delayed performance of the intervention would lead to a serious or lasting impairment of the patient's state of health.(2)

2 The patient's consent shall not be required if failure to carry out the given intervention or action

a) would seriously endanger the health or physical safety of others, including also the foetus beyond the 24th week of pregnancy, furthermore

b) if the patient's life is in direct danger – also taking into account Sections 20 – 23.

Section 18

1 If, in the course of an invasive intervention, an extension thereof becomes necessary which was not foreseeable, in the absence of a consent to such extension – with the exception of the case defined in Subsection (2) – it may only be carried out if

a) warranted by a state of emergency, or

b) failure to do so would impose a disproportionately serious burden on the patient.

2 If the extension of the intervention defined in Subsection (1) would lead to the loss of an organ or a part of the body or to the complete loss of the function thereof, in the absence of consent to such extension, the intervention may only be extended if the patient's life is in direct danger or in the case defined in Paragraph b) of Subsection (1).

Section 19

1 The patient's written consent shall be required to the utilization of any of his cells, cell components, tissues, organs and body parts removed while alive in connection with an intervention for any purpose not related to the patient's provision. The patient's consent shall not be required for the destruction of these materials in the usual manner.

2 Within the boundaries of this Act, the patient shall have the right to provide for any interventions regarding his corpse in the event of his death. According to the provisions of this Act, the patient may prohibit the removal of any organ and tissue from his corpse for the purposes of treatment, research or education.

The Right to Refuse Healthcare

Section 20

1 In consideration of the provisions set out in Subsections (2) – (3) and excepting the cases defined in Subsection (6), a patient with full disposing capacity shall have the right to refuse healthcare, unless its lack would endanger the lives or physical safety of others.

2 A patient shall be required to refuse the provision of any care, the absence of which would be likely to result in serious or permanent impairment of his health, in a public deed or in a fully conclusive private deed, or in the case of inability to write, in the joint presence of two witnesses. In the latter case, the refusal must be recorded in the patient's medical record and certified with the signatures of the witnesses.

3 Life-supporting or life-saving interventions may only be refused, thereby allowing the illness to follow its natural course, if the patient suffers from a serious illness which, according to the current state of medical science, will lead to death within a short period of time even with adequate health care, and is incurable. The refusal of life-supporting or life-saving interventions may be made in keeping with the formal requirements set out in subsection (2).

4 Refusal as defined in Subsection (3) shall only be valid if a committee composed of three physicians has examined the patient and made a unanimous, written statement to the effect that the patient took his or her decision in full cognizance of its consequences, and the conditions defined in Subsection (3) have been satisfied, furthermore if on the third day following such statement by the medical committee the patient declared repeatedly the intention of refusal in the presence of two witnesses. If the patient does not consent to the examination of the medical committee, his or her statement regarding refusal of medical treatment may not be taken into consideration.

5 Members of the committee defined in Subsection (5) shall be the patient's attending physician, one board-certified doctor specializing in the field corresponding to the nature of the illness who is not involved in the treatment of the patient, and one board-certified psychiatrist.

6 A female patient may not refuse a life-supporting or life-saving intervention if she is pregnant and is considered to able to carry the pregnancy to term.

7 In the event of refusal as defined in Subsections (2) to (3), an attempt shall be made to identify the reasons underlying the patient's decision through personal interviews and to alter the decision. In the course of this , in addition to the information defined in Section 13, the patient shall be informed once again of the consequences of failure to carry out the intervention.

8 A patient may withdraw his or her statement regarding refusal at any time and without any restriction upon the form thereof.

Section 21

1 In the case of a patient with no disposing capacity or with limited disposing capacity, healthcare as defined in Subsection (2) of Section 20 may not be refused.

2 If in the case of a patient with no disposing capacity or limited disposing capacity, healthcare as in Subsection (3) of Section 20 has been refused, the healthcare provider shall institute proceedings for obtaining the required consent from the court. The attending physician shall be required to deliver all medical care necessitated by the patient's condition until the court passes its final and absolute decision. In the case of a direct threat to life, it shall not be required to obtain a substitute statement by the court for the required interventions to be carried out.

3 An attending physician, in the interest of satisfying his or her obligation defined in Subsection (2) may use the police force, if necessary.

4 In the course of the proceedings to substitute the statement defined in Subsection (2), the court shall proceed in out-of-court proceedings, without delay. Such proceedings shall be exempt from charges. Unless it otherwise follows from this Act or from the out-of-court nature of the proceedings, the provisions of Act III of 1952 on Civil Proceedings shall apply, as appropriate.

Section 22

1 A person with full disposing capacity may refuse in a public deed, for the event of his eventual subsequent incapacity,

a) certain examinations and interventions defined in Subsection (1) of Section 20,
b) interventions defined in Subsection (3) of Section 20, and
c) certain life-supporting or life-saving interventions if he has an incurable disease and as a consequence of the disease is unable to care for himself physically or suffers pain that cannot be eased with appropriate therapy.

2 A person with full disposing capacity may name in a public deed, for the event of his eventual subsequent incapacity, the person with full disposing capacity who shall be entitled to exercise the right defined in Subsection (1) in his stead.

3 The statement defined in Subsections (1) – (2) shall be valid if a board-certified psychiatrist has confirmed in a medical opinion, given not more than one month earlier, that the person had made the decision in full awareness of its consequences. The statement shall be renewed every two years, and may, at any time, be withdrawn, regardless of the patient's disposing capacity and without formal requirements.

4 In the case of a declaration of refusal of a medical intervention made by a person with full disposing capacity in keeping with Subsection (2), the committee defined in Subsection (4) of Section 20 shall make a declaration on

a) whether the conditions set out in Subsection (1) exist, and
b) whether the person defined in Subsection (2) has made the decision in cognizance of its consequences.

Section 23

1 An intervention as defined in Subsection (3) of Section 20 may only be terminated or dispensed with if the will of the patient to that effect can be established clearly and convincingly. In case of doubt, the patient's declaration made ulteriorly and personally must be taken into account; in the absence of such declaration, the patient's consent to the life-supporting or life-saving intervention must be assumed.

2 In the course of refusing healthcare, a patient, or the person defined in Subsection (2) of Section 22 must not be forced by any means to alter his decision. Even in the case of refusal of an intervention set forth in Subsection (3) of Section 20, a patient shall have the right to receive healthcare intended to ease his sufferings and reduce pain.

The Right to Become Acquainted With the Medical Record

Section 24

1 A patient shall have the right to become acquainted with the data contained in the medical record prepared on him or her, and shall have the right to request information on his or her health care data, with regard to the contents of Section 135.

2 The health care provider shall dispose of the medical record, while the patient shall dispose of the data contained therein.

3 The patient shall have the right to

a) be informed of the management of the data related to the medical treatment,
b) become acquainted with the health care data relating to him,
c) gain access to the medical record and to receive copies thereof at his own expense,
d) be given a discharge summary upon discharge from the healthcare institution (Section 137),
e) receive a written summary or abridged opinion of his health data for justified purposes, at his own expense.

4 A patient shall have the right to initiate completion or correction of the medical record relating to him, that he deems to be inaccurate or incomplete, which shall be entered in the medical record by the attending physician, or by another person handling such data, together with his professional opinion. The erroneous health care data may not be deleted following the entry thereof, and shall be corrected in such a way that the data entered originally can be established.

5 If the medical record prepared of a patient also contains information concerning another person's right to confidentiality, the right of inspection and other right set forth in subsection (3) may only be exercised in respect of the part thereof relating to the patient.

6 The right to inspect the medical record of a person with no disposing capacity shall be exercised by a person as defined in Subsections (1) and (2) of Section 16.

7 In the course of health care delivered for his current condition, a patient shall have the right to give written authorization to a person designated by him to inspect the medical record relating to him and to have copies made thereof.

8 Following the conclusion of the patient's medical treatment, only the person being authorized by the patient in a fully conclusive private deed shall have the right to inspect the medical record and to have a copy made thereof.

9 During a patient's lifetime, or following his death, the spouse, a lineal kin, a sibling or common law spouse shall have the right to become acquainted with the health care data, upon written request, if such health data is required in order to identify a reason that might influence the life or health of the spouse, a lineal kin, a sibling or common law spouse, or provide healthcare to the persons set forth in Subparagraph a); and b) there are no other ways to become acquainted with such health data or to establish them by inference.

10 In the case set forth in Subsection (9), only those health data may be learnt that are directly related to the reason defined in Paragraph a) of Subsection (9). Information on the health data shall be provided by the patient's attending physician, or the director of medical services of the healthcare provider, in keeping with the requirements on the provision of medical information, if necessary, based on consultation with the attending physician of the claimant.

11 In the case of a patient's death, his legal representative, close relative, or heir shall have the right, upon written request, to become acquainted with health data that is, or may be, related to the cause of death, and data that is related to the medical treatment preceding death, furthermore

to inspect the medical record and to be provided by copies thereof, at his own cost.

12 The detailed rules of handling and protecting healthcare and related personal data shall be established by a separate law.

The Right to Professional Secrecy

Section 25

1 A patient shall have the right to have persons involved in his health care disclose his health care and personal data which they might learn in the course of delivering such care (hereinafter: 'medical secret') to those entitled thereto and to have them handle such data confidentially.

2 A patient shall have the right to make a statement as to who are to receive information on his illness and the expected outcome thereof and who are to be excluded from becoming partially or fully acquainted with his health care data.

3 The health care data of the patient concerned shall be disclosed even in the absence of his consent thereto when
a) ordered by law,
b) required in order to protect the lives, physical safety and health of others.

4 Health care data, the lack of which may lead to the deterioration of the patient's state of health may be disclosed to a person in charge of a patient's further nursing and continuing care, without the consent of the patient concerned.

5 A patient shall have the right to have only those persons present during the course of his examination and medical treatment whose involvement is necessary in delivering such care, furthermore those persons to whose presence he has consented, unless otherwise provided by law.

6 A patient shall have the right to have his examination and treatment take place under circumstances whereby it cannot be seen or heard by others without his consent, unless this is unavoidable due to an emergency or critical situation.

6 A patient shall have the right to name the person who may be notified of his admission to an inpatient healthcare institution and the development of his state of health, and he shall have the right to exclude any person there from. The inpatient healthcare institution must inform the person named by the patient of his admission and any change in his placement, as well of any significant change in the patient's state of health.

Obligations of the Patient

Section 26

1 When using a health care service, the patient shall respect and observe the legal rules relating thereto and the institutional order.

2 If allowed by his state of health, a patient shall cooperate with the health care workers involved in his care according to his abilities and knowledge, as follows:

a) inform them of all details necessary for a diagnosis, the preparation of an adequate treatment plan and for carrying out the required interventions, in particular, of his history of illnesses, medical treatment, medicinal drug use or use of para-medicines, and his health damaging risk factors,
b) inform them of every detail in connection with his illness which may endanger the lives or physical safety of others, in particular, of any communicable diseases, and of illnesses and conditions disqualifying him from pursuing an occupation,
c) in the case of communicable diseases set forth in the relevant decree of the Minister of Health, name the persons from whom he may have contracted the communicable disease and whom he may have infected,
d) inform them of all former legal statements that he might have made in connection with health care,
e) comply with the instructions received from them in connection with the medical treatment,
f) observe the house rules of the health care institution,
g) make the co-payment as provided for by law,
h) show credible proof of his personal data as required by law.

Section 27

1 In the course of exercising their rights, the patient and his relatives shall respect the rights of other patients.

2 The exercise of the rights of a patient and his relatives may not violate the rights of health care workers stipulated by law.

3 The method of exercising patients' rights shall be regulated by the house rules of the institution, within the boundaries of this Act.

Patient advocacy according to Act CLIV of 1997 on Health The Patient Advocate

Section 30

1 The patient advocate shall represent, in keeping with Subsections (2) to (5), the rights of patients defined in this Act and shall help them become acquainted with, and enforce, these rights.

2 Patient advocacy services shall include especially the following:

a) assistance to patients with having access to medical records, making comments and asking questions thereon,

b) assistance to patients with verbalizing their complaints, and initiating the investigation thereof,

c) based upon the patient's written authorization, lodging a complaint with the head of the health care institution or the maintaining entity, furthermore taking actions with the competent authorities in matters related to the patient's medical treatment, and representing the patient in the course of such actions,

d) informing, on a regular basis, health care workers of the rules relating to patients' rights and any changes therein, as well as of the enforcement of patients' rights in the health care institution.

3 The patient advocate may only proceed in individual cases within the boundaries of the authorization granted by the patient.

4 The patient advocate shall draw the attention of the head of the service provider or maintaining entity to any unlawful practice and other shortcomings in connection with the operation of the health service provider that he might have experienced in carrying out his duty, and shall make proposals regarding the termination of such practices and shortcomings. Should this action prove to be unsuccessful, the patient advocate shall have the right to turn to the competent agency or person.

5 The patient advocate shall pay special attention to representing patients' rights of those at a disadvantage due to their age, physical or mental disability, health status or social situation.

Section 31

1 The patient advocate shall have to right, within his competence, and in a way which does not jeopardize the undisturbed delivery of health care services, to:

a) enter the premises of the health service provider,
b) have access to the relevant documents,
c) address questions to health care workers.

2 The patient advocate shall be bound by professional secrecy concerning the patients and shall handle patients' personal data in compliance with the relevant legal rules.

Section 32

1 The patient advocate shall operate within the organizational framework of the county (Budapest) institution of the NPHMOS.

2 The patient advocate may not be in employment relationship with the health service provider which provides health services for the patients to be represented by him.

Section 33

1 The health service provider shall ensure that patients and their relatives may become acquainted with the identity of the patient advocate(s) and the way in which he (they) can be contacted.

2 The comments and remarks of the patient advocate shall be investigated, to the merit thereof, by the head of the health service provider within 10 working days, and by the maintaining entity within 30 working days [or, where the maintaining entity is a municipality or municipal assembly, at the next assembly meeting]; any position formulated upon such comments shall be communicated to the patient advocate.

Mediation Council

Section 34

1 With a view to resolve legal disputes which may arise between a patient and a health service provider in out-of-court proceedings, the parties may jointly initiate the settlement of such legal disputes within the framework of mediation proceedings.

2 The provisions of a separate Act shall apply to the order of mediation proceedings and the composition of the mediation council

How to enforce patients' rights?

1 Health care service provider or its maintainer

According to the Health Care Act (Act CLIV. of 1997.) the health care service provider must inform the patient - upon admission or prior to the actual delivery of care, depending upon his state of health - of the rights of patients, of the possibilities of enforcing such rights and of the house rules (bylaws) of the institution.

A patient has the right to lodge a complaint regarding the health care service provided with the health service provider or the maintaining entity.

2 Patients' Rights Advocates

A patient may ask for the assistance of the Patients' Rights Advocate. According to Health Care Act, the Patients' Rights Advocate represents the rights of patients defined in the Act and helps them become acquainted with and promote the realization of these rights.

3 Ethical Committee

Inpatient healthcare institutions have hospital ethic committees operating within them. One of the roles of the hospital ethics committee is to participate in enforcing patients' rights.

4 Mediation Council

With a view to the resolution of legal disputes which may arise between a patient and a health service provider in out-of-court proceedings, the parties may jointly initiate the settlement of such legal disputes within the framework of mediation proceedings.

5 Administrative procedure

The complainant can address a request for administrative procedure to the supervisory organization of the health care institute or the Ministry of Health which, independent of the legal grounds of the compensation, can examine the medical treatment being related with the concerned person's disease.

6 Hungarian Medical Chamber

In matters of ethics and disciplinary procedures, a patient has the possibility to turn to the Medical Chamber.

In cases of a possible violation of ethical norms, the Hungarian Medical Chamber conducts its own hearing and disciplinary action.

7 Civil Court Procedure

A patient has the right to start civil court proceedings against the health care service provider. The regulations of Civil Code and the Law of Civil Procedure apply to the proceedings. (Act III. of 1952, Act. IV. of 1959)

8 Criminal procedure

A patient may make criminal charge against the physician or other members of health care staff in cases of serious breaches of duty. (Act I. of 1973)

9 Parliamentary Commissioner for Citizens' Rights.

According to the Constitution and Act LIX. of1 993, it is the task of the Parliamentary Commissioner to have the abuses of constitutional rights investigated. The Office of the Ombudsman can conduct investigations if the decision, the procedure or the omission of some public authority or public service provider violates or jeopardizes constitutional rights. Any citizen can lodge a complaint to the Office of the Ombudsman in cases of violation of patients' rights by an authority.

10 Civil organizations

There are several civil organizations offering services to help patients enforcing their rights.

The Szószóló Foundation gives legal help to patients and provides information for any member of the public who requests it.

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Web sites related to the topic:

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http://www.spin.nl/npcf1001htm
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About Thalassaemia

Recent epidemiological data demonstrate that about 5% of the global population are carriers of an abnormal haemoglobin gene. Importantly, 6.7% of pregnant women and 1% of couples worldwide are carriers of a significant haemoglobin variant and are at risk of having a child affected by a serious haemoglobin syndrome, mainly thalassaemia and sickle cell disease or a combination of these, namely sickle cell/-thalassaemia. It is reported that over affected children are born every year across the world, (2.3/1000 live births) more than 80% of whom in developing countries. Of these, 82% have sickle cell disease and 18% major thalassaemias, constituting 2.8% of all deaths of children under 5.

-thalassaemia, the disease on which the Thalassaemia International Federation focuses its work and activities, is a severe disorder requiring lifelong blood transfusions and iron chelation therapy.,Without appropriate care, patients with thalassaemia experience many complications, a poor quality of life and early death. In countries of Northern Europe and the USA, where centres of excellence have been established offering appropriate medical care, the quality and life expectancy of thalassaemia patients have dramatically improved, with patients living a near normal life. Advances have also been made in these countries in bone marrow transplantation procedures, in research into alternative ways of treatment and towards a final cure through gene therapy - advances that have offered great hope to patients across the world.

On the other side of the bridge, however, in low resource countries where treatment is sub-optimal or even non-existent, and where the great majority of patients are born, increased rates of morbidity and mortality continue.

About the Thalassaemia International Federation

The Thalassaemia International Federation (TIF) was established in 1987 with the mission to promote the establishment of national control programmes for the effective prevention and appropriate clinical management of thalassaemiain every affected country of the world. TIF is a Federation "umbrella", comprised of 98 national thalassaemia associations from 60 countries, representing hundreds of thousands of patients worldwide.

TIFhas had official relations with the World Health Organisation (WHO), since 1996, and works closely with the European Commission (Ec) and the Council of Europe (CoE). It has an extensive network of collaboration with scientific and medical professionals from more than 60 countries, as well as with other international and European health bodies, pharmaceutical companies and patients' organisations, including the International Society for Blood Transfusion (ISBT), the European Patients' Health Alliance (EPHA), the Global Collaboration on Blood Safety (GCBS-WHO), the PanEuropean Blood Safety Alliance (PBSA), the European Organisation for Rare Disorders (Eurordis), the UK Sickle Cell Disease Society (SCDS), and the European Haemophilia Consortium (EHC).

TIFs' educational programme is one of its most important activities, and includes the organisation of local, national, regional and international workshops, conferences and seminars, as well as the preparation, publication, translation and distribution leaflets, magazines and books for health professionals and patients/parents, in more than 60 countries.

For more information, visit our web-site:
www.thalassaemia.org.cy

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