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The Right of the Citizen to Health Information

A modern concept of the Citizen. The Fundamental Right to Health Information. Special reference to children. Conclusions. Bibliography.

Proposal raised to the Health Division of the Council of Europe for the inclusion in the Terms of Reference (TORs) of the Preparatory Conference of the project "Health care in Europe – for and with children", which took place in Madrid on the 16th and 17th of April 2009

European Pharmaceutical Law Group

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1. The European Pharmaceutical Law Group and the Preparatory conference “Health care in Europe – for and with children”

The European Pharmaceutical Law Group (Eupharlaw) is a private company operating within the European area. For over 10 years, it has focused its work on promoting and defining pharmaceutical law and the health rights of the citizen, based on the fundamental premise of the right of citizens to health information.

Eupharlaw was the first European company to make an official proposal (in 2004) to the European Union regarding Health Rights.

We have recently taken part in the Preparatory Conference of the project “Health care in Europe – for and with children” of the Council of Europe- which was held in Madrid on the 16th and 17th of April 2009. The company was represented by Francisco Almodóvar, specialist lawyer in health rights and author of numerous works and papers on the health rights of children, in particular, the right of children to health information.

In the Preparatory Conference, our main proposal was the inclusion in the Terms of Reference (TORs) of the concept of the “right of children, as citizens, to health information”.

During his paper “From Madrid to Strasbourg: next steps”, Dr. Piotr Mierzewski, Head of the Health Division of the Council of Europe, invited all those present to assist and co-operate in the project “Health care in Europe – for and with children”, by means of their active and ongoing participation.

Following the recommendations of Dr. Piotr Mierzewski, we have prepared this report with the intention of helping the Health Division of the Council of Europe to study in depth the legal aspects of citizens’ rights, in particular the right of children to health information.

Our aim is for the proposal to be included in the TORs of the Preparatory Conference “Health care in Europe – for and with children”.

In this report we will set forth a number of basic considerations regarding the Fundamental Right of the Citizen to Health information. From a legal point of view, we defend the modern concept of the citizen in health-related matters as opposed to the concept of the user/consumer/customer/patient. Finally, we will address the specific issue of the right of the citizen-child to health information.

We will confine our observations to the European area, bearing closely in mind the work of the Council of Europe, since such body has been pioneering on an international level in defending human rights in general, and in particular those rights concerning biomedicine and biomedical research.

2. The modern concept of the Citizen. A History. Progress & Development. New realities.

A history of the status of the citizen

Athenian citizenship (5th century BC) implied the establishment of democracy and the birth of the idea of equality of citizens before the law, although women and slaves were not considered as such. Thus, the concept of citizens' freedoms and the autonomy of peoples came into being. The citizen became a person with civic values and contributed to defending the community as a whole.

It is an interesting point in this regard that in classical Greece a person who was only concerned about himself and who did not participate in the political and social life of the community was called an "idiot".

The arrival of Christianity brought a new concept: the idea of the universality of the equality of human beings. This is an extremely spiritual and immaterial concept of equality. Freedom goes hand in hand with the divine revelation. The deepest foundations of individualism started to be set, as a freedom inherent to the spirituality of the soul, to the capacity of discernment, and to the resulting affirmation of free will and individual responsibility.

The modern concept of citizenship was forged with cultural secularisation. The essential components of the Age of Enlightenment were the laicism of the State and the absolute freedom of conscience.

A Letter Concerning Tolerance (1689), by J. Locke, acknowledged to be the father of liberalism, is an emblematic document on the freedom of conscience, and lays down one of the basic foundations of the status of citizenship: ideological neutrality and mutual respect between citizens. Thus, the idea of liberal contractualism emerges. In this regard J. Locke stated: “The commonwealth seems to me to be a society of men constituted only for the procuring, preserving and advancing of their own civil interests Civil interests I call life, liberty, health, and indolency of body; and the possession of outward things”.

Kantian ethics also sought a new state of being for man in the world and in society, which was defined as the status of citizenship. “*Sapere aude*” (Dare to Know) and “...act according to that maxim whose universality as a law you can at the same time will” of Kant, constitutes the supreme and definitive exaltation of the value of the individual conscience, and therefore of human dignity, whose broad realisation requires a social framework of freedoms.

Progress & Development: A concept undergoing permanent change

After numerous bloody class-based conflicts, progress followed the path that would take us from liberal citizenship, reflected in the Declaration of the Rights of Man and of the Citizen of 1789 (civil and political rights) towards social citizenship, with the Universal Declaration of Human Rights of 1948 (economic and social rights).

Under the post-war social pact, reflected in the Declaration of 1948, of an inter-class nature, apart from the classic civil and political rights already established, citizens were guaranteed the universal access of all persons to basic rights ensuring the dignity of life, which indirectly give meaning to other acquired rights. Basic rights such as education, health, old-persons’ pensions, other social security protections, etc., were part of such mutual guarantee, which allowed the idea of a true national solidarity to be restored. This new pact implied a significant reform of the State, which left behind the stance of “*laissez faire, laissez passer*” to become a State redistributing wealth and public services.

New realities: globalisation, the information society, the environment, the genome and biotechnology

The idea of an association between citizenship and nationality put forward in the second half of the 20th century implies that nationals of countries other than the country in which they reside are not treated as citizens for all purposes. However, this concept of citizenship, closely related to the concept of State-Nation, has for some time been called into question, for various reasons:

a) The Declaration of Human Rights of 1948, which has been signed by practically all countries (in Europe we also have the European Convention of Human Rights of 1950, adopted by the Council of Europe) grants a set of rights to all human beings merely as a result of being a human being, irrespective of the country of which they are nationals in legal terms. This means that we should actually refer to “citizens of the world” and not citizens of a specific country.

b) We live in an increasingly globalised world, in which the labour market requires greater flexibility, and in which the number of individuals contributing to the economic development of a country other than that in which they are legally nationals is greater.

c) There are a growing number of political authorities above the State-Nation. This is the case with the institutions of the European Community. Within this context, we may talk of European citizenship.

d) The Information Society and its implications, requires us to embrace the Right to Information as a Fundamental Human Right. New needs have arisen with regard to the health-related information of the citizen: Clinical and therapeutic information, information on biotechnology and genomes, information on environmental health, information on food health, information on new technologies and the protection of health data, etc.

e) The right of the citizen to the enjoyment and protection of the environment and their natural surroundings must also be treated as a Fundamental Human Right.

f) The concept of the “e-citizen” must contribute to fostering the effective participation of the citizen in political issues, thereby leading to a renewal of democratic principles. The concept of e-health also encourages the greater involvement of the citizen in their health.

The European Pharmaceutical Law Group has been focusing its efforts on ensuring the global recognition of a new concept of the “citizen in health-related terms”, which implies that citizen is regarded above all as a person and is protected by all Fundamental Human Rights (civil, political, economic, social...), irrespective of their place of birth, economic and social status and cultural level (a broad concept of equality and universality).

This type of “new citizen” also has obligations vis-à-vis society and with respect to their health, which must also be reflected in the applicable law.

3. The Fundamental Right of the Citizen to Health Information

In Europe there is insufficient legislation governing the Fundamental Right of the Citizen to Health Information. In this regard, we believe that the Council of Europe, as a pioneering international institution in the fight for and defining of Human Rights and the dignity of the human being with respect to the applications of Biology and Medicine, by means of the European Convention on Bioethics (Oviedo, 4 April 1997, hereinafter referred to as the Oviedo Convention), has a great opportunity to be a leader of opinion with respect to the regulation of Health Information for the Citizen.

The new needs regarding health information require immediate efforts, in promotion of human rights, to permanently unify and connect the two Fundamental Rights: Health + Information.

The Right of the Citizen to Health: a modern and real vision

The Right to Health appears in the first fundamental rights of the Universal Declarations and the European Convention on Human Rights, without distinction of race, religion, political ideology or economic or social status.

However, the European public authorities, for political reasons and due to historical circumstances, have focused on the implementation of the right to “health

protection”, which has certainly implied a significant step forward in social and economic terms, but which nevertheless is insufficient.

The idea of the citizen (autonomous person) was gradually abandoned in favour of the status of the Patient and User (a person that is protected and cared for, with limited active participation), of a notably protectionist nature, with the legal implications that we shall see later on.

Our European society is demanding a broad vision of the citizen in health-related terms, where not only the nationals of a specific State (the classical concept of citizenship) enjoy the Fundamental Right to Health, but all persons, i.e., citizens (modern concept of citizenship) residing in such place, ensuring at all times the two fundamental facets of such Right in Europe: equality and universality.

“No poor health for poor people”

Some illustrative examples of new requirements in the area of health are as follows:

Example of globalisation of health: Outbreak of flu originating in the United States and Mexico.

Example of multiculturalism and health: non-national persons, without financial resources or without social insurance and with different approaches to health and illness.

We view that the status of the citizen in health-related terms must prevail over the status of the patient and user. The latter has implied a significant step forward in the implementation of the right to health protection and care, but we are falling behind with respect to new needs that must be covered owing to the Fundamental Right of the citizen to health information.

The new needs: the Fundamental Right of the citizen to health information

“Information is difference that makes difference”. Gregory Bateson.

The Oviedo Convention is an important legal precursor of the right of the citizen to health information. It enshrines in legal terms the ethical principle of the freedom of will of the person, based on the right to information.

The Member States that ratified the Convention have implemented it into their domestic legislation, but only with regard to certain aspects of the right to health information, i.e., they have only established provisions regarding clinical information (a protectionist and care-oriented vision based on the concepts of the patient and the user), forgetting the freedom of will of the citizen with respect to their health.

We continue to make progress, but there is still a lot of ground to cover in order to implement the concept of comprehensive health, as defined by the World Health Organisation in its constitution: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. This is a broad concept of health, which is not only protectionist. It also implies a real idea of health, which takes into account the subjective nature of the individual, and is therefore a right of the same kind.

“Health is an individual right of the person and as such is a Fundamental Right for which they must be accountable, in order to take their decisions. It may not be left exclusively in the hands of other agents, including health professionals” (Manuel Amarilla. Chairman of the European Pharmaceutical Law Group).

The citizen, for their own benefit, now seeks to acquire their own knowledge, and in order to achieve this, they must demand accurate, adequate and true information.

It is for this reason that the traditional agents who create, issue and oversee such information must cater for this new social reality, if they do not wish to be left behind in the past.

Eurpharlaw has been examining this situation for over ten years by means of works such as “Therapeutic Information Direct to the Citizen” (2005). We have quoted some

paragraphs from this book below, in order to understand better this new situation with regard to health:

“It is a question of paving the way for new health scenarios, with new principal players, and obviously with changes of conduct which lead us towards a fairer and more balanced reality.

Member States, and those persons who in general are assigned the role of guardians of accurate health information, must make sure that such goal becomes a reality, ensuring the protection of all the legal guarantees available to citizens.

They have made us believe that information is based on the fact that normally there is no deliberate intention to deceive (protectionism), but this is not the case. In the area of health, we may cite some significant cases: Lipobay, Baxter dialyzers, Bio-Bac, Vioxx and Celebrex, mad cow disease, Asian pneumonia, bird flu, etc.

The doctor–patient relationship, as it is currently regarded, is starting to become the social problem of our time. The rules and values underlying such relationship no longer have any meaning as such relationship has ceased to be real.

Today’s doctor cannot continue to be the main agent responsible for communicating general health information which they do not in fact know themselves, and therefore, may less still be the sole guarantor of such information.

Society must accept that this is a real social problem, since none of the other agents in the area of health assume full responsibility for the information provided by them, having purposely passed on such responsibility to the doctor.

It is therefore necessary for there to be a total consensus between all parties, in order to reconsider the real responsibilities that exist with regard to the provision of information.

Citizens of the 21st century need health priorities to be refined from a real and well-balanced perspective, ensuring that new meaning is given to information of all kinds, by those persons occupying positions of social, legislative power, etc.

A new theory and praxis of the Information Society must be created, and in particular of health information. The theory, since this will give shape to a new concept of

accurate, adequate and true information, and the praxis, since it will make this reality possible, through more effective legislative developments for the health of individuals.

The objectives of the above may be clearly seen:

- 1) To improve the quality of life of citizens.
- 2) To increase levels of knowledge through health education.
- 3) To obtain more accurate information.

All of the above will result in a new political, legal, educational and social context, thereby ensuring the better health of citizens.

For this purpose, basic changes are necessary with regard to the responsibility of all agents for any actions or omissions with respect to information and their consequences.

The new level of knowledge and demands of citizens lead as to reconsider the information provided, making it more effective so as to allow citizens greater freedom in health-related decisions.

We are aware of and welcome the fact that lists of patient's Rights and Obligations already exist, but we believe that such lists should be extended to all citizens. Their participation should also be effective (the actively participating citizen), and not as it has been up until now (the non-participating patient and user)".

The perspective of the patient in health-related matters is important, but we believe that as citizens, in addition to being patients, we are also persons, who on many occasions do not obtain adequate answers with regard to health-related matters. We seek a situation where the economic growth of Europe may be combined with the growth of Human Rights in general and in particular health rights, to achieve real development and well-being, not just from a consumer-related perspective.

The General Consumers and Users Laws and Laws on Defective Products have fostered industrial development, but with respect to health-related issues such laws are obsolete and as a result are detrimental to our health, although they make us believe that they protect our health.

Example: In cases of civil liability for damages caused by health-related products and services: the General Consumers and Users Laws and Laws on Defective Products establish liability provisions which do not allow us to examine the facts of the matter at depth and to identify the real causes of the damage caused.

The damaged party only has to prove the existence of the damage and the relationship of cause and effect in order to be compensated by the manufacturer or seller. The compensation is paid by an insurance company, and the damaged person receives financial compensation more quickly, but the moral damage caused is not assessed and the real causes and the responsible parties are not identified. It is only necessary to establish the relationship between the use or consumption of the product and the damaged sustained. In this sense, strict and non-contractual liability gains ground over fault-based and contractual liability, but this is a misleading “oasis” which would seem to help, but which in the long term is damaging to the citizen’s interests.

Thus, the time has come for a new framework of Knowledge Management in the area of health, from a contractual perspective, in which information is the basis of a contract; of an obligation vis-à-vis citizens shared between all agents providing them health-related information (co-liability of agents for the issue, control, supervision and updating of information).

Example: The patient information leaflet of medicines should take the form of a contract between the pharmaceutical industry and the citizen. In the case of damage caused by information on medicine, civil or criminal laws should be applied and not consumer protection legislation.

As a result of such change, this new Information Direct to the citizen, whether it be therapeutic information, food-related information or information on mental, occupational and environmental health, etc., will irreversibly start to appear, regardless of attempts to stop its progress. However, such information must also entail greater liability than currently exists for the issuers thereof.

For this purpose, the citizen will be required to increase their level of knowledge and their demands, since a passive and non-participating role will no longer be effective, as they must also be responsible for their actions in health terms.

4. The Right of children to Health information

At Eupharlaw we have been working for many years on defining and disseminating the right to health information of children. Through the work *“El menor maduro ante la salud reproductiva y la anticoncepción de emergencia”* (“Child Reproductive Health and Emergency Contraception”) and conferences and opinion articles, we have defended the freedom of will of the child in the taking of decisions affecting their health, as a Human Right, a right of the person, and a right of the citizen.

The Convention on the Rights of the Child, of the United Nations, of 1989, as well as the Resolution A 3-0172/92, of the European Parliament, which approved the European Charter of the Rights of the Child, marked the beginning of a new philosophy with respect to the child, based on greater recognition of the role that the child plays in society and on the requirement of their greater participation (Definition of the child: “a child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier...”, article 1 of the Convention).

As patient and user, the child is protected and cared for, although until the Oviedo Convention no provisions directly covered their right to health information; specifically, their right to clinical and health care information.

“Every person has the right to receive adequate information if they so require, and the consequences of not receiving such information in true and accurate form shall define future legal liability” (Manuel Amarilla. Chairman of Eupharlaw).

“Can we talk of young persons and citizens at the same time in order to look at how both categories are interrelated in our contemporary societies or should we continue to operate using the old concept of youth as a stage of waiting and preparation which implicitly places young persons in a position of semi-citizenship or of second-class citizenship?” (Jorge Benedicto and María Luz Morán in the book *“Aprendiendo a ser ciudadanos”*, “Learning to be citizens”).

In the Preparatory Conference of the project “Health care in Europe – for and with children” of the Council of Europe, which took place in Madrid on the 16th and 17th of April 2009, we all agreed that the new requirements of knowledge and participation in all areas of our society, including health, make it necessary for children (“not legally unable”) to be treated as full citizens, in all personal decisions affecting them, and as a result, it is essential to promote the adoption of the principle of freedom of will.

For today's society, the challenge in this regard is to effectively teach young people to be citizens in an open and all-embracing environment, making their active participation possible, including in decisions relating to their health.

We need ideas of modernisation and efficiency in order to gradually ensure the integration and involvement of our young people in a society which, in the end, is and will be theirs. Above all, it is necessary that they actively participate in any matter which may interest and affect them at any time.

The Right to Health information is a right belonging not only to the adult citizen, but also to the citizen-child capable of taking decisions regarding their health.

Children have been traditionally regarded by the law as "unable", even to take decisions relating to the needs of the treatment. Fortunately, in recent years, and after the Oviedo Convention, the trend in legal doctrine regarding clinical information and informed consent has resulted in real progress in terms of the appraisal of the child's capacity.

The Council of Europe, aware of the rapid progress made in biology and medicine, and pre-empting to a certain degree the new information requirements, recognised the importance of children in health-related matters. The Oviedo Convention, in articles 5 and 6, reflect the trend in Europe in this regard:

Article 5: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time".

Article 6. "Protection of persons not able to consent

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.
2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity”.

In this regard, Spanish legislation (“*Ley 41/2002, de autonomía del paciente*”, “Act governing the autonomy of the patient”) has been pioneering in Europe, establishing provisions regarding the right to clinical information of the child, which must be fitting for their level of maturity.

In Spain, the legal age with regard to health-related matters is 16. However, it is true that after 12 years and 1 day it is legally presumed that the child is intellectually and emotionally able to understand the scope of the intervention, and will be entitled to give their consent (respect for the freedom of will of the patient).

If the doctor decides that the child is not able to understand the information, they must make a note in their clinical records of the reasons for reaching such conclusion, and will restrict the right of the child to give their consent, due to not being sufficiently mature.

In addition, in the event of an action which in the opinion of their doctor implies a serious risk, the child’s parents or their legal representative or guardians will be informed, and their opinion will be taken into account in order to take the relevant decision. The meaning of “serious risk” has not been clearly defined, leaving the doctor free to make their own interpretation.

As regards the voluntary interruption of a pregnancy, the conducting of clinical trials and the carrying out of methods of assisted human reproduction, these are still governed by the general provisions established regarding the legal age (18 years), thereby conflicting with the legal age for health-related matters, fixed at 16.

The Spanish General Council of the Judicial Power (Consejo General del Poder Judicial) recently issued a ruling with respect to the voluntary interruption of pregnancy from 16 years onwards, deeming such alternative to be in compliance with Spanish law.

5. Conclusions

Both the Oviedo Convention and Spanish legislation set forth provisions on clinical information in the area of health, which implies significant progress.

If we read both texts in detail, we may see that a paternalistic approach still persists with regard to the right to health protection and care, but we are now starting to see a cautious shift towards the modern concept of the citizen in the area of health, who through information is acquiring a greater role and decision-making capacity.

However, important factors in the area of health have been forgotten, such as, for example, the defining and implementation of the concept of therapeutic information and specific consent in relation thereto, which reflect a reality (therapeutic activity) radically different from the reality of clinical and health care.

In our opinion, it would be a significant step forward if the Council of Europe took the lead in establishing provisions governing true and accurate health information. By means of the Oviedo Convention, thus far it has led movements to promote Clinical and Health Care Information, necessary at such time, but insufficient in the light of the new circumstances and developments in the area of health.

The new needs in the area of health require in-depth discussion of three important concepts:

- The new concept of the citizen, who as a person has fundamental health rights and obligations (defining of the status of the citizen in the area of health, which covers and absorbs the status of patient).
- A broad and comprehensive vision of health (not only covering protection and care, but also prevention, education, training, effective participation in policy, etc.).
- The right to health information, which is the essential building block for implementing the principle of the freedom of will of the citizen in the taking of decisions regarding their health (informed consent, not only clinical, but therapeutic, with regard to genomes, food health, sexual health, etc.) and

which is necessary for establishing new legal responsibilities (co-liability of agents) for the production, transfer and dissemination of such information.

The European society of today and of the future requires the implementation of the concept of Health information Direct to the Citizen, by means of more effective legislative developments for the health of persons. Children are also citizens, and therefore have the same right to receive health information which is true, accurate and adequate.

At Eupharlaw we wish to thank the Council of Europe for giving us the opportunity to express our opinion regarding the health rights of children, which is the product of our ongoing research and analysis of the current social and legal circumstances.

We offer to continue collaborating and assisting in all matters related to the right of the citizen to health information, in particular the right of children.

It would also give us great satisfaction if the programme of the Council of Europe “Health care in Europe –for and with children” included in the TORs of the Preparatory Conference of the project, which was held in Madrid on the 16th and 17th of April 2009, the concept of the “Right of the child, as a citizen, to health information”, for examination and discussion in subsequent meetings and works.

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