



## ***Research***

# ***Comparative Analysis of legislation on assisted reproduction in the Adriatic Area: Regulation and Technologies***



**Edited by**

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## Table of Contents

Introduction	3
Architecture and joint analysis technique	9

### Part One: The context

Territories	15
Causes of infertility	38
Access to techniques: a comparative analysis	40

### Part Two: Concept of family law in the European Union

Relationship between MAR and Family Law	43
Ethics and Bioethics	49
Rules relating to MAR	52

### Part Three: The policies of the European Union

The evolution of health policy from the Establishing Treaty to the revision of Lisbon  
Building a dynamic future with the Europe 2020 strategy

### Part Four: The search

Methodology	
Map of the interviews	
Results: legislation	
Results: regulatory compliance	
Results: professional and training needs	
Results: information on the improvement of EU legislation	
Results: technological aspects	

### Conclusions

Brief summary note

### Questionnaire



## Introduction

The purpose of this paper is to outline the methods of "Medically Assisted Procreation" (MAR), offered and documented within the partner territories of the project "Future Medicine", approved in the light of an overview of the Community legal framework and its application to 'Member States' domestic partners.

In the analysis, the technological change along with key aspects of social life will be taken into account, such as: the right of the person, the family law, but also the dynamics of demographics, the socio-economic impacts. Finally, the bioethical perspectives in relation to different religious influences will be analyzed.

This latter aspect becomes reasonably decisive as the progress in biotechnology, related to human reproduction, are no longer the exclusive preserve of specialists. The hopes and efforts of millions of couples who use assisted reproduction techniques have transformed the theme of "non-natural fertilization" into a complex social practice. It touches the origins of man, awakening fantasies and desires buried in the human psyche.

The logical thread of analysis will also try to focus on the influence of MAR techniques aimed at treating infertility. Techniques that are usually applied if it is not possible to restore spontaneous fertility or whether the treatment both medical and surgical to correct or remove the causes of infertility, have not been successful.

In the event that there is still a residue of spontaneous fertility in the infertile couple, the procedures of MAR are correctly applied, considering the age of the woman and the duration of infertility, when they offer higher chances of pregnancy than the spontaneous conception.

They should be included in a correct diagnostic and therapeutic process, which has carefully considered the possibility of a spontaneous fertilization.

MAR techniques are all those processes that include the treatment of human eggs, sperm or embryos as part of a project aimed at achieving a pregnancy. These processes include the homologous insemination, in vitro fertilization and embryo transfer (IVF), gamete intrafallopian transfer, zygote intrafallopian transfer, embryo intrafallopian



transfer, cryopreservation of gametes and embryos, pre-plant diagnosis, heterologous fertilization using gametes extraneous to the couple. These techniques are currently represented by a range of therapeutic options with different degrees of invasiveness both technical and psychological on the couple.

The techniques of MAR are divided, depending on the complexity and degree of invasiveness, in levels.

Techniques Level I:

- ✓ supra-cervical insemination in natural cycle (IUI) performed using techniques of preparation of seminal fluid;
- ✓ Multiple ovulation induction with or without associated supra-cervical insemination performed using techniques of preparation of seminal fluid;
- ✓ Single induction of ovulation in amenorrheic patients (therapy with gonadotropins) (DGR n ° 23-2687 of 24 April 2006)
- ✓ possible cryopreservation of male gametes.

Technical Level II (executable procedures under local anesthesia and / or sedation):

- ✓ fertilization in vitro and embryo transfer (FIVET);
- ✓ intracytoplasmic sperm injection (ICSI);
- ✓ testicular sampling of gametes (withdrawal or percutaneous testicular biopsy);
- ✓ possible cryopreservation of male and female gametes and embryos;
- ✓ intrafallopian transfer of male and female gametes (GIFT), zygote (ZIFT) or embryos (TET) by transvaginal ultrasound-guided or hysteroscopy.

Techniques III level (procedures that require general anesthesia with intubation):

- ✓ microsurgical withdrawal of gametes from the testis;
- ✓ Oocyte retrieval by laparoscopy;
- ✓ intrafallopian transfer of male and female gametes (GIFT), zygote (ZIFT) or embryos (TET) laparoscopically.



These requirements should be directly related to Community and National legislation that recognized centres must follow.

The assisted reproduction techniques can be divided into two main types:

1) *Artificial insemination in vivo*: the methods used in this type of insemination are the artificial insemination and the one known as GIFT. The artificial insemination consists, beyond methodological differences, in the injection of sperm (from the partner is homologous, from a donor is heterologous) in the genital part of women. The GIFT, however, consists in the gamete intrafallopian transfer: an injection inside the fallopian tube of both sperm (from the husband's or a donor) and egg cells (from the woman herself or a donor).

2) *Fertilization In Vitro*: with this kind of insemination the place of the beginning of the formation of the first embryonic cells is different; it 's no longer within the body of woman, but in a test tube. The main technique used is the so-called F.I.V.E.T. (in vitro fertilization and embryo transfer). It is a complex and invasive process (especially for the female body) which takes place in two steps: the meeting of gametes (male and female reproductive cells) in a test tube (FIV) and subsequent transfer of embryos in the uterus (ET). The ovaries of women are subject to treatment with pharmacological agents, followed by close cycles of controls and treatments. After 34-36 hours, under general anesthesia, the aspiration of oocytes (the female gamete or egg cells) is performed. Within 18 hours the fertilization process can take place inside the tubes. The selected embryos (usually two or three) are then transferred into the female uterus (or in the fallopian tubes).

These methods leave, from a bio-ethical and legal point of view, still "open questions". For example, the homologous "in vivo fertilization" (the gametes belong to both partners), seems to involve only medical problems related to the intrusion into the intimacy of the couple relationship, and manipulation of the body (especially of woman). The heterologous one (the gametes belong to a donor) instead, raises much more complex issues, especially of legal nature.

Some of the questions that might arise concern the paternity (if the donor is a man) or maternity (if the donor is a woman) of a child: what rights does the donor have towards the child? Does the child have the right to know his/her biological father? Should the



father, the mother and the child know the identity of the donor, considering the fact that the baby will have the genetic makeup of the biological parent?

With regard to these questions we should add that medical science is not yet able to rule out with certainty whether a male or female gamete can be the bearer of some form of disease: today's techniques may be able to detect or exclude only certain types of illnesses.

However, the fact that in vivo fertilization leave the act of conception of human life inside the womb, it avoids a number of complex problems inherent in vitro fertilization.

Also, not to be overlooked is the issue of what has been called the "medicalization of life": the autonomy of the individual, his own ability to act, seem to give way to the choices of the "technician of life", a man himself too, but invested with an authority that allows him to manage and control existential opportunities and modalities of other human beings.

This involves the intrusion of the medical factor in the couple's relationship, the choice, delegated to supposed scientific criterion, between life, death and cryopreservation (freezing) of embryos.

Particular attention is paid to the technique for embryos produced in fertilization in vitro.

In this case, the fundamental question is: can we attribute to the human embryo the status of "person" and therefore preserve it from any manipulation?

One wonders whether it is right to recognize to the embryo the inherent rights of developed human individuals, first of all the unequivocal right of life.

The concept of "person" presents itself the inherent difficulties in its definition, which is not an easy one. They are, in fact, the different understandings of the concept and in many ways radically opposed to each other.

In today's debate on the status of the embryo there are two opposite hypothesis:

- The position, supported mainly by Catholicism, which gives legal status of person to the embryo since the formation of its first cells, basing on the sacredness of life.



- The position, conventionally defined as laical (but not lacking among its supporters several religious people), which considers the embryo at its initial state as a combination of cells devoid of such characteristics (such as self-awareness) to be recognized as a person. However, the proponents of this hypothesis have conventionally established a maximum limit of 14 days to manipulate the embryo.

These two approaches are compared, often with harsh tones, by virtue of the fact that the supporters of the second position believe the first is a kind of brake on the scientific development: once the embryo is not recognized as a person, it would be possible, on the basis of some scientific studies, to find a cure for diseases that are currently incurable through the study of totipotent stem cells. Some scientists speculate, in fact, about the possibility of controlling the development of these cells toward a specific and desired specialization.

Proponents of the personality of the embryo argue that studies in this aspect are quite uncertain, pointing out that totipotent stem cells have a very high possibility of mutating into cancer cells. Primarily, moreover, their aversion is also due to the fact that the study of these cells results in the killing of the embryo itself at the time of their collection.

It is obvious that there is a total incompatibility with a personalistic view of the embryo.

It should be reminded that, in addition to embryonic stem cells, there are two other types of stem cells on which scientific research is addressed:

- stem cells found in umbilical cord blood;
- fetal stem cells that are derived from abortions;
- the circulating stem cells in the adult;
- the "induced pluripotent stem cells" derived from differentiated cells.

The study of these cells may, however, for admission of the entire scientific community, solve the same problems that research on embryonic stem cells intends to overcome.

The tests on the latter does not complete the field of research having as its object the embryos.



Modern technologies, together with the knowledge of the genetic makeup that they themselves have made possible, allow to foresee some possible diseases that the embryo, once it becomes adult, might develop.

This introduces the question whether it is right or not to intervene on its genetic heritage in order to modify and eliminate the risk of such possible diseases.

Furthermore, serious problems could arise when, with the knowledge of the genetic heritage of an individual, you could put problematic options, such as the one to choose the physical characteristics of the unborn child, or to create an “ad hoc” individual with the desired physical traits, or resort to cloning superior or inferior subjects, in order to program the "perfect beings" for the society.

Men would become creations of other men and they would be deprived of their freedom of being born from natural coincidences and not preconceived ones, and consequently they would also lose their social freedom, being, in any case, the result of choices made by the dominant social preferences, that is the eugenics criteria.

Having said so, it should be noted that there are more than fifty thousand couples that each year go through artificial insemination in Italy. And in the rest of the world the situation is the same, with data growing. These couples face a difficult and challenging path, especially from the psychological point of view. Quite often to be able to have a child desired for a long time, they have to undergo multiple attempts, which create enormous stress in the couple.

The increase of infertility in couples is now a widespread problem. However this is a subject which is unknown to most people, on which there is little information and above all a lack of understanding.

Many couples are often hindered or difficulty in walking the road of the search of a child, and still end up feeling ashamed when they resort to assisted reproduction to have one. Natural procreation is allowed, while the artificial one is often denied or, when authorized, it is not seen positively, especially in Catholic countries. There is a widespread idea that all these manipulation techniques of procreation should be rejected because they split the unitive-affective dimension of the sexual act from the procreative one.



Difficulties also arise when you try to determine what are the couples who, as sterile, may undertake the treatment of their problem with the techniques of artificial insemination.

It is often required that the couple is legally married. In the most permissive cases in which the marriage is not required, however, the couple is asked how long they live together in order to understand the stability.

Therefore who decides to have a child naturally or through assisted reproduction, should simply assume this responsibility. And this should be the general rule, both for married couples and unmarried couples, for same-sex couples and single moms. Without discrimination to anyone. Otherwise, not accepting this reality, people will be forced to go elsewhere, where there is more tolerance.

These are just hints to the subject to which many others concerning bioethics are connected, which should be treated.

Actually, the crucial question to which we try to answer in all the work concerns the relationship between the process of fertilization and the evaluation on the legal front, concerning the various techniques of MAR. The answers to the question regarding the type of procreation remains in the background, as well as the relationship between the one who is born and the parents he comes from.

### **Architecture and joint analysis technique**

Infertility is a condition that covers 10% to 15% of couples in fertile age. In Italy, for example, each year about half a million couples ask for consultation about infertility. This phenomenon is rising sharply, both because the couple decides to have a child later and later, and also because there are adverse environmental and social factors that play a major role as, for example, the style of life, work, pollution, stress, etc..

For this reason, the project aims to solve the problem through the recognition of the patient's right to self-determination, with an emphasis on health as a public good, and make medical care more humane. All this will be achieved through the constant training of different teams of doctors who specialize in this field, which involves the



organization of meetings and frequent clinical encounters in some of the best Italian centers.

In general, the project aims to create centers of excellence both for the study and treatment of sterility in couples and for the stem cells.

The project, for these reasons, has been structured in such a way that the know-how acquired so far, in particular the cultural and scientific knowledge obtained from the partners, also thanks to the previous projects, are not lost.

The project, as it has been articulated, includes a series of specific objectives such as:

- ✓the creation of a network of telematic information for the study and treatment of diseases that cause infertility of couples, which can be diagnosed and treated by medical and instrumental techniques;
- ✓the training of staff involved in the study and preparation of behavioral protocols for the diagnosis and treatment of infertility of couples together with the creation of centers for the medical information network;
- ✓the planning, organization and management of courses, seminars and advanced meetings destined to constantly update the knowledge of the groups involved;

On this basis, the analysis project has been structured, distinguishing three specific steps. In the first phase of the study the legal material produced at Community level has been collected and analyzed, comparing it with the contents of the constitution of the European Union (TUEF).

The result of this work has been to synthesize some directions and related educational contents on the basis of the Community guidelines.

We have then tried to raise national standards of application of Community rules within each Member State. Unfortunately, however, this research has not had the expected result because the little material was found in the language of the partner. For this we have faced for the first Italian legislation in order to begin to define a model to be considered a benchmark for the other partner.

Again we tried to synthesize a formative proposal capable of giving added value to the whole project and contribute to the achievement of the objectives set by the same.



Finally a questionnaire has been produced that has been sent to all partners with the request to extend it to other centers located in the same State.

This does not allow us to be able to make sweeping statements but, however, it allows us to infer the guidelines that they too, can be a benchmark for project stakeholders and policy makers.

The additional effort that we have tried to make is to synthesize the collected material and the information produced by the questionnaire in a formative proposal that arises from the intersection between supply and demand for training.

All these objectives are in line with the objectives of the project, namely those referred to in WP 4, which aims to create clinical and research laboratories on first level stem cells.

The aim is to promote the exchange of experience and transfer of skills and competences in the social and health sectors. The beneficiaries of these actions are professionals and researchers who have already participated in EU-funded programs and, at a later time, will allow their institutions (hospitals and universities) to take measures to improve health services, improve the cost-benefits and increase the medical success rate.

Therefore the centers of excellence of medically assisted procreation, both for diagnosis and treatment of infertility in couples who are involved in the project, can count on information and training activities that aim to exploit all EU requirements applicable to facilities, equipment and personnel engaged in the provision of assisted reproduction services.

In particular, the work of analysis leads us to suggest to the partners the definition of specific training catalogs and transfer of experiences able to give support to the objectives of WP 4, that is:

- ✓the creation of a clinical network (through the expansion of the scientific network that had already been implemented);
- ✓structural adjustment of the MAP centers in order to put them in line with the (minimum) requirements set by the EU;



- ✓training, scientific and cultural updating of groups of specialized doctors (human resources) involved in both previous projects and in this one;
- ✓the use of IT techniques for the network management and for a permanent computerized communication;

The main objective, however, remains the further development of cultivation, modification and differentiation of stem cells with the adoption and development of the necessary procedures for their clinical application in the field of perinatal medicine, reproductive medicine and gynecological oncology.

Finally we must not underestimate the fact that the work of analysis, as well as the project as a whole, have involved all the beneficiaries who have expressed their needs on technical adaptation needs of their labs in order to meet the minimum standards required.

In conclusion we point out that the scientific training and the matching of knowledge structures (human resources) in particular specialized medical teams of the seven MAR centers, thanks to the information collected with the analysis, may be used with the ultimate goal to meet the Community quality standards requested to laboratories of stem cells of the first level. For this purpose, a series of training seminars will be designed and then organized, run by a scientific committee with participation of representatives of the seven centers and at the same clinical and operational level with regard to the treatment of adult stem cells and supported by the scientific coordinator of the project.



## **Part One: The context**



## The territories

Europe is undergoing one of the most critical and complex time since the signing of the Treaty of Rome. Demographic trends, major changes in the awareness of the needs and structure of the responses, the advent of globalization and the current destabilization of the current economic system, generated by the financial and real crisis are gradually eroding the network of ancient certainties.

The high reduction in the birth rate in the old continent and the consequences on the balance of population are the subject of a wide debate. The demographic transition has deeply transformed in the last half-century, a relatively short time to demographics, behaviors and structures of the European population. The opposite dynamic of the extraordinary benefits in survival, on one hand, and the strong reduction of the birth rate on the other hand has returned an age structure of the population greatly aged. Furthermore it contains within itself the basis for a further acceleration of the aging process.

This is the context in which the Italian falling birth rate is inserted, although the trend of the phenomenon has only marginally marked the contraction of the birth of the first child. Over 4 out of 5 women do not give up having at least one child. At the same time women's reproduction projects consider an average of at least two children. And this expectation will not change significantly considering the younger generation. It follows that the constraints which limit the Italian birth rate and that have made us one of the least prolific countries, do not interfere, if not only in part, on the decision to have a child, but they do on the ones to have more than a child, and already heavily, on the second. Women grow decisions on reproductive projects are conditioned by the role that is played by work in their lives as they increasingly participate actively in the labor market, where their permanence is becoming more stable.

It is also believed that in industrialized countries, to about 15-20% of couples, conception takes longer than it would be expected (generally 24 months)<sup>1</sup>.

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<sup>1</sup>

The probability of conceiving is achieved by using the indices of fertility (ability to conceive in a cycle) developed by WHO according to a mathematical model of many samples of the population.



The average fertility in young couples is around 25% per cycle. Time is therefore an essential element to be taken into due consideration: after two years of trying, about 19-20% of couples have trouble in conceiving. Out of these, about 4% will remain sterile (will complete or would have completed their life without children) and 15% will be subfecondo, which means that it will take longer to conceive (3-4 years) than it would be necessary for a normally fertile couple.

The variable “time” is also often accompanied by the woman's age because the risk of infertility is a 35-44 year old woman is twice as much as a 30-34<sup>2</sup>.

According to the WHO, the distribution of causes of infertility resulting from epidemiological surveys in industrialized countries is evident. The international organization estimates that the percentage of infertile couples in developed countries is around 15-20%, pointing out that the phenomenon in the near future is likely to increase, both for environmental reasons, related to lifestyle (stress, wrong diet), but also by complex entropic phenomena caused by atmospheric and food pollution, that increasingly affect reproductive capacity not only of men.

More than half of the mothers have a job and, from the data on the motivations to work and the degree of satisfaction expressed by women in relation to their work, it emerges that women care a lot for their work.

The statistics reveal that 1 out of 5 of those mothers that before pregnancy were employed, after 18-21 months after the birth of the child, have left the workplace. 36% of those who have continued to work have problems in conciliating work and family commitments.

These difficulties are evidenced by lower female activity rates for women with children and the inverse relationship between activity rates of women and number of children born. This phenomenon is not only Italian (for example in Germany and the Netherlands there is a similar trend), but not generalized in the European context.

Here, as shown in the introductory note, it is necessary, to understand the phenomenon, to try to describe some of the social aspects of the territories involved that result from

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The diagnostics provides investigation according to well-structured protocols that will lead to clarification of the various pathological factors of infertility.



demography. And on demographics affect the processes of development, the organization of society and cultural factors that change with time.

Below we have tried to highlight in a synthetic way all the aspects that may have a positive or negative impact on fertility.

### ***The social demographic framework of the partner countries***

The project partners are located in an area that is defined Balkan Mediterranean. In addition to Italy, which involves two particular regions (Abruzzo and Puglia) are included: Slovenia (Maribor), Croatia (Rijeka), Bosnia and Herzegovina (Sarajevo) and Albania (Tirana).

In the following paragraphs we are going to describe some of the essential aspects of the subject matter of demographics.

### ***Structure and dynamics of the Italian population***

On 31 December 2010 the resident population in Italy stood at 60,626,442, of which 29,413,274 males and 31,213,168 females. Compared to 2009 - the year in which the total resident population stood at 60,340,328 individuals - the increase amounted to 286,114 units.

The geographical distribution is almost unchanged: the North is characterized by the greatest number of residents, 27,763,261 (45.8% of the total population). The residents of the South are 20,912,859 (34.5%), followed by the Centre, with 19,503,220 inhabitants, or 19.7%.

Foreign residents in Italy as on 31 December 2010 were 4,570,317 (2,201,211 males and 2,369,106 females, with 335,258 new registrations in total), equivalent to 7.5% of the total resident population. Even in 2010, the upward trend of the previous years continued (7.0% in 2009).

From the previous year, the distribution of the foreign presence in the territory remains unchanged: more than 60% of the foreign population resides in the North (35% North West and North East 26.3%), followed by the Centre with 25.2% , South (9.6%) and the Islands (3.9%).

Even taking into account the presence of foreigners in relation to the resident population as a whole, the scenario is the same as in 2009: the impact of foreign population is



higher in the North East (10.3%) and North West (9.9%), followed by Central (9.6%), the South (3.1%) and the Islands (2.7%).

The natural balance has increased from -22,806 (2009) to -25,544, while the migration is on the rise in 2010 (362,343 versus 380,085) and it is still essential to counteract the negative effect. From the analysis of the natural component we get the confirmation of the reduction of births reported again from 2009: it goes, in fact, from 568,857 live births in 2009, to 561,944 in 2010.

With reference to the fertility rate, there is a basic stability of the value recorded between 2008 and 2009 in the case of Italian mothers, and a slight decrease in the case of foreign mothers (2.2 vs. 2.3), while the average age at first birth is increasing, which goes from 29.6 years in 2005 to 30 years in 2008.

As for the marriage, in 2009, the downward trend of marriages is confirmed: 230,613 against 247,740 in 2008. If you take into consideration the ceremony, the religious marriage, despite the general downward trend, is still the one preferred by couples: in 2009 the 62.8% of marriages were celebrated with religious ritual.

Regional differences remain unchanged: in the North-West and the North East civil marriages are, as in previous years, a higher percentage than in other areas (48.6% and 50.2% respectively), while in the South in 2010 over three-quarters of marriages (79.9% in the South and 72.4% in the Islands) were still celebrated with religious rite.

In 2009, the separations were 85,945 and 54,456 the divorces. Compared to 1995, the separations have increased by over 64% and divorces have practically doubled (+ 101%).

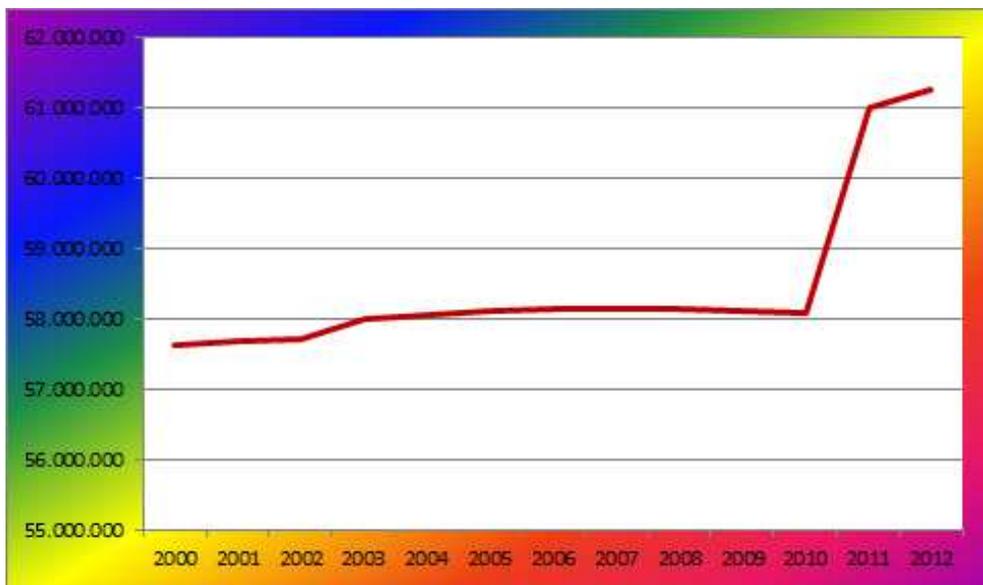
These increases were observed, as said before, in a context in which marriages decrease and therefore can be attributed to an effective increase in the propensity to break the conjugal union.

In 2008, as in previous years, the increase in life expectancy rises, as a consequence of the constant reduction in the risk of death for all ages: life expectancy at birth for males is 78.8 years (78.7 was in 2007), while the one of women is 84.1 years (an increase in this case too, although slight, compared to 84.0 years in 2007). The same values are found in the estimates of 2009, while, if we analyze the estimated data of 2010, the

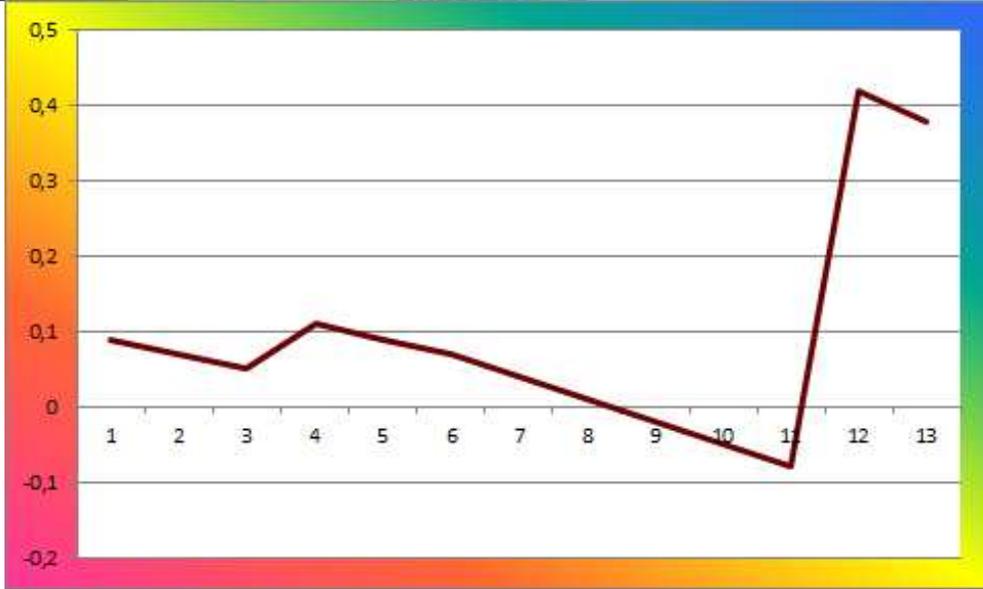


indicator reaches 79.2 years for males and 84.4 years for females. Considering the data at a regional level, in 2010 the North East is confirmed, once again, the area with the highest life expectancy (79.5 years for males and 84.8 years for females), opposed to the South that continues, however, to be, both for men and for women, the area with the lowest average life age (respectively 78.8 and 84 years).

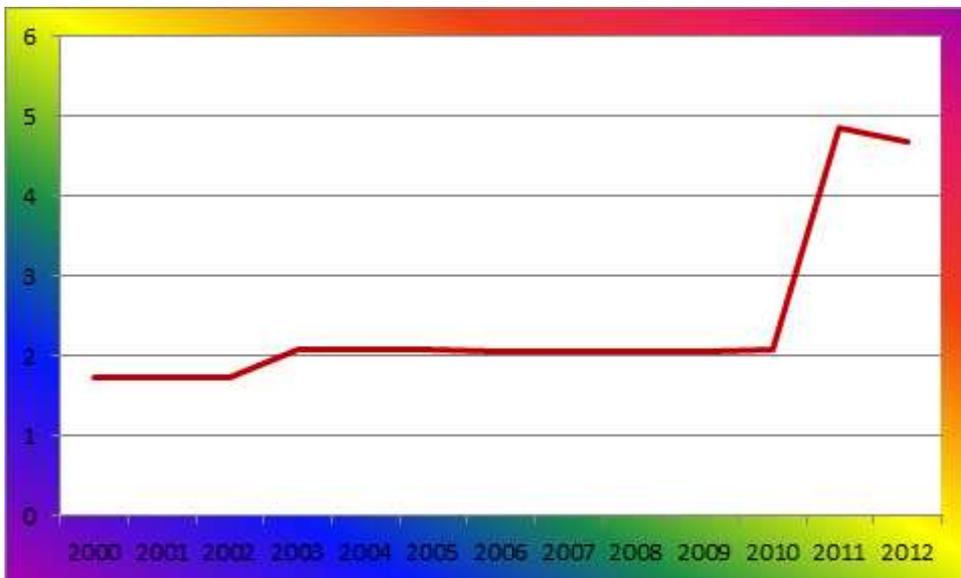
### Population



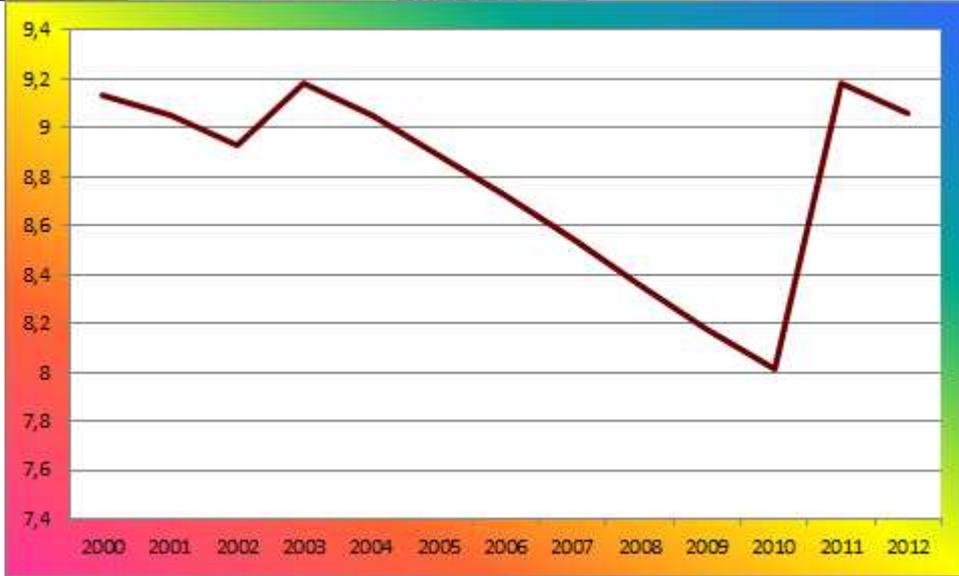
### Growth rate of the population



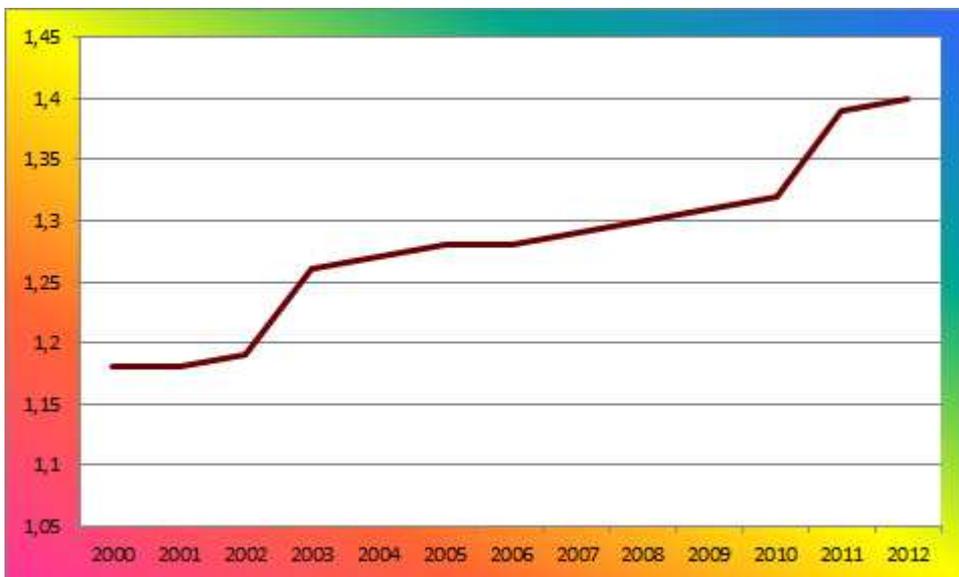
**Net migration rate (emigranti/1.000 population)**



**Birth rate**



### Fertility ratio



### *Structure and dynamics of the Slovenian population*



Slovenia is one of the smallest and youngest countries in Europe: it is independent only since 1991 and since 2004 is part of the European Union.

On 31 December 2010 the resident population in Slovenia was nearly 2,046,000, 49.47% of which were males and 50.53% females and with a life expectancy of 75 years for men and 82 for women. The annual increase was 0.1%, with a fertility rate (no. children / woman) of 1.43 and an average number of family members of 2.46. The geographical distribution is almost unchanged, characterized by a lack of uniformity. In fact, 51% of the population is concentrated in urban areas while 49% live in rural centers, while the south-west of the country and the mountain areas are depopulated.

The demographic trend is linked to changes in the size of populations and the factors that regulate them over the time. With this in mind we can say that in Slovenia there is a very low growth of the population.

The basis of this slow growth, common to the whole of Europe can be attributed mainly to the decrease in the birth rate.

The population dynamics is then determined by the demographic behavior originating biological events (births, deaths) or social events (migration).

Not surprisingly, despite the country has only recently entered the area of development, the division of the population into age groups makes slovenia get closer to the EU Mediterranean states. Children under school age (0 to 14 years) are only 13.5%, less than the over 65 representing the 16.5% of the population, while the average age is about 42.4 years.

Foreigners residing in Slovenia are 30,603, which is 1,5% of the total resident population. Only 2,631 of these are repatriated Slovenian emigrants.

In Slovenia there is a significant Italian presence in Istria, Hungarian to the east and an increasing immigration from Serbia and Bosnia.

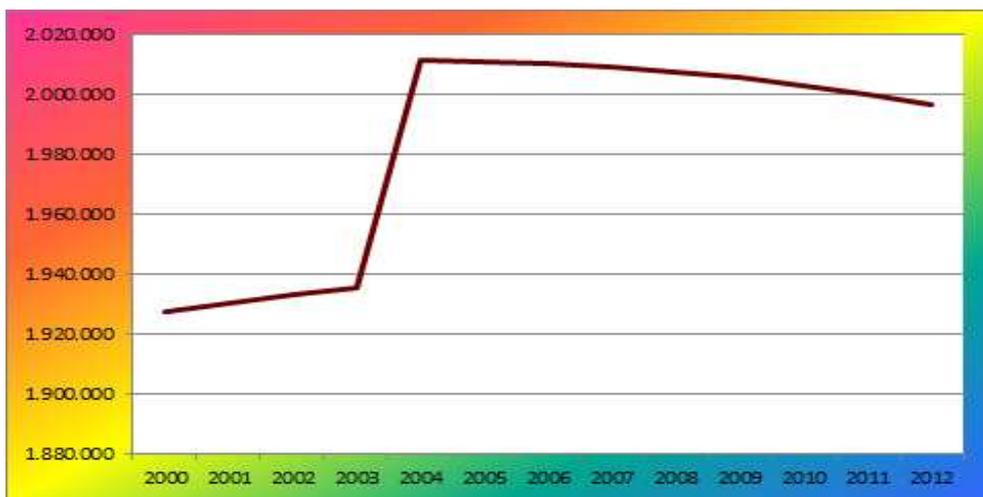
The data provided by the National Statistics reveal that Bosnian immigrants in Slovenia constitute the first major group with regard to the flow of migration. Bosnian immigrants are well over 13,000, while the other ethnic groups are Bulgarians, Italians and Germans, respectively, in the second place, third place and fourth place.



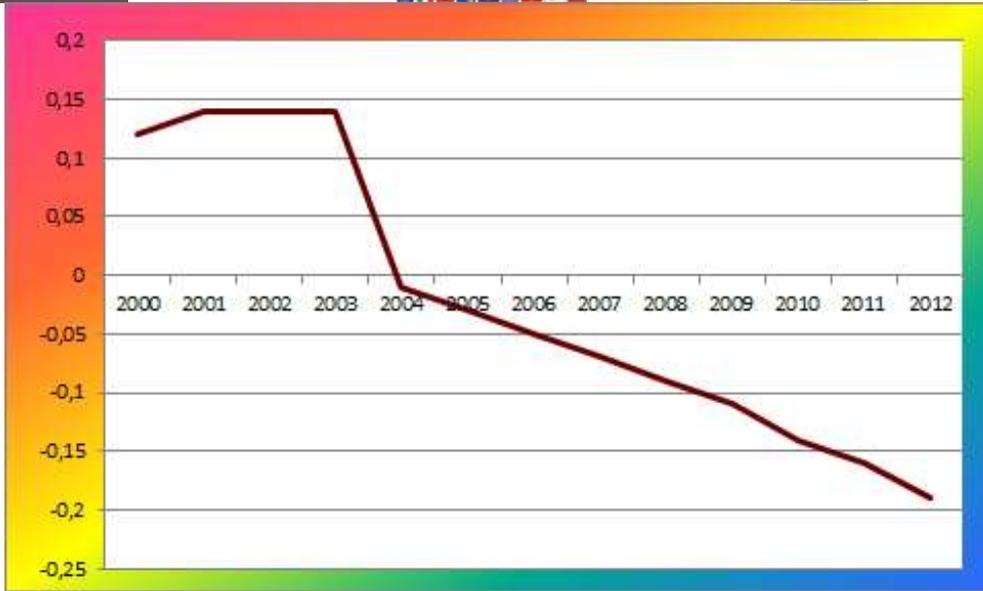
The natural growth rate is -0.2%, while, thanks to the contribution of migration, which is 0.39%, essential to counteract the negative effect, the annual growth is around 0.1%.

Despite immigration, the ratios of the confessional components remain virtually unchanged: Catholic 83%, Muslim 2.4%, Orthodox 2.3%, Protestant 2.2%, atheist or agnostic 10.1%. The increase in life expectancy grows in 2012, as in previous years, a result of the constant reduction in the risk of death for all ages: life expectancy at birth for males is 75 years, while that of women is to 82 years. From the distribution of the population the country is still relatively young, even if all the demographic indicators highlight the aging process, which also affects this young country.

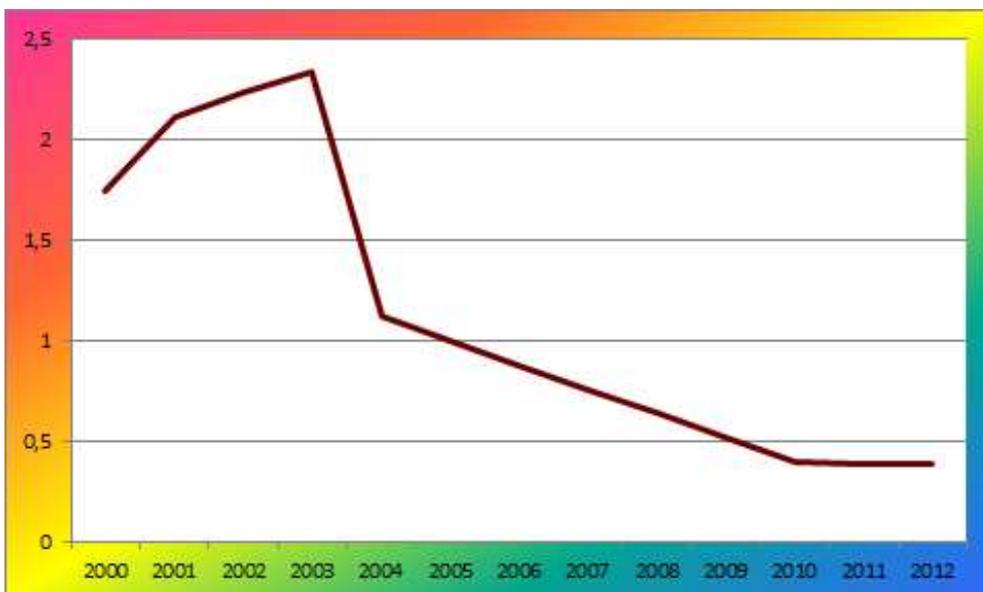
## Population



## Growth rate of the population

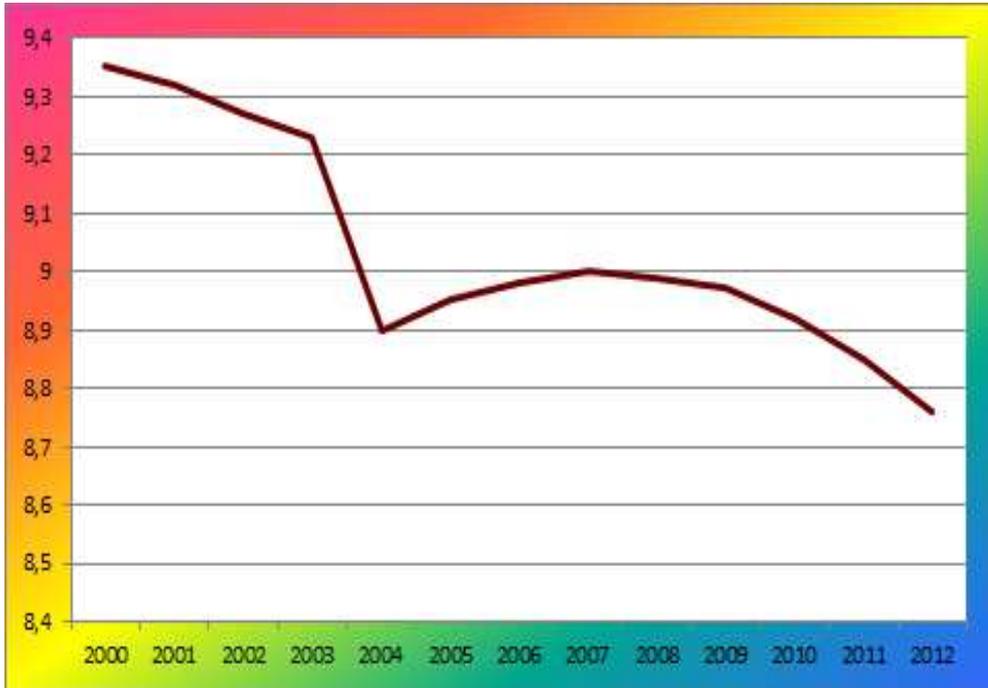


**Net migration rate (migrants/1.000 population)**

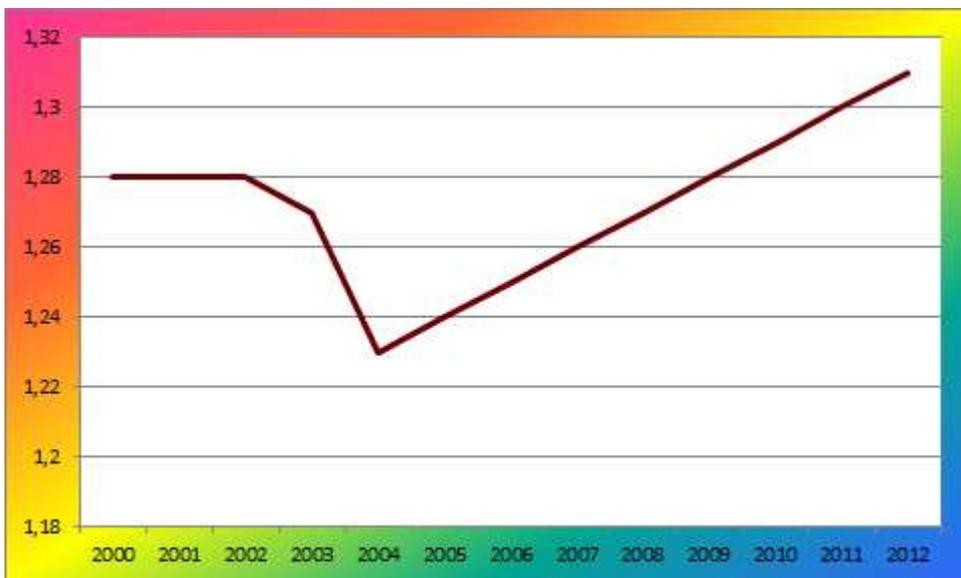




### Birth rate



### Fertility rate





### ***Structure and dynamics of the Croatian population***

Croatia, officially the Republic of Croatia, is a country in Central Europe that from 1 July 2013 has become the 28-th European Union Member State.

At the census of 2011, Croatia had a population of 4.4 million inhabitants. 4,399,364 (99.14%) of this population had Croatian citizenship, 44,340 (1%) of whom had dual citizenship. 17,902 people (0.40%) were of foreign nationality, stateless persons were 9,811 (0.22%), while the citizenship of 10,383 inhabitants (0.23%) has not been established .

The composition of the ethnic structure of the country sees a clear predominance of Croatian Catholic ethnicity (90.4%) of people surveyed in April 2011. The largest minority is traditionally the Serbian one, with 186,633 people, which is 4.36 percent of the population, 0.18 percent less than in 2001. In 1991, before the beginning of the war and the breakup of Yugoslavia, the Serbs in Croatia were 12.2 percent of the total population, with nearly six hundred thousand inhabitants. The Bosnians are in the third place (0.73 per cent), followed by Italians that are 17,807, 0.42 percent of the entire population. The number of Catholics has decreased (3.9000000 to 3.7000000), which in 2001 were 88 percent, while now they are down to 86, 3 percent. The share of almost all other religions has remained roughly unchanged (4.44% are Serbs-Orthodox, 1,47 Muslims), with a considerable increase on the number of atheists, agnostics and non-religious. In fact, while in 2003 there were nearly 100,000 in the census conducted in 2012 they were 196,000, 6% of the total.

The rate of increase of the population has suffered in recent years, however, a decline of 2.9 per thousand.

The urban population is gradually increasing, and we are now at a rate of 59%. It should however be pointed out that there is a contradictory behavior of the capital that from a census to another has seen a decrease in the number of inhabitants from 860 thousand to 780 thousand.

The last census, in addition to highlighting a significant decline in the population, compared to 10 years before, shows a considerable aging.



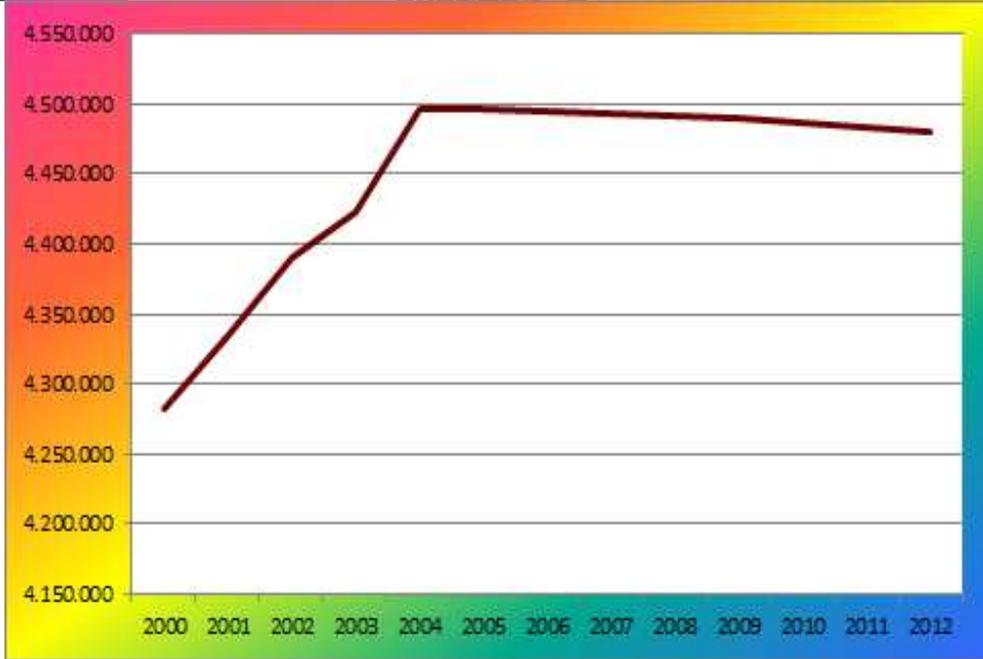
The age structure shows a weight of young people between 0 and 14 years of 16.2% (373.638 of which are males/354,261 females); those included between 15 and 64 years, 67% (1,497,958 of which are males and 1,515,314 females), over 65 years, instead of the weight is 16.8% (male 465,098 288.480/females).

The survey puts to the fore the tendency to a rapid aging of the population of Croatia, and the decrease in the active population, worrying aspect in the context of the economic crisis. While in 2001 the average age was 39.3 years, is now 41.7 years. The most numerous age range includes the population between 50 and 65 years of age, that are 950 thousand. The number of elderly people over 65 years old has for the first time passed that of children under 14 years. In this regard it should be noted that the life expectancy in Croatia is 74.68 years: 71.03 years for males and 78.53 years for females.

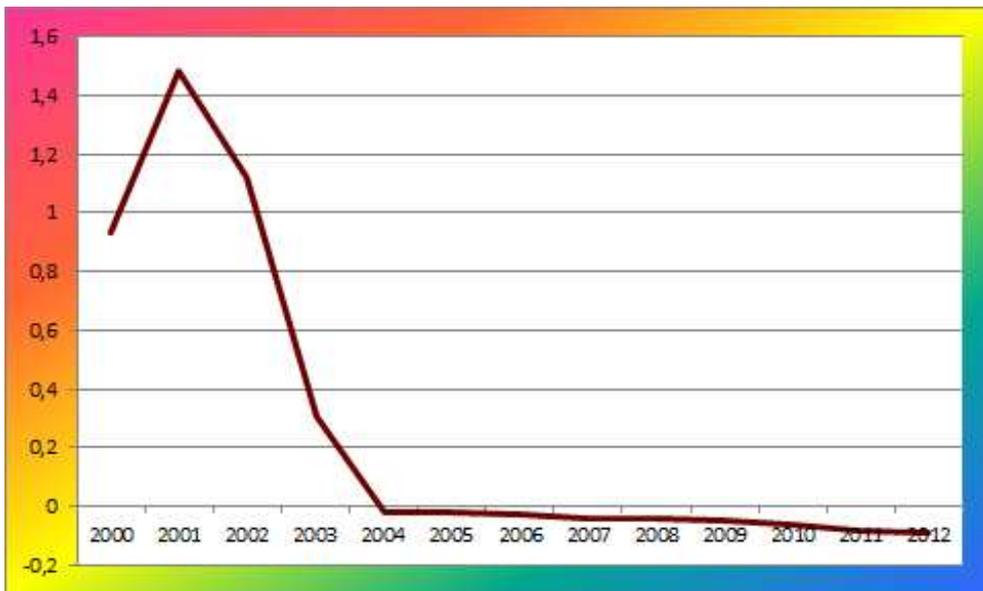
The elderly now represent 17.7 percent of the inhabitants of Croatia, and are 106,000 more than the children (15.2 per cent). The active population (in the age group from 15 to 64 years) has dropped by nearly one hundred thousand units, 2.96 to 2.86 millions.

The negative growth rate of the population should not be underestimated, which is - 0.03%, which comes together with a total fertility rate of 1.4 births per woman, while the rate of net migration is 1.58 immigrants/1.000 inhabitants .

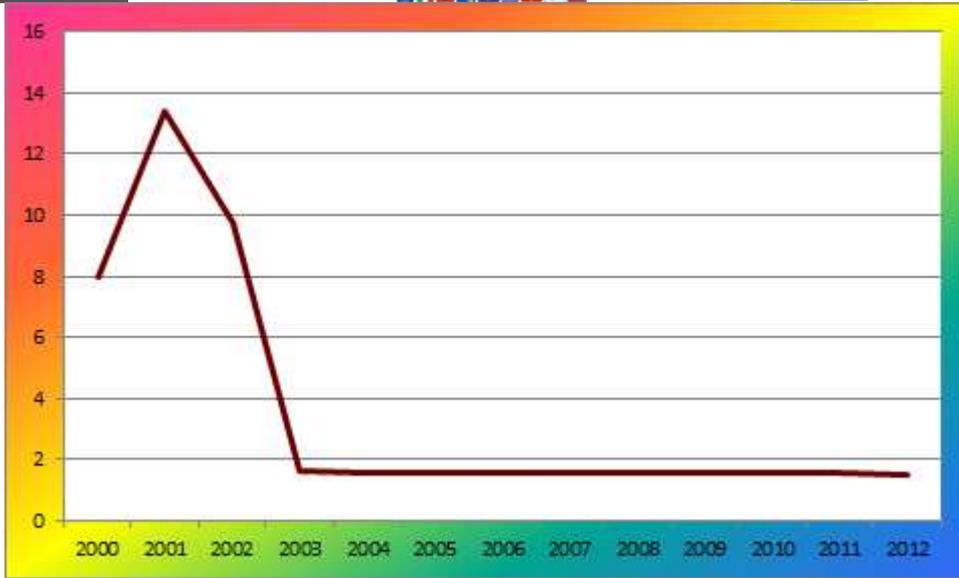
## **Population**



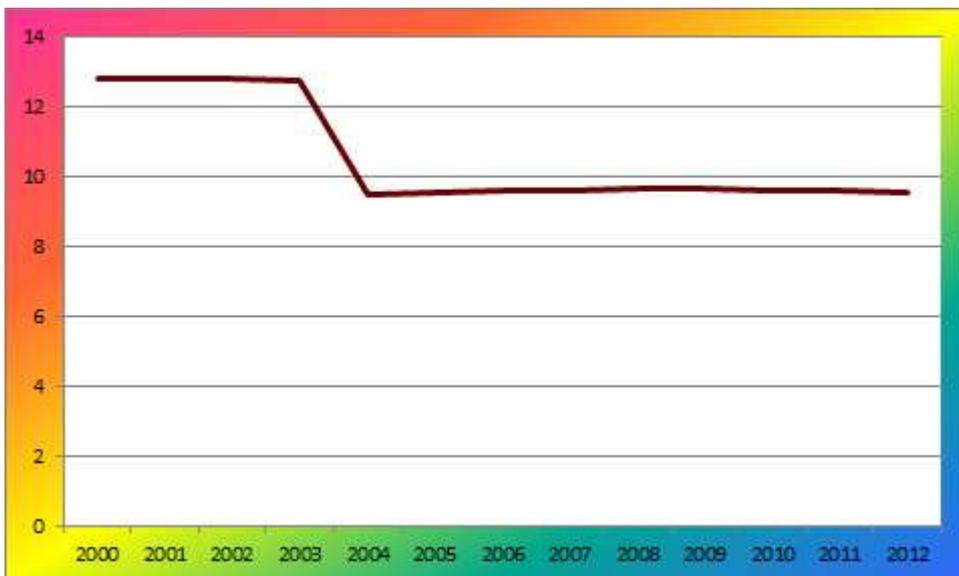
### Growth rate of the population



### Net migration rate (migrants/1.000 population)

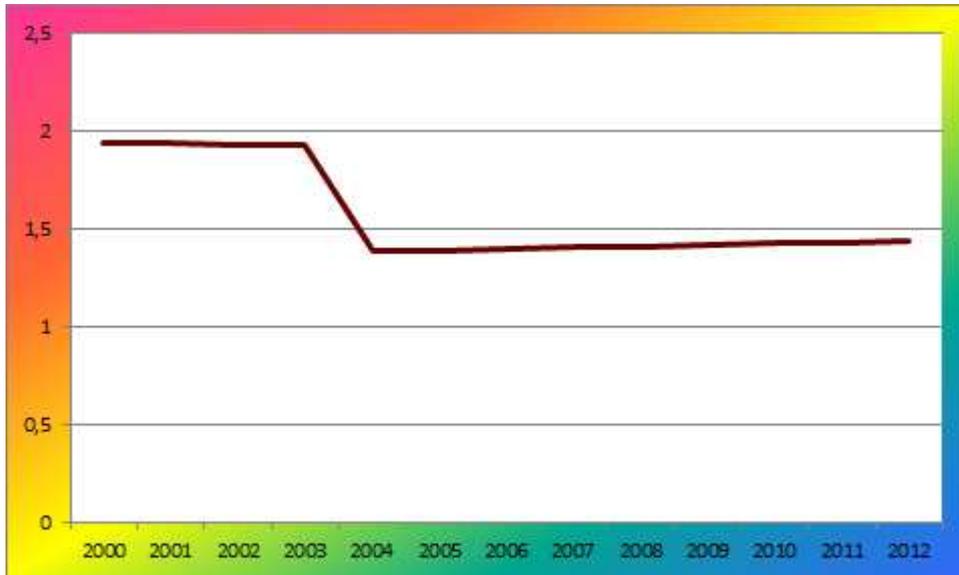


### Birth rate





## Fertility rate



### *Structure and dynamics of the population of Bosnia Herzegovina*

In December 2007, Bosnia and Herzegovina has signed the agreement of Stabilization and Association with the European Union (that is, has signed for acceptance of the content of the document), the preliminary phase with respect to the submission of the application (potential candidate).

According to the Dayton Agreements (1995), the state has retained the territory formerly belonging to the Federal Republic of Yugoslavia, Bosnia and Herzegovina, but has been split into two distinct entities: the Serb Republic (Republika Srpska) and the Federation of Bosnia and Herzegovina (Federacija Bosne i Hercegovine), respectively with 49% and 51% of the territory.

The resident population in Bosnia and Herzegovina is estimated at 3,879,000 inhabitants with a life expectancy of 68.5 years.

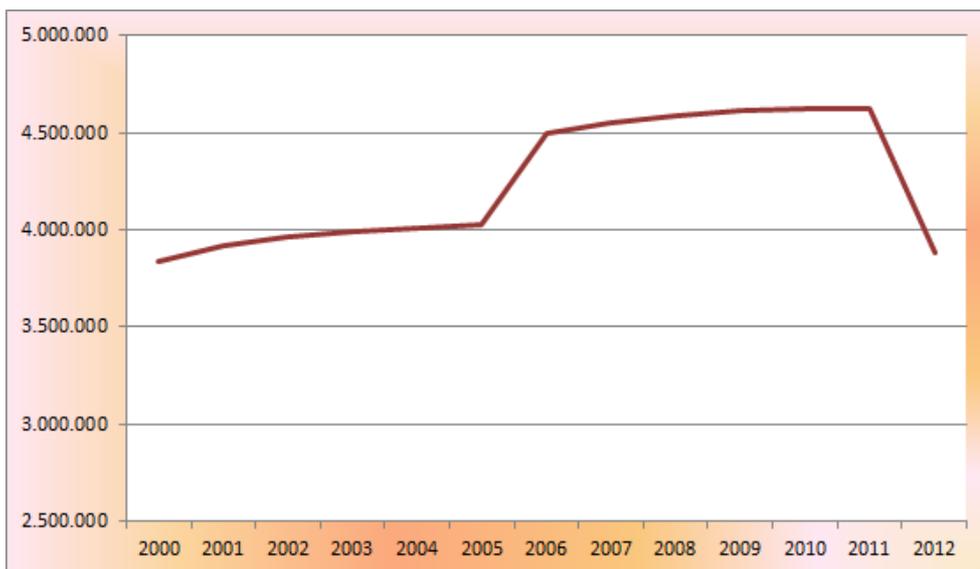
Bosnia and Herzegovina has experienced a gradual population decline as a result of the long civil war, which has caused 300,000 victims and a strong exodus, partly temporary and partly permanent (with the formation of large groups of refugees in Serbia and Croatia), of about 1,900,000 people. This has led to a negative natural growth rate (-



2%). Another demographic phenomenon has been the movement inside, directed towards urban centers, which together are home to nearly half of the population; urban dimensions are reduced, with the exception of Sarajevo and Banja Luka.

The process of recomposition of the social-ethnic identity of the state has developed over the course of nearly five years of war. The last official document concerning the demographic composition of the territory was, unfortunately, in 1991. Some United Nations estimates of 2010 indicate a presence of 44% of Bosnians (Muslims already registered: name, even in the days of the former Yugoslavia, that transcended religious significance for that of true nationality), 31% Serbs, 17% Croats and the rest by various groups, among which the most significant is that of the Montenegrins. The ubiquitous spread of Serbian-Croatian, spoken mainly in its Bosnian variety, provides substantial linguistic unity. The percentages relating to nationality are also indicative of the composition of the population by religion: Bosnians are almost all Sunni Islamic faith, the Serbs are Christian Orthodox and the Croats are in absolute prevalence Catholic (18%)

### Population

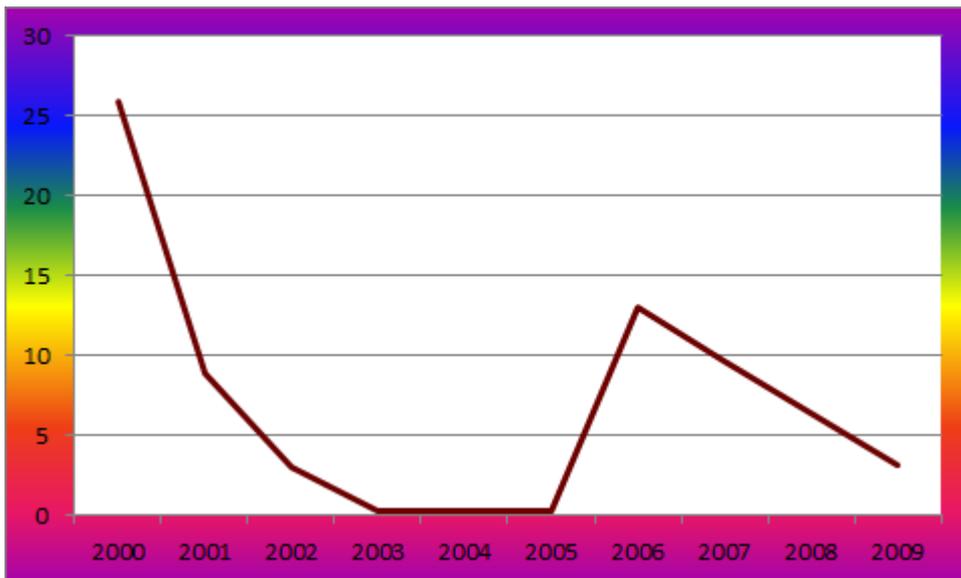




### Growth rate of the population

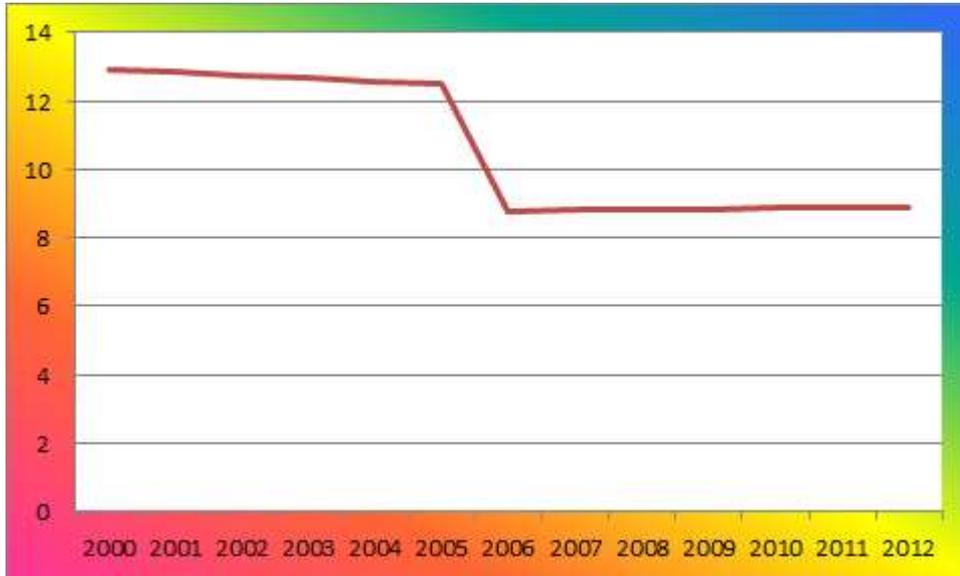


### Net migration rate (migrants/1.000 population)

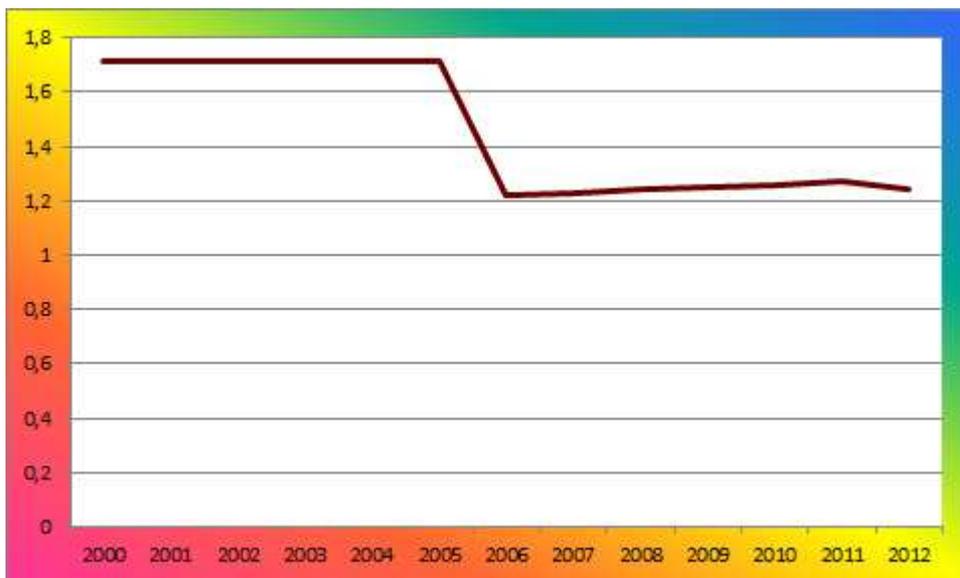




## Birth rate



## Fertility rate





### ***Structure and dynamics of the population of Montenegro***

Montenegro is a very small country with a population of less than 600,000 inhabitants divided into 21 municipalities.

The population is composed of Montenegrins (43%), followed by Serbs (32%), Bosnians (8%), Albanians (5%, mainly concentrated in the South-East of the country), 1% Croats and other groups; the majority of the population is Christian Orthodox (74%) and Muslims constitute 17.7% of the total.

The rate of increase of the population has suffered in recent years a progressive decline caused mainly by economic difficulties that the state has experienced following its independence in 2006.

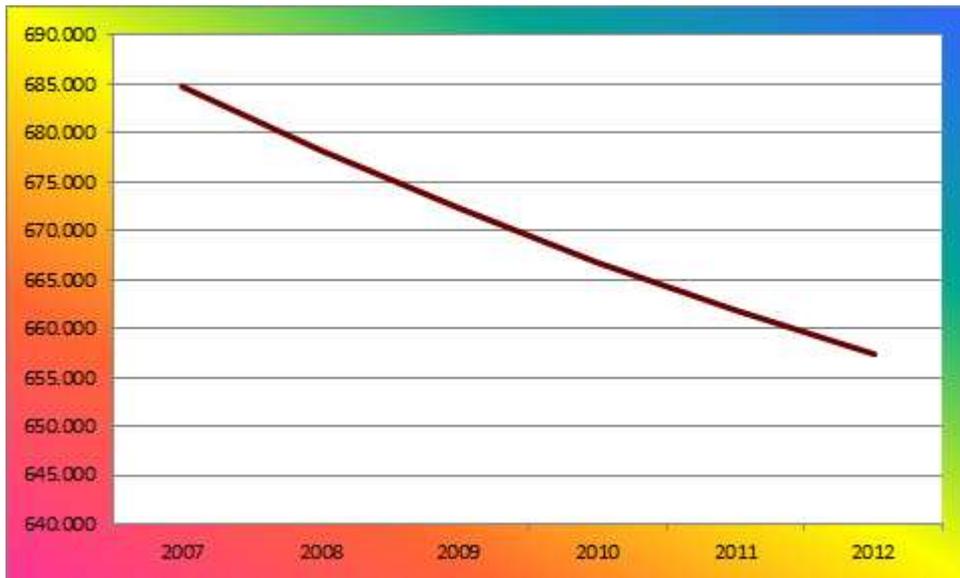
The urban population is gradually increasing, drawn mainly from the capital but the phenomenon of urbanization, that all the states of the former Yugoslavia show, still remains far.

The survey puts to the fore the tendency to a recovery in the younger age classes and, therefore, the country is experiencing a slowing of aging, despite the effects of war and migration. The weight on the total population of the elderly over 65 years old is 13.5%, below that of children under 14 years (15%), while the age group that includes people aged 15 to 64 is 71%.

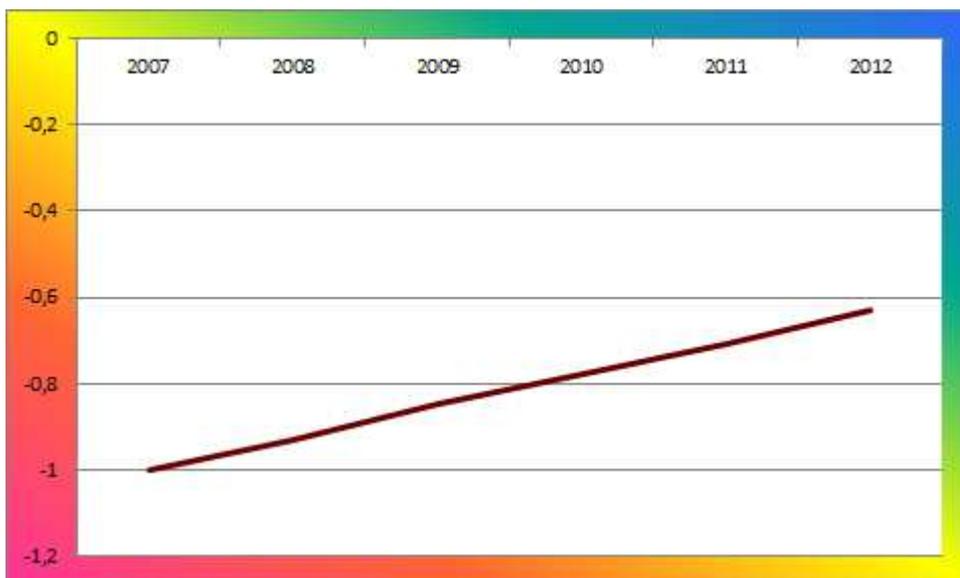
The negative growth rate of the population should not be underestimated, that from 2007 to 2012 fell by almost 1% per year. The decrease is also accompanied by a decreasing fertility rate, but still quite high compared to the average of European countries.



## Population

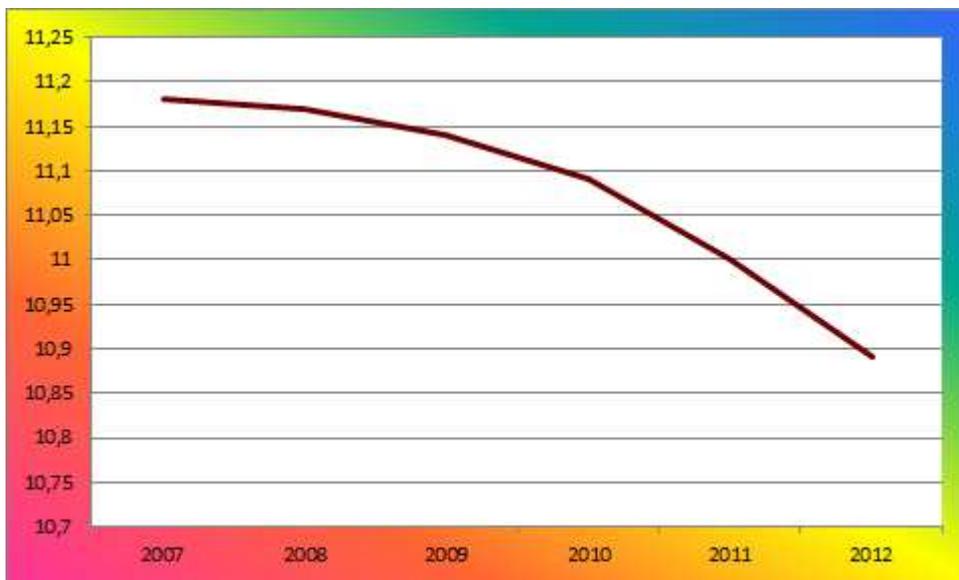


## Growth rate of the population





## Birth rate



### *Structure and dynamics of the Albanian population*

Although it is now almost twenty years since the fall of the communist regime, Albania is still considered a "country in transition" for its path toward Western-style democracies and, more particularly, for its convergence process to the institutional standards of the European Union, which Albania intends to join. In its twenty-year journey, the Albanian economy has experienced two periods of great economic and social crisis. The first is the one that accompanied the collapse of the regime (1989-1992), with the disintegration of entire industrial complexes, and the abandonment of the countryside, the decommissioning of many services and the great wave of migration (with the end of the totalitarian state that considered emigration a crime, the Albanians



have started to leave Albania). The second moment of economic crisis, but also political and institutional, was that associated with the collapse of the "financial pyramids" (early 1997), which destroyed a large part of family savings (largely the result of remittances) and strengthened the degree of dependence of Albania from the international financial aid.

The population of Albania is of 2,851,741 inhabitants, made up by 50.2% males and 49.8% females. For the first time in the history of the Albanian censuses, the percentage of the population in urban areas is higher than in rural areas, with 53% living in cities while the remaining 43% in rural areas.

The Albanian population has a highly homogeneous ethnic composition, represented by 98% by Albanians, a group believed to descend from the Illyrians, Indo-European people who once lived in the region.

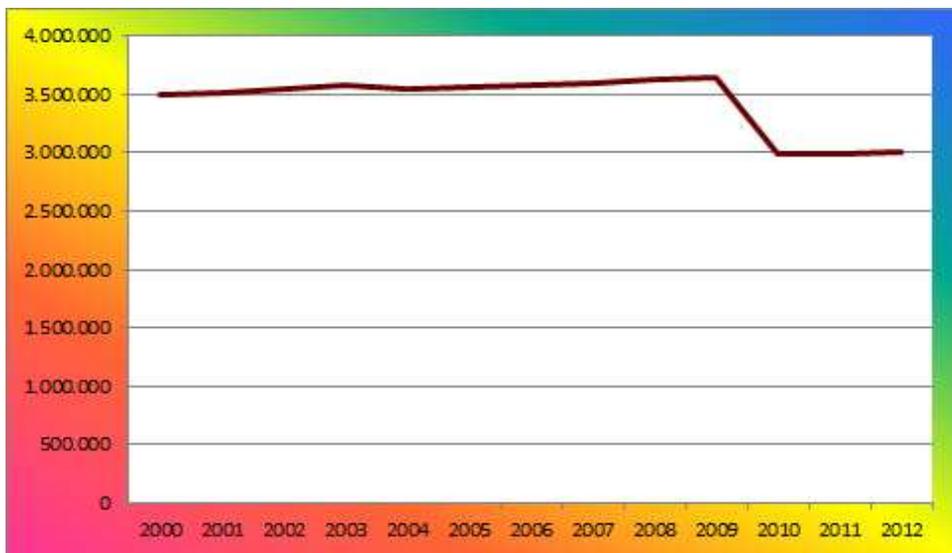
The numerical increase of the Albanian population was extremely conspicuous enough to be counted among the most extensive in Europe, this trend is the result of a modest reduction in the birth rate which was offset by a systematic and significant reduction in the mortality rate. The interpretation of this development can be sought in:

- 1) socio-cultural reasons (the strong presence of an agricultural economy that requires, in predominantly archaic societies, the need for a large number of arms);
- 2) prevalence in the population belonging to the Muslim religion (religion away from practices of family planning);
- 3) ideology of the communist regime that has seen with kindness and favor, stimulating it, the increase in population, particularly in the rural areas.

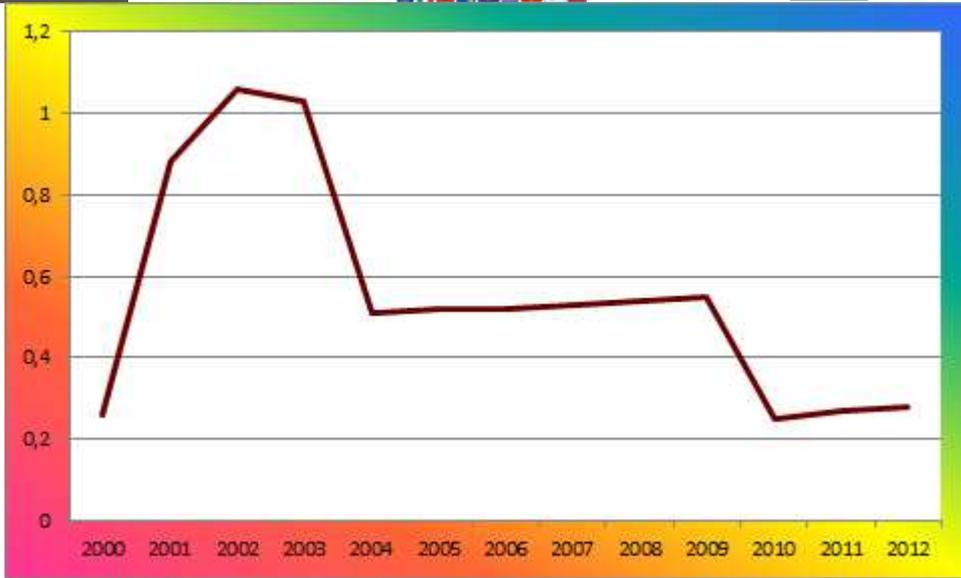
The positive growth trend can be attributed to the values of the birth rates that are very close to those recorded in developing countries, the coexistence of events that led to the Albanian population to nearly triple in the interval between 1948 and 2006. This trend, although with lower rates, is also evident in recent years. Population growth, however, is attenuated by the processes of emigration still affecting the country.



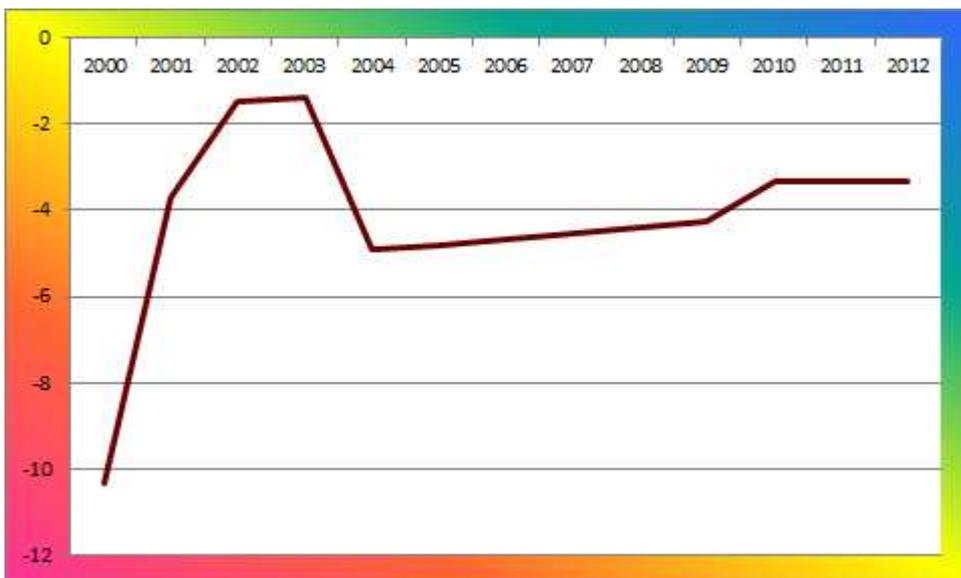
## Population



## Growth rate of the population

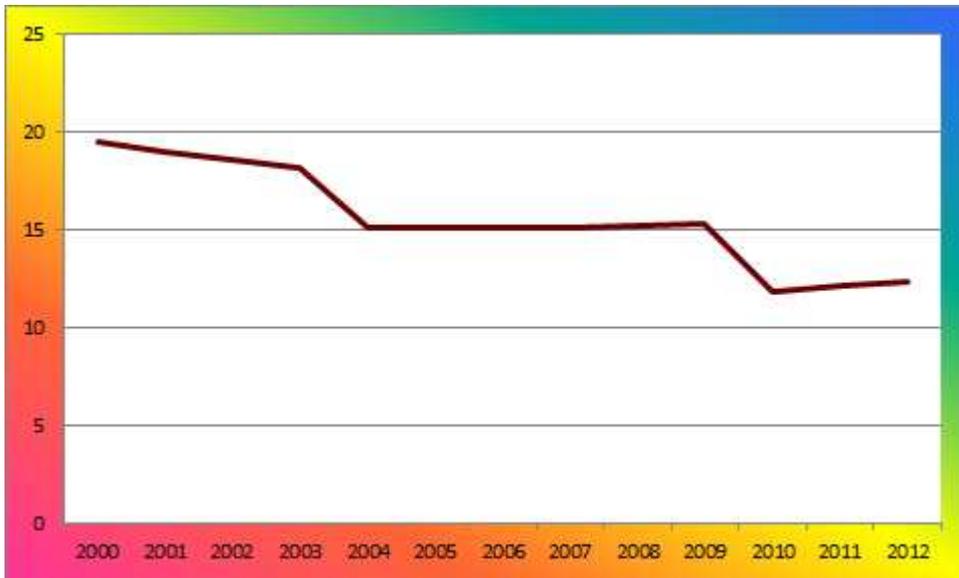


**Net migration rate (migrants/1.000 population)**

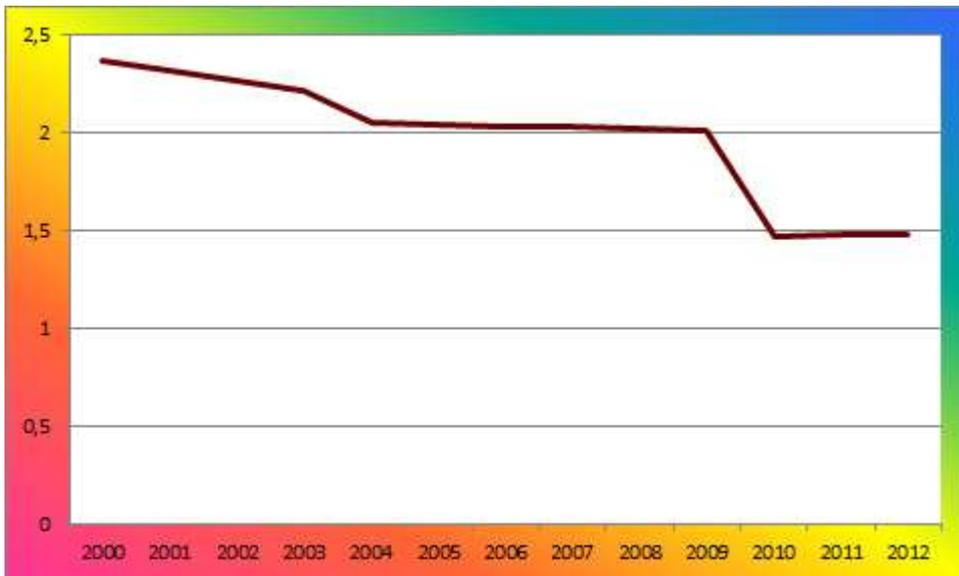




## Birth rate



## Fertility rate



## The causes of infertility



According to a first definition, infertility, at least in women, should be distinguished from infertility, meant as the inability to conduct pregnancy until the time of fetal vitality. In humans, however, since the concept of abortion obviously extraneous to the pathology of reproduction, the two terms are widely used as synonyms.

According to another definition, a couple is considered infertile when they have not been able to conceive and procreate a child after a year or more of unprotected sexual intercourse, while the couple is sterile when one or both the partners are suffering from a permanent physical condition that does not make possible procreation. According to this interpretation, the term "sterility" refers, therefore, to a more serious condition and in anyway absolute of "infertility" regarding the couple and not its individual member.

The absence of conception is defined sterility (infertility), as well as cases of recognized disease, after 12/24 months of regular unprotected sexual intercourse.

The causes for women can be attributed to diseases of the tubes (20%), to hormone deficiencies (25%), uterine (3%), to recurrent miscarriage due to chromosomal abnormalities, anatomic abnormalities of the uterus, fibroids, "weakness" of the cervix, hormonal imbalances and immunological disorders, as well as other causes such as endometriosis.

The causes of infertility for men are: the varicocele, which is the dilation of the veins of the spermatic cords, infections, pituitary hormone deficiencies, trauma of the testis, the undescended testes in the scrotum, along with other causes less characterized.

Furthermore, in our society different motivations of social, economic and cultural kind, lead many women to postpone beyond the third decade of life, the search for a conception. According to the latest data on the birth rate in Europe, in fact, it is shown that the average age at which the Italian woman gives birth to the first child is 30 years, increased data compared to the previous one which was 29 years old.

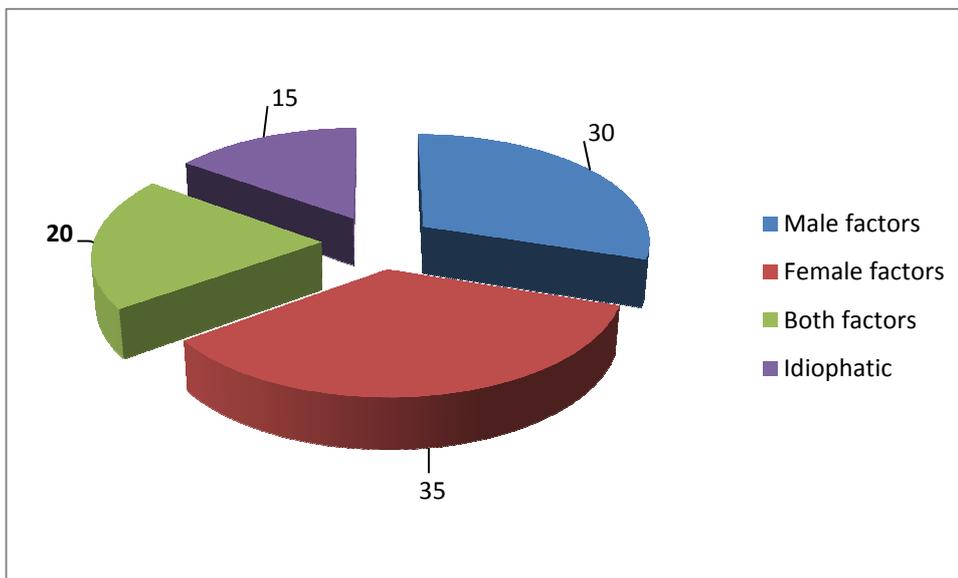
The time factor is expressed in three different ways and it influences the diagnostic strategies:

- ✓ age of the woman;
- ✓ exposure to the probability of conceiving;
- ✓ ovarian reserve.



The age of the woman is one of the main limits on human fertility. With age, in fact, the risk of miscarriage increases. This risk is about 10% for women under the age of 30 years, to 18% for those aged between 30 and 39 years, to 34% for women in their 40s. Women over the age of 35 have a higher chance of having reproductive difficulties and higher frequency of karyotypic abnormalities, eg. aneuploidy, largely determined by chromosomal **non**-disjunction.

### Causes of infertility



The reproductive capacity of the couple undergoes a decline with age. This phenomenon manifests itself much more in women, the expectation of having a child for a couple in which there is a woman over the age of 35 years is reduced by 50% compared to couples in which women are younger. Although there is scientific evidence that fertility in women decreases from 25 - 28 years, it is recognized that the reduced reproductive capacity in the female partner starts around 35 years with a progressive and significant decrease until the complete exhaustion of ovarian function.

Exposure to the probability of conceiving: the duration of infertility is the criterion that selects the couple's reproductive prognosis regardless of the diagnosis of infertility.

Couples with a condition of sterility of long duration have a unfavorable reproductive prognosis.

The ovarian reserve, the female gonad, unlike the male one, is constituted by a finite number of follicular units, and therefore of egg cells, which represents a predetermined



heritage susceptible to an irreversible depletion. There is a critical threshold of follicular heritage, below which there is a reduction in the reproductive potential of the woman which may be the only determining element the sub-fertility, which may be due to advanced reproductive age but also to a congenital reduced follicular heritage (dissociation between age and follicular heritage), or to the interference of iatrogenic or pathological factors on the consistency and consumption of the follicular heritage (infections, surgical outcomes, environmental factors, lifestyles, etc..).

Guidance on the ovarian reserve can be obtained through the assessment of the levels of FSH and estradiol performed on III day of the menstrual cycle.

<i>Types of infertility</i>	<i>% of affected couples</i>
<i>Ovulatory disorders</i>	<b>20-30</b>
<i>Tubal abnormalities</i>	<b>15</b>
<i>Endometriosis</i>	<b>10</b>
<i>Cervical factor</i>	<b>4</b>
<i>Abnormal sperm</i>	<b>20-25</b>
<i>Other male causes</i>	<b>2-5</b>
<i>Disorders of sexuality</i>	<b>6</b>
<i>Unexplained infertility</i>	<b>22-28</b>

### **Access to techniques: a comparative analysis**

The transplantation of human tissues and cells is an area of medicine that is growing very quickly and offers great opportunities for the treatment of so far incurable diseases. The quality and safety of the technologies used should, however, be ensured, in order to ensure its effectiveness and to avoid side effects, potentially severe, eg. development of tumors.



The use of techniques of medically assisted procreation is only allowed when it is found impossible to remove in a different way the causes that do not permit procreation. However, it is limited to cases of sterility or infertility from a known cause, or unexplained, as well as certified by official medical documentation.

The techniques of medically assisted procreation are applied in accordance with the following principles:

a) graduation, in order to avoid the use of interventions that have a higher degree of technical and psychological invasiveness, based on the principle of minimal invasiveness;

b) informed consent, to be carried out in accordance with Article 6.

In Italy, for example, the use of techniques of medically assisted procreation of heterologous type is not allowed.

A careful anamnesis and a proper objective examination are the first major step in the first interview with an infertile / sterile couple. During this phase, in fact, a specific cause of infertility / sterility can emerge and this can help focus subsequent diagnostic evaluations on the factors most likely responsible for the infertility / sterility itself.

The causes of infertility / sterility must be sought in a systematic, effective way, in order to identify the most relevant factors.

The route and duration of the investigation must take into account the wishes of the couple, the woman's age, the duration of infertility / sterility and personal data emerged from the anamnesis and the objective examination.

A clinic card must be filled in, containing the feedback and relevant data of the couple, which will be kept by the center.



## **Part II: Preliminary considerations on the regulatory framework**



## Relationship between MAR and Family Law

The evolution of man and his achievements have always been accompanied by the evolution of social relationships with others, and therefore to its organization in society. Even as a matter of survival, men have organized in tribes to hunt, grow and defend themselves.

In early ages, tribes represented the social nucleus on which to base their expansion. Religion itself, at some point in human evolution, put fertility as a primary aspect of the survival of the human race, considering sterility a divine punishment. Sexuality too was seen as the only way to procreate.

Actually, even today, despite the fact that sexuality has taken on very different characteristics from the mere reproductive function, infertility is seen as a major problem. Infertility is not only an organic problem, but it has important implications also on the psyche of the individuals involved, on the social life, sex life and well-being of a married couple.

Family since ancient times has therefore played a crucial role in human life, evolving at a linear equation between social structure and economy.

In many societies the concept of family has "suffered" an evolution up to coincide with the concept of family to "marriage." Initially, family was based on purely religious rules to become subject, albeit conditioned by spiritual power, of temporal legislative interventions.

Family law in more recent times has gone through significant transformations which, triggered by substantially similar changes of social reality in many European contexts as well as the growing importance of the fundamental rights of the individual, have significantly reduced the differential traits existing – also due to cultural contexts not always fully homogeneous - among the systems.

Nowadays we tend to draw attention, also in view of a complex perspective of harmonization, to common values, with respect to which the differences are believed to be regarded as a mere result not so much of the diversity of environments of reference, but rather of the speed with which national systems, also due to the political balance, pander to the demands for reform.



Therefore wondering which features takes the family in front of contemporary law is not a mere rhetorical exercise because, while it forces us to deal with sudden and profound changes in values and social relations, on the other hand, just because of this evolution, it imposes a careful reflection on the ethical, moral aspects and of legal nature of the non-natural birth.

The notion of family even in the modern society of the third millennium remains central in the reflections of EU and national policy makers.

We find the foundation of the family already in Roman law of the Holy Roman Church, that identified it in marriage. Since then, many changes have been made but they have never tarnished some of the principles that we still find today in existing law .<sup>3</sup>

The first true modern codification of family law is due to the Napoleonic Code of 1804, whose influence on subsequent codes was of extreme importance. The Napoleonic Code had accepted most of the principles proclaimed in the Doctrine of Natural Rights and individualistic philosophy of the eighteenth century, which had taken away from the family every religious or political purpose.

By the time family has become a real institution recognized by the law, which grants it very specific functions also in terms of filiation. The evolution of society, as claimed by the sociologist *Bauman*, becomes more and more liquid, and brings family institution to take on improper social and economic functions, with tasks of social safety net of the great uncertainty and of propulsion of informal welfare.

The evolution of the family model that from "patriarchal" has become first "nuclear" and then opened, is leading the European Union law and of many Member States to change its uniqueness. All this because today the right of the person wins and this is leading to give recognition also to the so called de facto family, ie not based on marriage (cohabitation of unmarried, divorced and people of the same sex).

These changes are very important because they have a direct impact on the possibility of having children, and not just for infertile couples, but also for the homosexual ones, that can not have children in a natural way.

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These are some basics such as the consensual and monogamy.



There are many aspects that can influence the object of our research and this is why the legislation on family law appears today fundamental on the aspects concerning artificial procreation.

First we should mention the European Convention for the Protection of Human Rights and Fundamental Freedoms<sup>4</sup>.

Reflection, therefore, can only build on the significant changes introduced by the Charter of Fundamental Rights of the European Union in the field of fundamental rights of the person. Among the various political and social events, the process initiated by the Nice Charter eventually came to its conclusion, in technical-legal sense, with the entry into force of the Lisbon Treaty on 1 December 2009.

The new framework of European integration outlined by the Treaty raises to jurists, together with the need to rearrange the complex system of 'multi-level protection' of fundamental human rights in the European system, questions, research perspectives, completely new and innovative applicative solutions, also compared to the recent past. The problem, if not that one of recognition, of the so called "Decentralized execution" of Fundamental Rights of the European common space, finally finds an answer of positive law to the extent that the Treaty confers legal importance, in terms of Community law, both to the Charter of Nice and to the European Convention for the Protection of Human Rights and fundamental Freedoms (ECHR)<sup>5</sup>.

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<sup>4</sup> The Charter of Fundamental Rights (Nice Charter) puts the individual at the center of Community law. For more details, please refer to the text in the OJ series C 364 of 18 December 2000.

<sup>5</sup> The Convention is an international treaty drawn up by the Council of Europe signed in Rome on 4 November 1950 and entered into force on 3 September 1953. It was subsequently ratified by 47 member states of the Council of Europe (22 June 2007). The ECHR was later supplemented and amended by 14 additional Protocols. The Protocols II and III (entered into force 21 September 1970), V (entered into force 20 December 1971), VIII (entered into force on 1 January 1990), IX (entered into force on 1 October 1994) and X (never entered into force) relate to procedural aspects and were overcome by the XI Protocol, signed in Strasbourg on 11 May 1994 and entered into force on 1 November 1998, while Protocol I ("additional Protocol", which entered into force on 18 May 1954), IV (entered into force on 2 May 1968), VI (entered into force on 1 March 1985), VII (entered into force on 1 November 1988), XII (entered into force on 1 April 2005) and XIII (entered into force on 1 July 2003) have added other rights (in particular, the first one



The evolution of the framework of the fundamental freedoms puts in a completely new light the main issues which policy makers have always wondered:

- ✓how can you ensure equal protection for European citizens;
- ✓how can you govern a system of "multilevel protection of rights", among international, European, national and local sources of law;
- ✓how to regulate the relationship between the responsible judicial authorities: European Court of Justice, European Court of Human Rights, State Constitutional Courts, etc.;
- ✓how to determine the role of the state courts of merit in order to make the judicial protection of fundamental rights, proclaimed by supranational authorities, effective;
- ✓What are the mechanisms of harmonization that can be used in / by the system to ensure a uniform interpretation and application of fundamental rights in the Single European space;
- ✓Hierarchical or functional rule as discipline of the relationship among the various sources?

These issues are subtle problem comparing to the aim of achieving a complete European citizenship.

Within the above-mentioned problems and the significant changes introduced by the Lisbon Treaty, the preliminary issue to be resolved concerns the impact and reach in the domestic laws of the single EU member states, that the decisions of the European Court of Human Rights are meant to take in cases the domestic legislation should be different or contrary to that of the ECHR.

Priority aspect of this reflection is that relating to bioethical or of fourth generation. This essentially for two reasons. On one hand it is impossible not to note that the development of biomedical techniques and the related biotechnologies increasingly determine the overcoming of the naturalistic paradigm in matters of life beginning / average life / end of life, putting in a whole new light the relationship between the fundamental principles such as human dignity and autonomy, freedom and responsibility, informed consent and therapeutic freedom, equal treatment and

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protects property and decrees the right to education and to free elections and the thirteenth provides for the abolition of the death penalty in all circumstances).



prohibition of discrimination. It is a new area in which the law is not asked to regulate the effects arising from the relevant fact (birth, illness, death) but to issue rules governing the structure and organization of the fact itself.

It is therefore evident that from a substantive standpoint different solutions may be presented, depending on the policy and bioethics option accomplished among individualism, utilitarianism and autonomy. The specific paradigm is constituted both by the spread of the techniques of artificial procreation as a remedy to the exponential increase of sterility / infertility that by exceeding the limits of objective and subjective nature of the phenomenon of procreation. In these areas arises in particular the need to define rules that recognize / delineate new spaces of freedom and autonomy that science makes the subject acquire.

A substantial step towards the recognition and demarcation of new spaces of freedom can be attributed to the ratification of the Lisbon Treaty on 1 December 2009, which, among other things, provides for the European Union's accession to the European Convention on Human Rights.

After decades of uncertainty it's been possible to see the final entry of the 'ECHR system' under the law of the EU, with any consequential implication in terms of arrangements for adapting the law to the supranational law and the relationship between multi-level regulatory systems.

For greater clarity, some essential aspects of the subject should be pointed out.

We begin by recalling that, as it is well known, on the basis of established case law, the relationship between Community law and national law must relate to two systems configured as autonomous and separate, although coordinated, according to the distribution of competence established and guaranteed by the Treaty.

The system of protection of human rights, as a result of the changes introduced by the Lisbon Treaty, becomes more and more sophisticated. It is represented as a pyramidal interlocking system: EU adheres to ECHR, composed of a plurality of States which adhere themselves and formed by a set of regions. In other words this means that the provisions of the Charter have spillover effects which directly affects our legal system.



Even if indirectly there are other Community interventions that affect motherhood in general. These are the social policies and the interventions in maternity protection, as working hours and social security.

The European Union's role in promoting a "sustainable family policy" has been planned since the signing of the Treaty of Rome (1957). The Council adopted guidelines and minimum requirements to encourage the improvement of the working environment and to ensure a higher level of protection of the safety and health of workers.

The European Commission in its action program for the implementation of the Charter of Fundamental Social Rights of Workers (Strasbourg, 1989) has determined the adoption of a directive on the protection of pregnant women and new mothers. In this specific context the Directive 89/391/EEC was adopted, just on the implementation of measures to encourage improvements in the safety and health of workers at work.

This directive comes from the need to standardize the different regulations in force in the Member States by promoting prevention, information of employees, their co-operation in ensuring effective protection on the job.

It represents a set of reference standards for the adoption of protective measures aimed at overcoming the principle of maximum reasonably practicable security, to represent the practical philosophy of the priority of collective protective measures over individual protective measures.

The Directive expressly provided in Art. 9, paragraph 1a that the so-called "risk groups", particularly exposed, should be protected against the dangers which specifically affect them. The groups at risk, for which we need a special protection, new and expectant mothers are included.

At this first general Framework of the Directive, 19 December 1992, the Council of the European Communities has issued a new one, 92/85/EEC, with regard to the



"introduction of measures to encourage improvements in the safety and health at work of recently given birth or of breastfeeding"<sup>6</sup> .

Deepening the obligations of the employer we should remember that, contrary to what is considered from the Member States' legislation, he must assess the hazards of working conditions and processes and implement appropriate preventive measures for the working mother who is exposed to physical, chemical and biological agents specifically listed.

With Directive 75/117/EEC the concept of "equal pay for work of equal value" is introduced, which exceeds the reference used above, of "same work". The adoption of common standards between men and women workers in the classification systems is also defined.

The Directive 76/207/EEC on the implementation of the principle of equal treatment for gender, puts as a condition to implement the goal, the absence of direct and indirect discrimination with reference to marital or family status.

The Directive 96/34/EC is the result of the first European union agreement between the European Trade Union Confederation (ETUC), private entrepreneurs (UNICE) and public entrepreneurs (CEEP). It provides, among other things, a parental leave of at least 3 months for children up to 8 years of age. The leave is an individual right of a parent (both mother and father) and then, in principle, non-transferable.

Directive 2002/73/EC is instead aimed at ensuring the implementation of the principle of equal treatment in the workplace. It provides instructions about the conditions of access to the workplace and to all levels of vocational guidance, training, retraining and further training and as regards working conditions and dismissal. The Directive also provides for the introduction into the legal systems of the necessary measures to enable those who consider themselves wronged respect the principle of equal treatment to pursue their claims by judicial process. The Directive confirms the notion of direct and indirect discrimination, both prohibited as contrary to the principle of equality between

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The directive for pregnant worker, for worker who has recently given birth and for breastfeeding worker, means any worker who informs her employer of her own condition, according to national law and practice.



men and women; prohibits sexual harassment, as they are deemed to be considered prohibited discrimination; it considers discrimination also the order to discriminate and the acts of retaliation. The Directive also contains the principle of legality of positive action, as aimed at removing obstacles to real equality, and urges Member States to take such measures to speed up implementation.

Even EU guidelines on equal opportunities are, therefore, a legislative important aspect, able to give guarantees to women who at some point in their lives decide to procreate, regardless of whether this is done by natural or due to medical care.

## Ethics and Bioethics

That of artificial insemination is an issue that somehow contains all the basic elements of the bioethical debate and brings to the fore the question of the *identity of the embryo*.

When it comes to ethics, people always think of cages inside which the freedom of decision is closed, while instead it has the sole task of guiding the freedom, of describing a space within men can properly exercise their freedom.

Assisted fertilization falls into one of these spaces of freedom. The desire to have children for a couple, in fact, more and more often conflicts with the inability to generate in a natural way. To solve this problem that is affecting an increasing number of couples, we may resort to the use of assisted reproductive technology of homologous and heterologous type <sup>7</sup>.

In the case of heterologous filiation there could be some problems which are not easily resolvable, within the fundamental rights of the person, affecting both the unborn child that the donors. In fact, as stated by senior figures in the legal and ethical field, we can

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For heterologous fertilization there are rulings on the nature of judgments, judgments, ordinances,. On the subject of heterologous fertilization there is a jurisprudential issue still not resolved as a result of some judgments of 2010 in some Member States.



not neglect all the risks and abuses that may arise when you choose the path of heterologous fertilization, because it can easily lead to slip towards the forms of eugenic

<sup>8</sup>  
choice .

The risks arise particularly if the gamete or the egg comes from a country or from collection centers which are unscrupulous and that select certain genetic characteristics,

<sup>9</sup>  
operating a selective choice of eugenic type .

One must also ask a further dramatic question, namely what will happen to the born from heterologous fertilization, when there might be the need from the point of view of health and development, to know the genetic profile of the parents (DNA, inherited diseases, genetic predisposition to certain health risks). And yet, when faced with a situation of differences of treatment of donor data from country to country, there is the risk of anomalous and absurd situations of contrast or subterfuge with eugenic purposes, although condemned by all.

Similarly when it comes to admit the filiation of purpose, you might get to produce a degeneration of the filiation with the aim of generating an individual by genetic

<sup>10</sup>  
characters of a previous child who requires transplants .

The management of the centers that provide this type of service requires in fact, proper governance, responding to requirements of quality and safety for patients who have

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The prohibition of eugenic practices, in particular those aiming at the selection of the people is confirmed by Art. 3, paragraph 2, of the Charter of Fundamental Rights of the European Union (2010 / C 83/02), formerly known as Nice Charter.

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There is no explicit prohibition to eugenics in the Convention of 1950 (instead, it exists in the Nice Charter), and the court says that to avoid eugenics it is not necessary to prohibit the heterologous procreation, but it is sufficient that it is practiced by medical specialists with their professionalism and their ethics. The court puts his trust in the medical profession, although in the past it was this class to study and develop eugenics.

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There is a significant sensitivity of the American Cinematography, certainly not inclined to ethical profiles, that on social and psychological aspect it has had the opportunity to highlight a number of doubts and confusion on the discomfort and the risk of the situation of children and couples in cases of heterologous fertilization. The reference is to the movie "My Sister's Keeper" with Cameron Diaz, the episode "Who is your father" series dr. House, the film "Two hearts and a test tube" with Jennifer Aniston and "The Back-Up Plan" with Jennifer Lopez.



access to, and at the same time takes into account the national legislation and the legal, ethical and scientific problems that this type of technology continually arises. The European standards, along with recent judgments of the Court, require an adjustment in the organization of MAR in all Member States or Associated States.

It is also necessary that MAR centers adapt to European standards governing the quality, safety and traceability of the cells that are collected, stored and processed in the centers (Directive 23/2004). This will improve the quality and security of the centers MAR, giving greater transparency to the followed procedures also through a more conscious information to couples who will call on.

Nor can we underestimate a true technological explosion that has spread over the last few decades, both in the field of life sciences and in the field of clinical medicine. Technological progress, if it has increased considerably our diagnostic and therapeutic possibilities, it has increased in an unpredictable way the moral responsibilities of health personnel which is more and more often in the situation of having to answer the question whether it is morally permissible to act in what has become technically possible. The natural consequence of technological progress has therefore been the broadening of the concept of medical ethics.

It was born with the medicine itself that has been and always will be a moral enterprise. But, at some point, medical ethics has prepared the ground for the construction of more general ethics, the bioethics, which "designates a much more inclusive universe than the one represented by the realm of medicine." Medical ethics has thus lost its position of main character and has become a chapter, albeit very important, of the bioethics.

Paradoxically, the development of bioethics has put a little in the shade the clinical ethics that doctors of two generations ago had learned in the lane from the voice of their

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masters .

The clinical ethics studies the ethical issues concerning the relationships between the various members of the hospital medical teams and their relationship with the patient, and especially the problems and ethical dilemmas that emerge in the course of diagnosis and treatment of individual patients. These problems and dilemmas require medical attention in order to be solved.



Therefore we can define bioethics, as the science that governs human behavior in the field of human life and health; driven by universal values and moral principles. The moral value is the human being itself, and therefore an objective and knowable asset.

The field of bioethics includes, therefore, not only the discussion of issues related to recent progress in biology - such as in vitro fertilization and genetic engineering - but also embraces the traditional themes of medical ethics, such as abortion, sterilization, euthanasia, drug testing, patient's consent, etc..

The ethical aspect has value because modern man is likely to be a victim of vertigo omnipotence. For this reason we feel the essential need to combine the technique with ethics, namely technological action with ethical action. The utility to recall the meaning that we gather from the Prometheus Bound, brilliant tragedy by Aeschylus, metaphor of scientific culture, in which it is represented the illusion of demigod who challenges Zeus in compassion for men, believing that this would help them to get self-consciousness and self-determination, is as current as ever.

## **The rules on Medically Assisted Procreation**

The birth, meaning the separation of the mother's body from that of the child, has been considered the appropriate stage of biological evolution, for the right, to determine the time of the creation of the legal person.

The legal concept of person arises therefore from this biological fact, which can be considered the determining step of the process of evolution. The beginning of biological life, then, is not the beginning of the legal life which instead begins with birth. The cycle that leads to the gradual development of the human body is an obvious fact for biological science: it has been important on moral, philosophical and theological point, where it has been seen the principle of creation of the human being. The problem arises because the legal system pays special attention to this point because it contains the distinction of the recognition of individual rights and of legal capacity.



The different disciplines, from law to theology, from biology to morality have tried, over the decades, to offer their point of view in a strongly dialectic key.

### **The regulatory framework in Italy**

The law on medically assisted procreation (MAP) was finally approved by the House, on February 10, 2004 by secret ballot by 277 MPs in favor, 222 against, 3 abstentions. The law was subsequently enacted on February 19, 2004 under no. 40.

The new legislation instantly has become the subject of much criticism because, in the view of its critics, rather than trying to mediate between the position of the Catholics and the aspirations of the scientific world, it poses a series of prohibitions that may hinder either some branches of research, or the desire for parenthood.

The embryo, therefore, is not treated as a simple mass of cells, but as a subject of law. The acceptance of this ethical principle in the legal rules, however, comes into conflict with the demands of scientific research, to push the opponents of the law to promote a referendum to change it. Not having the necessary quorum, the referendum was not able to amend the law. Therefore, although contested by the public opinion, it's still in force retaining the text and the original framework.

Let us see what are the most controversial aspects:

a)The new discipline is based on the principle of allowing medically assisted fertilization, banning all those techniques that, using elements which are foreign to the applicant couple, may determine in future uncertainties on the attribution of paternity or maternity. We should remember that for the Civil Code, mother is the one who gives birth to a child, and father is presumed to be her husband. But when a woman receives in her womb the semen of a donor, or fertilized embryos of another couple, the fact is that the natural father and mother are not parents from the genetic point of view, due to the intervention of a third party in the reproductive process. To avoid the problems that may arise in these situations, the Law 40/2004 allows only the homologous fertilization, that is the one implemented with genetic material from the same couple who requests it; it prohibits, conversely, the heterologous fertilization, in which you use the genetic material from a donor outside the couple, that should remain anonymous. It is also



prohibited surrogacy, which is the conception of a child on behalf of others, through the mode of "surrogate mother."

b)The law is concerned then to identify the beneficiaries of medically assisted fertilization treatments, in order to avoid that this can lead to situations which are contrary to nature, like that of the child who is born from a very old mother (the so-called mothers-grandmothers) or from a couple where both parents are of the same sex, or frozen semen of a parent already dead at the time of conception. Techniques of artificial fertilization are therefore permitted only to couples of different sex and of potentially childbearing age, whose applicants are both living. In this way we exclude same-sex couples and the phenomenon of the so-called mothers-grandmothers is avoided. It also avoided that, being generated from the semen of a deceased donor, a child conceived in vitro may be an orphan at birth. Assisted fertilization can still use not only married couples, but also unmarried life partners;

c)The most important and controversial part of the law is that which refers to the rights of the embryo. Before the law 40/2004, the embryos were considered as mere clusters of cells. Therefore, they could be produced in large quantities to increase the chances of obtaining a pregnancy; once this was achieved, the embryos were destroyed or frozen and stored for research purposes (embryonic stem). The Article 1 of the new law sets certain limits to these possibilities, and in reception of calls from the Catholic world, it introduces a kind of subjectivity of the embryo. This legal recognition of the dignity of the embryo, however, involves a number of limitations, both with regard to medically assisted reproduction and in regard to the methods of scientific research. The law 40, in fact, provides that one can not produce more than three embryos at a time, and that the same should be immediately implanted in the woman. In this way we avoid the production of surplus embryos to be used for scientific research, but they also reduce the chances of getting pregnant with assisted reproduction treatments. Always as a consequence of the subjectivity of the embryo, it is also prohibited: cloning, genetic selection, selective abortion, manipulation and experimentation.

Of course, the law on a sensitive subject such as the one of assisted reproduction is object of a political debate which reflects the cultural orientations of a certain people in a certain age. The law 40, like it or not, reflects the sensitivity of a country such as Italy today, which is a laic state, but composed of a mainly Catholic population; therefore it



has formulated its own legislation not being regardless of the ethical problems but rather considering them with great attention to the search for solutions that balance the needs of scientific research and the natural desire for parenthood with the rights of the embryo, and therefore with the dignity of life. Just because legislative solutions are the result of a cultural perspective, they may be different from State to State.

The Italian civil law, article 1 of the Civil Code, states that the subject acquires the general legal ability only at birth<sup>12</sup>.

The theme of the embryo and its compatibility with the legal system have produced the Law of 19 February 2004, nr. 40 that gives "Rules on medically assisted procreation." The article 1 states: "In order to facilitate the solution of problems arising from the human reproductive sterility or infertility the use of medically assisted procreation is allowed, under the conditions and in the manner prescribed by this law, which ensures the rights of all, including the unborn". After more than forty years of conflict, the law 40 has marked a milestone, but not an end to the controversy. The analysis of the law highlights the difficulty of finding a unified inspiration in the specification of the various problems associated with assisted fertilization<sup>13</sup>. The position which is strongly protective towards the embryo, in practice, has shown the incompatibility with the needs of couples that for different reasons, want to resort to assisted fertilization. In the law there are numerous articles devoted to the discipline of the protection of the unborn: besides article 1 which outlines the aims, art. 8 outlines the legal status of the born, while Article 13, paragraphs 1, 2, 3, 4, 5, expresses in relation to embryo

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12

The constitutionality of article 1 of the Italian Civil Code" has been questioned in its relation to article 2 of the Constitution that states "The Republic recognizes and guarantees the inviolable rights of man, both as an individual, and in social formations in which he expresses his personality, and demands the fulfillment of the mandatory duties of political, economic and social solidarity": thus, Traverso, E. The right of the unborn child, known to Trib.Roma, April 12, 1977. In: Riv.it.prev.soc., 1979, p.966, for which article 1 c.c. would set an illegitimate general principle that breaks the link between the human dignity of every human being and legal capacity.

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P. Stanzione, G. Sciancalepore (Eds.), Assisted Reproduction. Commentary on the Law of 19 February 2004 n.4, Giuffrè, Milan, 2004, p. XIII. The authors refer to the issues of health of the person and, more generally, of the couple, individual freedom with regard to reproductive choices, freedom of scientific research, the autonomy of the medical practice.



experimentation and art. 14 (paragraphs 1, 2, 3, 4, 5, 6, 7, 8, 9) sets limits to the application of the techniques on embryos. With regard to the protection of the interests of couples who rely on medical support to arrive to procreation, Law 40/2004 reiterates that the use of artificial insemination is permitted only as "solution of reproductive problems caused by human sterility or infertility" (Art. 1, 4, 5, 6): in other words, the use of assisted reproduction has a residual nature in the sense that it could be used only if there are no other therapeutic measures to remove the causes of sterility or infertility. It seems quite evident the principle at the base of the many prohibitions in the law 40/2004 (the prohibition of heterologous fertilization, of experimentation on embryos, of cryopreservation of embryos etc.), which is the need to protect always the priority interest of the conceived and the embryo. The strong protection afforded to the embryo seems to entail the sacrifice of other interests - that of the mother - and of other legally relevant subjective situations: the potentiality of life of the embryo prevails over the right of health of women, over her freedom of self-determination in regard to reproductive choices, takes precedence over the professionalism of the doctor, who is forced by the law to advise his patients, with misconduct in terms of ethics, cycles of hormonal stimulation which he knows to be harmful to their health, outweighs the interests of the patients destined to certain death because all forms of experimentation

14

that involves the use of embryos is not allowed . It seems necessary to ask whether it is permissible to provide the embryo such protection and guarantees that involve serious consequences for a wide range of subjects. And we must also ask how the embryo is to be considered, which is its legal status: the construction of a legal status based on the law n.40, in essence, shows how the embryo is more protected than the conceived, that acquires rights only at its birth, and more than the fetus, because the fetus can be suppressed if the conditions for the application of the law on abortion can be applied. But as conceived, embryo and fetus always refer to the same "person", that is to the same person that, once conceived and developed in the fetus, then it could come to light, this discipline offers differentiated protections according to the age and stage of development, in addition to the fact that creates a legal status, superior to the embryo

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The Charter of Fundamental Rights (Nice Charter) puts the individual at the center of Community law. For more details, please refer to the text in the OJ series C 364 of 18 December 2000.



and inferior to the fetus. Hence its conflict - also - with the discipline of abortion dictated by Law 22 May 1978 no. 194.

The role of genetics - as well as being one of the most modern branches of medical science - is to treat, in a more refined way, the mass of genetic information contained in the human body: having reached such importance so quickly leaves no time to category and public institutions to support it with appropriate regulation.

The deciphering of the complete genetic code of the human genome in 1999 seems to have opened a "Pandora's vase", allowing new applications of science and opening research perspectives to the reflection of the jurist. An example is the uses of genetic investigations in the field of criminal justice or in the civil one, in relation to the recognition or non-recognition of children, or even concerning insurance.

The idea of "liberal genetics" meant as indifferent approach to the rules, produces concern about the possible consequences from the practical point of view: for example, those practices which refer to the discretion of the parents, the intervention on the genome of the fertilized ovules, affecting a natural assumption for the conscience of the person who wants to act in an independent and responsible way.

In other words, people may no longer be considered as the authors of their own life story.

The issue of pre-implantation diagnosis raises questions on how to design interventions to genetics and is one of the most "sensitive" and controversial topics of the entire law 40/2004. There are in fact competing rights and interests which are not always easy to assemble; the right to health of the woman as the unborn, the right to self-determination of the intended parents in decisions that affect the private and family life, the necessary protection that must be afforded to the embryo, and not least the difficult configurability of a "right to procreate." The legislator, however, perhaps moved by the difficulty of finding a full reconciliation of interests, has avoided taking a position.

As for the arguments of an ethical nature, the main objection that is raised about the eligibility of pre-implantation diagnosis, consists in its use for the purpose of eugenic selection. Despite the persistence of a distinction between positive eugenics and negative eugenics, the Italian legal system is particularly strict prohibiting eugenic practices: in addition to the already mentioned provisions of medically assisted



procreation that expressly prohibit "any form of selection with eugenic purpose of embryos and gametes" (Art. 13), Law no. 194/1978 contemplates that the voluntary interruption of pregnancy can take place only for the purpose of protection of physical and mental health of the woman (Articles 4 and 6), since there is no possibility in Italy for eugenic abortion. In light of these preliminary considerations, the issue has to be analyzed, which is highly controversial both in doctrine and in jurisprudence, relating to the inclusion or not of pre-implantation diagnosis between the practices of eugenic type, and therefore illegal, or it has to be considered as one of the many diagnostic tests with cognitive aims, which the woman undergoes that leads to a program of artificial insemination. Since, as we shall see, this response is not provided by the analysis of normative data, it is in the lines of the many judicial decisions on the subject, in the "living law", that we will need to make the terms of the issue.

The multiple interventions on the Law no.40 they have produced, in fact, an emptying: total couples suffering from infertility have been forced to assert their rights to go to court, resulting in a slow removal of its borders from what was his original formulation.

The different pronouncements of jurisprudence which have been issued in recent years, give an account of an "interpretative" evolution which has led the Court to gradually move away from the letter of a law in which there are a few contradictions and logical traps.

With the D.Leg. of November 6, 2007. 191 implementing Directive 2004/23

D.Leg. of 16 January 2010 no. 16 implementing Directive 2006/17

D. leg. Of 30 May 2012 n. 85 amending and supplementing Decree n.16/2012 implementing Directive 2006/17 and 2006/86

Ministerial Decree of 10 October 2012 concerning the "procedures for the export of tissues, cells and human reproductive cells intended for human application.

An interesting fact is the distribution on the Italian territory of the centers of medically assisted procreation and the differentiation between public, private and agreed upon centers.



In fact, of these about 36.4% are public centers, 18.2% is accredited private, while 45.4% is private. Looking at the number of centers, a very uneven distribution on the territory is highlighted.

#### Authorized Centers

Abruzzo	6	Friuli Venezia G.	5	Molise	0	Toscana	23
Basilicata	2	Lazio	51	Piemonte	25	Trentino A. A.	7
Calabria	9	Liguria	6	Puglia	13	Umbria	2
Campania	40	Lombardia	60	Sardegna	4	Valle d'Aosta	1
Emilia Romagna	18	Marche	4	Sicilia	37	Veneto	37

#### The regulatory framework in Slovenia

#### The regulatory framework in Bosnia and Herzegovina

#### The regulatory framework in Croatia

#### The regulatory framework in Albania



## **Part Three: The policies of the European Union**



## The evolution of health policy from the establishing Treaty to the revision of Lisbon

At this point, after having defined the subject of the investigation, it is appropriate to describe the Community law and the legal aspects governing the matter. This is also because the jungle of EU rules is growing luxuriant. In addition to the treaties, in fact, the associated and members States must take into account the regulations that come into force immediately, directives that provide for a time of transposition of about two years and then the adjustment of national standards. In this maze made up of different levels of authority it is not easy to disentangle. For this reason, since the construction phase of the project, it has been considered useful to develop an overall picture of the basic principles and the main EU regulations in the field of medically assisted procreation and its historical evolution. During processing, however, it was decided to extend the analysis to a contiguous range of issues such as fundamental rights. This is not only because the rules on assisted reproduction are part of a system of "multi-level protection" but also because many sentences with the subject of medically assisted fertilization techniques are based on regulations about fundamental rights.

The Treaty of Rome does not contain any provision of general or specific nature relating to fundamental rights. Only since the sixties, the Court makes a control of the legality of acts including respect for fundamental rights that stemmed from the common constitutional traditions, from the international agreements in force and from the enunciation of general principles of law .

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The first encoding is found in the Maastricht Treaty:

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The European Convention of Human Rights (ECHR) was born within the context of the Council of Europe, which should not be confused with the similar sounding Community institution, an international organization that brings together 47 countries, including all EU countries and almost all those in Eastern Europe. Opened for signature in Rome on 4 November 1950 the ECHR came into force in Italy, with the ratification of the Law of 4 August 1955, n. 848. The Convention establishes a number of civil and political rights and freedoms, establishing at the same time a system designed to ensure compliance by States Parties with their obligations; in this last respect, the establishment in 1959 of the European Court of Human Rights, based in Strasbourg, has centralized the monitoring of such compliance.



1.The European Union is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the rule of law, principles which are common to the Member States;

2.The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950 and as they result from the common constitutional traditions of the Member States, as general principles of Community law.

In particular, with the subsequent Nice Charter, proclaimed in December 2000 by the Presidents of the Council, by the Parliament and the Commission, the Convention becomes binding due to the Article 6 paragraph 1 of the EU Treaty signed in Lisbon in 2009<sup>16</sup> .

Despite the prevailing general silence that has characterized the entry into force of the Treaty of Lisbon, signed by 27 member states in an attempt to remedy the overt failure of the project for a European Constitution, it should be noted that there are many points of interest, among them the not at all irrelevant topic as the one of the protection of fundamental rights<sup>17</sup> .

For what specifically concerns the position of the fundamental rights protected under the European Convention for the Protection of Human Rights, the first data that catches the eye, reading the text of the Treaty on European Union, is the explicit reference carried out in art. 6, paragraph 2. In this article, in fact, it is established the membership of the European Union to the conventional system of protection of human rights, subjecting all the law of the Union to the respect of fundamental freedoms and its control by the Strasbourg Court. In addition, it is established that they are part of the Union's law as general principles. In other words, with an ugly expression, we can say

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With this article, the EU recognizes the rights, freedoms and principles enshrined in the Charter of Fundamental Rights of 7 December 2007 in Strasbourg.

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The Treaty of Lisbon is a "deconstitutional" treaty, in fact it was conceived in the wake of the now abandoned Constitutional Treaty, which incorporates almost all of the content, but excluding those items considered "constitutional", in fact in this spirit the mandate for the Intergovernmental Conference says in a peremptory manner that "the constitutional project is abandoned." To this end are deleted, in an almost "maniacal" way, all the terminology referred to the word "constitution."



that the Treaty of Lisbon has institutionalized the principles of the ECHR, which, incidentally, although with quite a few problems of interpretation, had already been placed in numerous judgments of the Court of Justice.

The importance of this article is related to the recognition of the Charter, although it an external source to the system of the EU sources, not only to its binding legal force but also of the legal value of the Treaties, that is the primary source of the Union, recognizing the value of treaty law to a source that is not really a treaty.

Another important novelty is represented by art. 6, par. 2 of the Treaty that states the membership of the Economic Union to the European Convention on Human Rights and Fundamental Freedoms of 1950 and also on this occasion it is reiterated the notion that this provision does not extend in any way the competences of the EU .

The Accession Agreement shall guarantee that the specific characteristics of the Union and Union law should be preserved. From a specifically procedural point of view, the accession to the ECHR is mentioned in art. 218 TFEU concerning the rules on the conclusion of agreements by the Union and provides an aggravated procedure comparing the ordinary one. In fact, for accession to the ECHR, the European Parliament is expected to have previously approved the proposal and that it is not only consulted in advance, that the Council deliberates unanimously (not at majority) and that there is also the prior approval of the Member States. This choice is the willingness to engage in a more incisive way the European Parliament, in order to ensure more democracy to the accession to ECHR and therefore the legitimacy of the popular will<sup>18</sup> .

From this analysis of the protection of fundamental rights, following the entry into force of the Lisbon Treaty, we would deduct an optimistic consideration. The new dimension of the human rights enshrined in the Treaty of Lisbon will provide better protection to individuals, precisely because of the possibility of intervention of several courts that will provide protection to ensure a subsidiary of rights.

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The EU's accession to the ECHR is the right conclusion of a process very rights of man as understood by the Court of Justice and the protection of the European Court of Human Rights later ECHR). As a result, therefore, that accession to the ECHR will be competent to carry out a check on subsidiary protection of the fundamental rights as guaranteed within the EU legal order. This will be done by the State acts for the implementation of Union law, to implementing acts and for the acts of the institutions.



Having made these aims theirs, the last step for the realization of the European Union has been marked, whose basis were laid down in the Treaty of Rome that introduced fundamental concepts such as the economic and social cohesion. This has also allowed EU action, despite the historical reluctance of Member States, to make a quantum leap in view of a as better integration as possible, not only based on economic aspects, as in the past, but also by introducing as essential factors also the political and social ones.

In reality, however, the basis for a European strategy for active labor market policies and social protection have been strengthened by the Single Act by which the Commission has established a process of turning of Community social policy with the transfer of some national powers in Brussels. The ratification of the revision of the Treaty has enabled us to remove the restrictions based on nationality, allowing residents of a Member State to seek work freely within the EU. Similarly it was also guaranteed, in accordance with Articles 39 and 42 of the Treaty, to migrant workers and their families the access to social benefits and professional training, as well as all the fiscal and social advantages of the resident workers. In addition, the freelance professions have been the subject of legislation that has harmonized, by means of directives, the conditions for access to regulated professions.

The act by which for the first time the Commission places on the carpet the reflection on labor policies is the White Paper on growth, development and employment with which the Member States were invited to the front of the severe employment situation to abandon the traditional assistance to the unemployed with active interventions to promote access to, or re-entry into the world of work .

In subsequent years, the Treaty of Amsterdam marked another break from previous policies, taking a further step forward in the management of European social policy, namely promoting a strong action of consolidation of fundamental rights and the extension of the principle of non-discrimination, until then applied to nationality, sex, race, religion, age and sexual orientation, strengthening it especially on gender equality.

The theoretical assumption underpinning the White Paper's proposals are based on the claim that the labor market is not without flaws but rather, in the long run tends to underestimate the need for adaptation to change, especially in technology, for the weaker sections of society and this policy must activate certain mechanisms of collective solidarity.



The Treaty, in fact, was provided with an entire chapter (VIII), whose articles (125-130) stated both objectives and how to achieve them<sup>20</sup>. Considering the concurrent competence the Treaty has classified the subjects according to relevant authority as follows:

- to the Council (by qualified majority) safety and health of workers, working conditions, integration of people excluded from the labor market, information and consultation of workers, equal opportunities of gender;
- to the Council (unanimously) social security and protection of workers, contractual protection, representation and collective defense of the interests of workers and employers, conditions of employment for third-country people working in the Member States, financial subsidies to promote employment and to create new jobs;
- to the Member States pay and right of association and strike.

The Treaty has also defined the four pillars (employability, entrepreneurship, adaptability and equal opportunities) on which joint EU policies by establishing guidelines that sought to translate into concrete measures and on which the Member States have been asked to take action.

This action has had its official consecration with the publication of the first *Social policy agenda* with which, in addition to ensuring coordination between the policies as directed by the Cardiff process, certain sanctions have been introduced directed to suspend the rights of the member State that violates the fundamental rights<sup>21</sup>.

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The Treaty recognizes the Council the task of setting guidelines that the United States must follow in their employment policies and the latter is obliged to report annually on the measures taken to give effect to their policies for the sector.

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In June 1999, on the occasion of the Cologne European Council it was felt that it was appropriate to bring together in a Charter of the fundamental rights enshrined in the European Union. The Charter, drawn up by a Convention composed of representatives of the Heads of State and Government of Member States, a representative of the Prime Minister, members of the European Parliament and national parliaments, was adopted at the Nice Conference the following year with a preamble which read: "it is necessary, making them more visible in a Charter, to strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments." On this issue, see the Communication from the Commission to the Council and the European Parliament COM (2000) 379 final. of 28 June 2000.



In order to promote dialogue among the social partners and promote the development of human resources to ensure a high level of employment, as well as to facilitate the process of inclusion, the Commission has given a new impetus to the promotion of the social dimension of the EU policy with a new Agenda of fundamental rights, the purpose of which was to build a true European labor market.

The new "charter" has formalized the synthesis of the values shared by the Member States and met for the first time in a single text, the classic civil and political rights and the economic and social rights.

The Agenda 2005-2010, consisting of 54 articles, has been divided into seven chapters:

-Chapter I: Dignity (human, right to life and integrity of the person, prohibition of torture or degrading treatment, prohibition of forced labor)

-Chapter II: Freedoms (right to liberty, security, privacy, protection of personal data, of thought, conscience and religion, expression and association, right to education, right to property and freedom of enterprise, asylum);

-Chapter III: Equality (in front of the law, non-discrimination, cultural, religious and linguistic differences, gender equality, children's rights, of elderly and disabled);

-Chapter IV: Solidarity (rights of workers and company, right to negotiation and collective action, protection in the event of unjustified dismissal, fair working conditions, prohibition of child labor and exploitation of young people, safety and welfare, protection of health, environmental protection and consumer protection);

-Chapter V: Citizenship (right to vote and to stand for election, right to good administration, right of access to documents, freedom of movement);

-Chapter VI: Justice (law and an effective and impartial justice, presumption of innocence, principle of proportionality of punishment in relation to crimes, right not to be tried and punished twice for the same crime);

-Chapter VII: General Provisions.

In recent years, as part of the process of European integration, the social dimension has gradually developed, both as a consequence to the monetary integration and as the development of certain policies aimed at implementing the principle of social cohesion, as a founding objective of the European social policy.



After almost three decades in the Single Act the question that many still continue to ask is whether the European Union that is being built belongs to peoples or to merchants. As many have pointed out the construction of the Community was born out of a political vision, the one of the founding fathers, concerned above all to create the conditions that would make it impossible to return to the wars that had bloodied the continent during the previous century. But by choosing the path of efficiency and determined to lay the foundations for a solid construction, the promoters of the community took a more pragmatic approach: the common market, the common agricultural policy and the preservation of the principles of free competition and health. In this way, over the years an archetype of a technocratic Europe has been built, whose governance has been set by officials even if the initial project would never have been realized had it not been also supported by a clear political will, albeit conditioned by many national egos.

We also can not forget that with the reforms to the Treaty of Rome, European legislators have worked to give content to many social provisions such as free movement of workers, health protection, vocational training and harmonization of social systems.

The global crisis of recent years, together with the slowdown in the growth of the European Union, preludes, in the absence of social rules and a concrete action on the reduction of the gap in the development of the territories, a progressive worsening of the factors of destabilization. The greater welfare, the gradually lengthening of life of the people and, consequently, the change in the traditional family structure, the evolution of demographic trends, the realization of a social reality based on gender equality and on new forms of mobility and diversity, modern needs of the labor market and social protection, may in fact affect certain social risks that would lead to a reduction in welfare. They can then generate a less latent sense of insecurity and isolation, as well as increase the feeling of injustice, inequality and concern for the future of the next generations.

The realization that the opportunities and the risks of these changes are not distributed evenly among the population, but focus on specific groups depending on whether they are more prepared to reap the benefits or suffer the uncertainties of the acceleration of changes, requires interventions that, recovering the values that have helped to found the



modern society, delineate forms of solidarity that enable local communities to face the new challenges in a coherent way.

As well evidenced by the work of the Commission, throughout the European Union is taking shape a new social vision meant to increase the welfare, coping with the many risks that the Member States must deal with.

Even with a diversified approach the Commission has taken to the center of the new community vision this approach in order to achieve an ever wider distribution of opportunities for success within the Member States, by facilitating access to resources and services to the citizens according to the principle of solidarity<sup>22</sup>.

In this context, in which the macroeconomic policies are outlined the Commission develops individual strategies, albeit coordinated, of social policy. In order to give an order to the lines of Community intervention, policies in the social field are grouped into three distinct areas. In the first one are cataloged the principal regulations specifically aiming to strengthen the system of protection of fundamental rights within the European Union and to promote an inclusive Europe, the second one includes balance health policies and the third one rules in the field of medically assisted procreation (MAR).

### *Fundamental principles*

The establishing Treaty of the European Community (TEC)

Article 13 TEC - Fight against all forms of discrimination

Article 153 § 1 letter. The TFEU - Equal opportunities in the labor market and in the treatment in the workplace

Article 157 TFEU - Application of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation, including the principle of equal pay

Article 142 TEC - Equivalence holiday schemes pay

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See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Opportunities, access and solidarity: towards a new social vision for Europe for the twenty-first century" in COM (2007) 726 def. of 20 November 2007.



Charter of Fundamental Rights of the European Union (Nice, 2000)

Article 21 - Non-discrimination

Article 23 - Equality between men and women

Community Charter of the Fundamental Social Rights of Workers (Strasbourg, 1989)

European Social Charter of the Council of Europe

Major European acts: Regulations and directives

Regulation (EC) No 806/2004 of the European Parliament and of the Council of 21 April 2004 on the promotion of gender equality in the development cooperation

Regulation (EC) No 1922/2006 of the European Parliament and of the Council of 20 December 2006 establishing a European Institute for Gender Equality

Council Directive 79/7/EEC of 9 December 1978 on the progressive implementation of the principle of equal treatment between men and women in matters of social security

Directive 86/613 / / EEC of 11 December 1986 on the application of the principle of equal treatment between men and women engaged in an activity, including activities in the agricultural sector, and on the protection of motherhood

Directive 92/85 / / EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers who have recently given birth or are breastfeeding

Directive 96/34 / / EC of the Council of 3 June 1996 concerning the framework agreement on parental leave concluded by UNICE, CEEP and the ETUC

Directive 2000/78 / / EC of the Council of 27 November 2000 establishing a general framework for equal treatment in employment and occupation

Directive 2006/54 / / EC of the European Parliament and of the Council of 5 July 2006 on the implementation of the principle of equal opportunities and treatment between men and women in matters of employment and occupation

Directive 2010/41 / / EU of 7 July 2010 on the application of the principle of equal treatment between men and women engaged in an activity and repealing Council Directive 86/613/EEC



Directive 2010/18 / EU / 8 March 2010 implementing the revised Framework Agreement on parental leave concluded by BUSINESSEUROPE, UEAPME, CEEP and ETUC and repealing Directive 96/34/EC

## Health policies

The development of the concept of Europe of the citizen has given a strong impetus to the policy of protection of health. The priority that the Single European Act has assigned to that policy (pursuant to art. 129) was then picked up by a specific article in the TEU (Article 152). Nevertheless, the public health, which remains largely a national responsibility, sees that the European Union plays a subsidiary role, as support to the action of the Member States and help implement coordinate strategies. Some problems related to the field in fact require international responses and consequently a close cooperation between the Member States .

The health policies have been strengthened by the Treaty of Maastricht and, above all, by the Amsterdam one, where the action for the protection of health has taken a leading role to deal with the solution of problems of common interest. The inclusion of a title in the TEU called "Public Health" together with the Article 3 of the Treaty has elevated the protection of health to the rank of objective of EU policies. This has enabled the EU to concentrate on horizontal policies aimed at ensuring information, education, supervision and sanitary training. Community action has also enabled the launch of some global multi-year programs on specific topics of great interest to citizens such as cancer, drug addiction, AIDS and transmissible diseases. As a completion of this framework we should add that the Commission has also taken other forms of intervention in the field of transmissible diseases, in the field of blood transfusion and in that of smoking, as well as in the context of completing the internal market, in order to create legislation in the field of veterinary and phytosanitary controls, or even in the field of biotechnology, through its active support for research activities.



Community action has also emphasized the ability of the Council to adopt measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The importance of the adoption of the measures in the veterinary field and in that of the protection of public health have attributed a role to Parliament that thanks to the co-decision procedure may influence the final draft of the documents.

The new health strategy is defined by the White Paper "Together for Health: A Strategic Approach of the EU in 2008-2013" with which the Commission seeks to enhance a single strategic framework of Community cooperation in areas where it is appropriate for the individual Member States not to act alone. The proposed strategy for the coming years aims to enhance four principles which are: base the action on shared values, consider health one of the most valuable assets, not consider the health policy as the sole and decisive but integrate it with complementary policies (research, environment, regional policy, regulation of pharmaceutical and food industries products, social security and taxation on harmful products), contribute to the health in the world.

Several studies point out that in industrialized countries about a disease in three is due to external factors, of environmental type, including those related to lifestyle. In view of this data the priorities set by the Commission for the period 2004-2010 with the so-called SCALE strategy (Science, a focus on children, Awareness-raising, Legislation and continuous Evaluation, which concerns science, with special attention to children, awareness activities, legislation and continuous assessment) were included in an action plan for the environment and public health. The strategy faces in the specific some environmental factors considered the cause of health problems in children, one of the most vulnerable categories to these factors.

Given that national health services are facing the challenges of demographic change (aging of the population) and rising costs of health care, in 2001 the Commission published a Communication on the future of health care and care for the elderly in an attempt to give some suggestions on how to facilitate access to services for older



segments of the population, on the quality of services and on the financial sustainability of spending on these services .

24

The activities conducted by the Commission on health also affect the more and more frequent risk, due to the high mobility of people and things, that pandemics might spread in the European Union. The sensitivity of the subject has led the Commission to draw up a plan of coordinated action, and through the European Centre for Disease Prevention and Control, to implement a model for the evaluation of current and emerging health threats as well as designing effective systems of monitoring and alarm at Community level.

Considerable emphasis was also given to the Action Plan of the European Union regarding the problems arising from the use of drugs, integrating it with efforts meant to increase measures to combat drug trafficking and the crime related to it, carried out by Community policy in the field of justice.

The EU's action is based on its health strategy, that sets out three ambitious aims for helping people to live longer and in good health:

- promote good health in an aging Europe
- protecting citizens from health threats
- promote dynamic health systems and new technologies.

The EU Program for the health contributes to achieve the objectives of the strategy in order to complement, support and improve the effectiveness of policies and actions of the member countries, especially in the following areas:

- protect and promote health and reduce inequalities in the health field;
- provide more information and knowledge in matters of health;
- strengthen cooperation with stakeholders.

### **Some notes on judgments regarding medically assisted procreation**

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The study on the subject, please refer to the vision of the Communication COM (2001) 723 final. of 5 December 2001 which analyzes the impact of population aging on health care systems is that the costs that they incur.



The Court of Justice with the judgment *Brüstle* posed solution to a delicate question of interpretation of the Directive 98/44/EC on the legal protection of biotechnological inventions<sup>25</sup>.

The questions were resolved primarily through an extensive interpretation of the concept of human embryo, which also includes the "human ovule from fertilization", as well as the "non-fertilized human ovule into which the nucleus has been implanted in a mature human cell" and even any human ovum which is not fertilized that, through parthenogenesis, is induced to divide and develop". In brief, if there is one, even single-cell, where the process of formation of a human being can start, then you are in front of a human embryo, within the meaning and for the purposes of Directive 98/44/EC.

In this regard, the Court, while recognizing that the purpose of scientific research should be distinguished from industrial and commercial purposes, has decided that it can not be effectively separated from the patent application, so it can not allow the inventor to access protection of his work.

Finally, the Community Judge has dedicated to the technical process object of the challenged patent, stating that the prohibition of Directive no. 98/44/EC excludes the patentability of an invention "where the technical teaching object of the patent application, requires the prior destruction of human embryos or their use as base material, whatever the stage at which they take place and even if the description of the technical teaching subject of the claim does not mention the use of human embryos"<sup>26</sup>.

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The question was raised by the Community judicature referral by the Bundesgerichtshof, called to scrutinize appeal in the application by Greenpeace, a non-profit association, for the cancellation of the German patent already held by Mr. *Brüstle*. This patent relates to a method for obtaining, through the treatment of embryonic stem cells, neural progenitor cells isolated and purified, useful in the treatment of neural abnormalities in humans. The medical hypothesis underlying the patent system is that the neural progenitor cells can remedy the neural abnormalities such as Parkinson's disease, a disease for which, according to the file patent, it would have already caused the first clinical applications of the patented technology. The neural progenitor cells, however, exist only in the stage of development of the human brain, which would require the use of brain tissue of human embryos. It is a condition of very high concern for both the ethical problems that arise, requiring the destruction of embryos donors of cells, and the fact that this method "does not allow you to meet the needs of progenitor cells needed to make accessible to the public healing by cell therapy".

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The Court comes to this solution, noting that the patent in question had as its object the treatment of embryonic stem cells, whose taking of a human embryo at the blastocyst



As known, the biomedical research on stem cells is an innovative and promising field for the treatment of serious diseases, often debilitating and degenerative and currently incurable. It is natural, therefore, that the earliest commentators of the judgment have considered this aspect of the problem too. Among them, some have argued that the decision of the Court of Justice would not have a significant impact on scientific research, because the research is not prohibited for the only reason that it does not have the patent protection. The question is relevant because of considerable importance to the economic and financial challenges "related to this field of research and for the" legitimate expectations of those who hope in the progress of science to alleviate their sufferings. "

In other words, the ratio of the judgment remains that the construction of the European common market, which would be put at risk by mechanisms of competition among the different regulations due to the different patent protection consented in the different Member States.

The judgment has provided a broad interpretation of the prohibition on patentability, because:

- ✓the use of embryos aimed at scientific research has been included in the body exploitation (forbidden) of human embryos for industrial or commercial purposes;
- ✓the case of 'human embryo' has been "broadly" interpreted to include every cell from which a human being can develop, including the fertilized human ovum, the unfertilized human ovule in which the nucleus of a mature human cell has been implanted and the non-fertilized human ovule induced to divide and develop through parthenogenesis;
- ✓the notion of "use of human embryos," has been interpreted also incorporating those technical teachings that, while not directly entering the process of extrapolation of a stem cell from the embryo in the patent claim, are part of a procedural "context" which contemplates the destruction of an embryo in order to get an embryonic stem cell.

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stage involves the destruction of the embryo. Even in this case, in fact, there would be a use of human embryos, prohibited by. 6, paragraph 2, letter. c) of dir. n. 98/44/EC, irrespective of whether the fact that the destruction of the embryo takes place "in a previous phase well against the implementation of the invention", as it was in the case of the main proceedings.



The conclusions reached by the judgment Brüstle certainly do not come unexpected. Indeed, the solutions therein indicated are not only a solid connection in positive law, but were also already deployed in law and remarked in doctrine. In a commentary devoted to "ethical boundaries" for the patentability of biotechnological inventions shortly before the decision in question, it has been well noted that Directive 98/44/EC and the implementing regulation of the Convention of Monaco on the European Patent preclude the patenting of inventions concerning embryonic cells, which are obtained through the destruction of the embryo. Neither the exclusion clause can be overcome in the case in which the invention to be patented is "useful to mankind", as the patent on embryonic stem cells is assented "Only When the inventions would be very useful to the embryo Involved in terms of therapy or diagnostics. "

This conclusion can be reached if you consider that the principle of respect for human dignity, placed as lintel of the discipline of the field, has found accomplished and explicit execution in the laws that prevent the patenting of human body at the various stages of its formation and of its development. The principle of respect for human dignity, explicitly referring to the human body and the human embryo, necessarily directs the judge to a broad interpretation of the prohibition on patentability, especially where there are no other regulatory hooks that draw a derogatory area considered suitable by the Community legislature to safeguard and meet the same principle. So much is true both for the qualification of the "human embryo" case, with the extension to each unit cell able to develop a human being, and for the intake of the purposes of scientific research into the concept of "use" of the embryos, and also for the consideration of the technical context which requires the sacrifice of the embryo for the obtaining of an embryonic stem cell. In other words, the path followed by the Court of Justice is obliged, given the regulatory material relevant to the present case.

Obliged, it should be underlined, or at least consistent with the Directive 98/44/EC, was also the framing of the issue in a factual context, not limited to the elements considered in the patent claim of Mr. Brüstle, but extended to the condition for which the technical teaching which industrial property is sought for, requires, as a principle, the destruction of an embryo for the obtaining of the biological material subject of the patent itself.

This is for two reasons. In the first place the assessment of the patent application, having to focus not only on the final product of the technical teaching that you want to



protect, but also on the process from which this product comes, and on the use in terms of industrial utility (medical and pharmaceutical), lends itself to an extension, in the union about its legitimacy, to the circumstantial context in which the same question is located. It is well known that, especially in the field of medical and pharmaceutical patent, the inventor can not invoke the protection of the product (the substance, the composition of substances) without claiming the industrially relevant use, as it would fall in the field of scientific discovery and not of the invention, so that, instead, it is patentable the indication of the first use of a known substance, as well as the next several possible uses of the same substance. In other words, as it has been well described in the literature, "the invention of the product is protectable as a function of the correlation between the product and its use for the satisfaction of a human need." Under Community law, this rule has been (partly) used to reduce to the fullest extent possible the non-patentability of the "living person", of the human body, of genetic information, a fact that was contested by some Member States through the appeal to the Court of Justice pursuant to art. 263 (ex art. 230 TEC) of the Treaty on the Functioning of the European Union and which has been heavily criticized in literature, precisely because it opens the "disturbing" perspective of the patentability of elements isolated from the human body without even allowing a Member State to shift this hypothesis in the list of non-patentable inventions because conflicting with "public order".

From the brief description given so far it would seem that the criterion at the base of the principle of sufficient description can be folded in an ambivalent way by the interpreter in order to fall within or to exclude from the category of patentability of one or the other claims. It must therefore be stated that this criterion, in extreme cases, it is simply serving compared to the solutions timely indicated by the Directive. 98/44/EC. Not for nothing it has been brought to light that it is in the text of the Directive (Articles 3, 4 and 5) which are found the necessary textual hooks that allow derogations based on contextual claim of the product, of the technical process for its creation and of clear signs for the industrial use (category here that needs to be understood as including pharmaceutical use). In the case of the use of embryos, however, the only available textual basis on which, not surprisingly, the Court insists, is the worth of the patent (note how the concept of patent of "use" and not "product" comes back) meant to pursue "therapeutic or diagnostic purposes which are applied and useful to the human embryo."



The usefulness and potential of medical use of embryonic stem cells requires to verify the possibility of a different balance between the protection of the human embryo and the right to scientific research and the protection of health and if traces of it are found in the different legal experiences.

One of these possibilities is to consider that the scientific community has lines of active and replicable embryonic stem cells, usable for medical and therapeutic purposes and scientific research. This means that, while it is true that the patent Brüstle requires the destruction of an embryo for its implementation, it is equally true that this destruction is now verified and made available to the scientist (and to inventors or future users) active cell lines created in a legal manner, and that could well be brought to the attention of a patent office as the origin of the biological material used<sup>27</sup>.

This solution surely shows the due respect for the embryo, which, although it can not be joined, as a subject of law, to the living human person, must be regulated in a consistent manner with the fact that it can develop a human life<sup>28</sup>.

An attempt was made to account for the fact that the non-patentability of technical subjects involving embryos of art. 6, paragraph 2, letter. c) of dir. n. 98/44/EC frustrates the principle of freedom of scientific research (though indirectly, in terms of its promotion), also protected in Community law art. 13 of the Charter of Nice ("The arts

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It is a solution that has already been adopted in many Member States of the European Union and that moves from the realization that supernumerary embryos created for IVF are inevitably destined for cryopreservation and slow decay. Given this premise, the use of surplus embryos for purposes of scientific research related to the development of the ability to treat serious diseases and incurable certainly appears worthy and justified, especially in the face of destruction of the embryo that is inevitable anyway, his "sacrifice" in advance. In other words, the use for high biomedical research purposes is "the lesser of two evils and the approach That blackberries genuinely respects life than thawing and destroying [an embryo]."

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In particular, there is, in this case, the direct production of embryos for scientific research purposes as the embryos would be used only those created for the procedures of assisted fertilization and not more useful for this purpose. Second, the provision of a contribution voluntary, conscious (and therefore in compliance with the precept of informed consent), and free of the embryo exclude the possibility of a manipulation of the human body for profit which is explicitly prohibited by Article. 3, paragraph 2, point 3, of the Charter of Fundamental Rights of the European Union.



and scientific research shall be free. Academic freedom is respected"), and that a different regulation of matter that maintains the same high standard of protection for the embryo is possible. So that there is a doubt of the legitimacy of that same Directive, for infringement of the principle of proportionality, as the rules stated therein are exuberant, within the limits imposed, in relation to the purposes for which it is proposed.

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and human cells

Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for coding, processing, preservation, storage and distribution of human tissues and cells

2012/39/UE Commission Directive of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements relating to the tests carried out on human tissues and cells

The Rules Governing Medicinal Products in the European Union, Brussels, 25 November 2008 (rev.)

### **Access to health care across the EU**

The Schengen agreements, the increase in flows due to higher labor mobility and to an increase in tourism, the process of internationalization asked the Commission also an effort to regulations on the right of assistance to EU citizens and on the financial compensation of health services between Member States. For this purpose, the European health insurance card has been established, which allows to facilitate access to assistance and to facilitate the reimbursement of the incurred expenses.

Generally people prefer to be treated close to home, but sometimes it is easier or just necessary to travel to another EU country, for example, if the nearest health facility is beyond the border or if specialized care is available only abroad.

European legislation (that member countries should implement by 2013) on patients' rights in cross border healthcare will provide clear guidance on the right of European



citizens to seek treatment in another EU country and to be reimbursed. Furthermore, the

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legislation :

- will help national health authorities to cooperate and exchange information on standards of quality and safety for healthcare
- will ensure the recognition of medical prescriptions in all EU countries
- will pave the way for the creation of "European reference networks" to connect their specialized centers and allow experts from across Europe to share best practices in health care.

Another initiative already started some time ago, the European Health Insurance Card on the disease, helps those who are on vacation or traveling on business to obtain health care in another European country in case of illness. Thanks to these measures about 800 million European citizens will be able to choose the state in which they want to be cured: an extra opportunity for couples who want to undergo artificial insemination. In fact, the health service of each member state will then reimburse the services received. The Directive therefore sets the basis for a health service which is really European, or

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rather, as they say in the European capital, for cross-border healthcare .

It is likely that with comparable economies and especially in the border nearest regions, there will be some kind of competition for the best health performances. In theory, to the benefit of citizens. For example, for the timing: in fact the same law provides that if a structure of another Member State is able to ensure a more timely care, taking into account the urgency of the case, the covering of the costs triggers automatically.

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The Health Systems and Policies of the European Union are becoming increasingly interdependent for various reasons: a) patients can receive medical treatment across the EU, b) health professionals working in different EU countries, c) patients expect more from medical d) medical technologies are constantly evolving.

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The Directive, however, specifies that if it is just differences in methods, there is no need for authorization. A statement that seems to throw open a world for couples who for example want to undergo the IVF without having to suffer the restrictions imposed in their country.



## Challenges

Define clear rules and provide reliable information to patients about medical care in another EU country and its repayments: the new "National Contact Points" will work for this purpose.

Meet the needs of patients in terms of quality of medical care, which are even higher in the case of care away from home: thanks to information provided by national contact points on the quality of care and patient safety, the latter can make informed choices before receiving treatment abroad.

Ensure close cooperation between the EU countries in the interest of patients.

Put an end to years of legal uncertainty. The new rules also create the right balance between the sustainability of health systems and the protection of the rights of patients who receive medical care outside of their country of residence.



## **Part Four: The research**



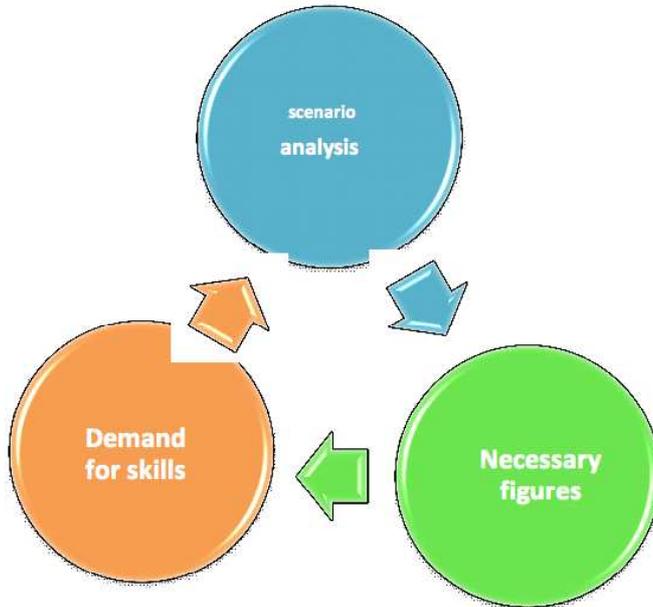
## Procedures and Methods

The problem of infertility has found a new response in assisted reproductive technology. These procedures, however, if on one side they represent the result of a considerable scientific technological development, on the other hand, through a more widespread application, they have made evident the complexity and the spread of the phenomenon of sterility and procreation, and have placed social, psychological, ethical, and above all, legal questions, originating a debate which is still open.

This research is essentially based on highlighting legal aspects. No effort has been devoted in providing undue solutions on major open issues, as highlighted by the European Community legislation, and by the direct input from individual project partners.

As we will see in the analysis that we will develop in the following paragraphs, not all individual national legal systems cover all legislative aspects for the exercise of assisted reproduction. On the other hand, the countries that have legislated regulations, have often created different regulatory frameworks for a specific study (see the following items).

For these reasons we decided to design a comprehensive overview of the different regulatory contexts, in order to propose a training framework aimed at improving (or making consistent) the different legal frameworks.



In the previous chapters we have presented a broad view with the aim to represent some future challenges of our society, where we have tried to represent points of social weakness and of technological strengths.

First we studied social aspects and their influence on the demographics of the areas examined. We have examined both the economic dynamics linked to births and migration. Phenomena which have a natural and decisive influence on other variables which affect the demographic structure of the population. We also examined indices of fertility and with them both socio economic issues and regulations relating to MAR. We were also made some reflections on the ethical aspects of artificial insemination. These aspects require a careful analysis as it regards their scientific, anthropological, legal and ethical dimensions.

Based on these aspects we then divided the research project by highlighting the structural characteristics of health to then define the methodological research. We have defined the survey instrument (questionnaire), we have defined the survey sample (project partners), we have identified reference opinion leaders, we set the questionnaire for interviews with Expert centers. The implementation of the survey was designed through the administration of the questionnaires. The analysis of the question and the answers to the questionnaire have provided us with the necessary information to begin

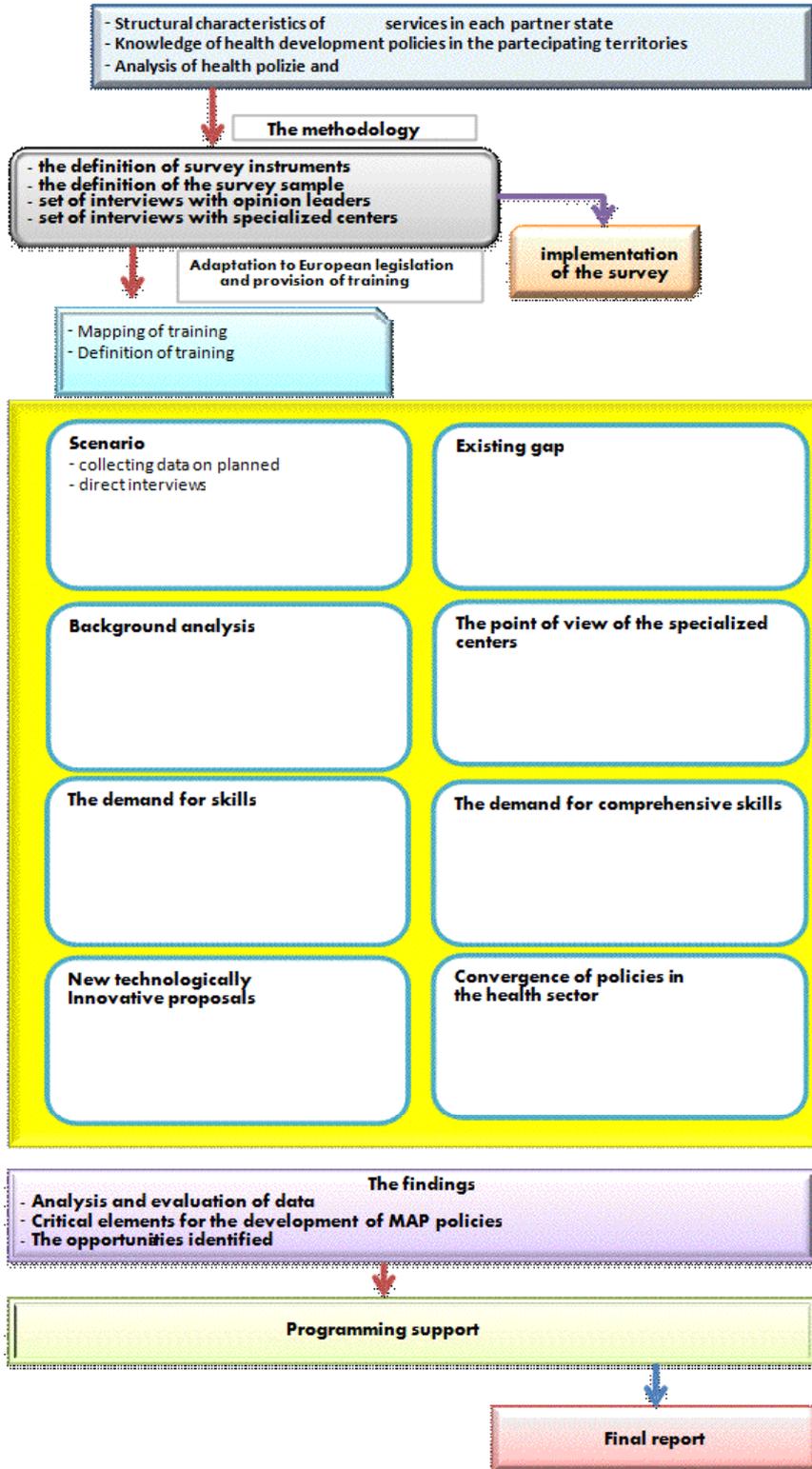


to map out training needs. The mapping also enabled us to define, without going into detail, the training contexts to develop and propose to the parties of the territory. Furthermore, the information that research has revealed, has allowed us to give some guidance for the planning of policies to support the actions of assisted reproduction. We should not underestimate that, as clearly shown by the survey, there are important aspects to consider about the so-called health tourism.

The training and skills development for human resources, are an essential component for the implementation of improvement processes and the management of the stages of change and, in particular, adaptation of national legislation to EU guidelines. However, the training plans that we propose to the Partners do not meet all the needs of individual territories. The study allowed to identify the implicit training needs (legal-administrative area), but also implicit ones related to communication, research and quality improvement. The implicit training requirement is completed with the aspects related to the assessment.



### Flow chart of the research project





## The map of interviews: general information

With regard to the references of EU legislation concerning the activities of Medically Assisted Procreation, a first reference is to the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004, on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>31</sup>.

Reference is also made to the Directive Committee 2006/17/EC of 8 February 2006 implementing previous Directive<sup>32</sup> that regards certain technical requirements for the donation, procurement and testing of human tissues and cells; to the Directive Committee 2006/86/EC that regards the requirements for traceability, reporting relationships and serious adverse events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells<sup>33</sup>; to the Directive Committee 2012/39/UE amending Directive 2006/17/EC, as regards certain technical requirements relating to the tests carried out on human tissues and cells<sup>34</sup>.

The directives are then followed by the "*Guidelines on Medically Assisted Procreation*", published November 25, 2008, relating to indications and methods of procedures and techniques of medically assisted procreation.

The aim of the Guidelines is to provide clear guidance to the operators of the facilities authorized the application of techniques of medically assisted procreation ensuring full compliance with the Directives themselves.

The objective of Directive 2004/23/EC, as stated in the Chapter I (General Provisions) Article 1, if it can not be achieved by the Member States, the Community may adopt measures in accordance with the Principle of Subsidiarity, as implemented in Article 5

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31

See also the Directive published in GU L 102 of 7 april 2004.

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See also the Directive published in GU L 38 of 9 february 2006.

33

See also the Directive published in GU L 294 of 25 december 2006.

34

See also the Directive published in GU L 327 of 27 november 2012.



of the Treaty. Directives also regard defining the scope (Article 2) and set the definitions of terminology as described for the field of application (Article 3).

In Chapter II, however, the Directive describes the obligations of the Member States' authorities on supervision relative to the supply of human tissues and cells (Article 5) in addition to accreditation for institutions and processes for the preparation of tissues and cells (Article 6) and inspection arrangements with the control measures (Article 7). Article 10 provides for the creation instead of Registers in which tissue establishments report the quality of tissues and / or cells procured, preserved, processed, stored. In Chapter III the principles of selection and evaluation of donors are outlined. In Chapter IV provisions concerning the quality and safety of tissues and cells are indicated. Chapter V provides for the codification of information together with forecasts of penalties for infringements of national provisions adopted for the implementation of the contents of the Directive. The articles referred to in Chapter VI describe the technical requirements and their adaptation to scientific and technical progress. Finally, in Chapter VII the final provisions and in particular the terms of implementation of the Directive in the laws of the Member States, the time for the entry into force and the addressees of the Directive are indicated.

Directive 2006/17/EC, which aims to implement the previous Directive, is based on international experience derived from the "*Guide to ensure safety and quality of organs, tissues and cells*" of the Council of Europe. The Directive consists of 9 items, and four annexes beyond that. In the first part, it lists the selection criteria for donors of tissues and / or cells (except for donors of reproductive cells). In the second part, it lists the laboratory tests required for donors while the third part describes the selection criteria of the laboratory tests. In the fourth attachment, it defines the procedures relating to the donation and procurement of tissues and / or cells.

The Directive Committee 2006/86/EC published on 24 October 2006<sup>35</sup> proposes to implement the Directive 2004/23. As provided for in Article 1, the Directive applies to the coding, processing, preservation, storage and distribution of human tissues and cells for human applications and the manufactured products derived from human tissues and

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See also the Directive published in GU L 294 del 25 ottobre 2006.



cells.

The Directive consists of seven annexes, whereby the first two list the requirements for accreditation, designation, authorization or licensing of tissue establishments. In the third and fourth attachment the facsimile for notifications and reports of serious adverse events is reported. In the Fifth Schedule, the pattern of notification and annual reports relating to adverse events is reported.

The Directive 2012/39/UE<sup>36</sup> proposes to modify some aspects of Directive 2006/17/EC, in particular those concerning the technical requirements relating to the tests carried out on human tissues and cells.

Finally, we point out the guidelines published by the Commission on 25 November 2008 (rev) on good manufacturing practice for medicinal products for human use.

### **The findings: context analysis**

In almost all countries the sterility (or infertility) of couples, defined as the inability to conception within two years of reports of deliberate fertilization, shows stable percentages, if not increasing, between 10 and 20% worldwide (14% in Europe), of couples of reproductive age. It is estimated that about 80 million couples in the world are suffering from infertility.

The questionnaire (Slovenian data) shows that the causes of infertility / sterility are attributable to a higher percentage of women who suffer predominantly ovulatory and tubal problems. This also shows that in all countries the average age of conception is higher and the majority of women give birth after 30 years, while the average age of male parents exceeds 40 years.

The diagnosis and treatment of infertility of couples have undergone significant improvements in recent years with significant success. This has been made possible thanks to a body of therapeutic measures defined as MAR, which offered an important solution, unfortunately not all, the high incidence the phenomenon.

The Centers of MAR are spread all over the world, and, especially because of the

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See also the Directive published in GU L 327 del 27 novembre 2012.



change in life styles, they are used more and more often.

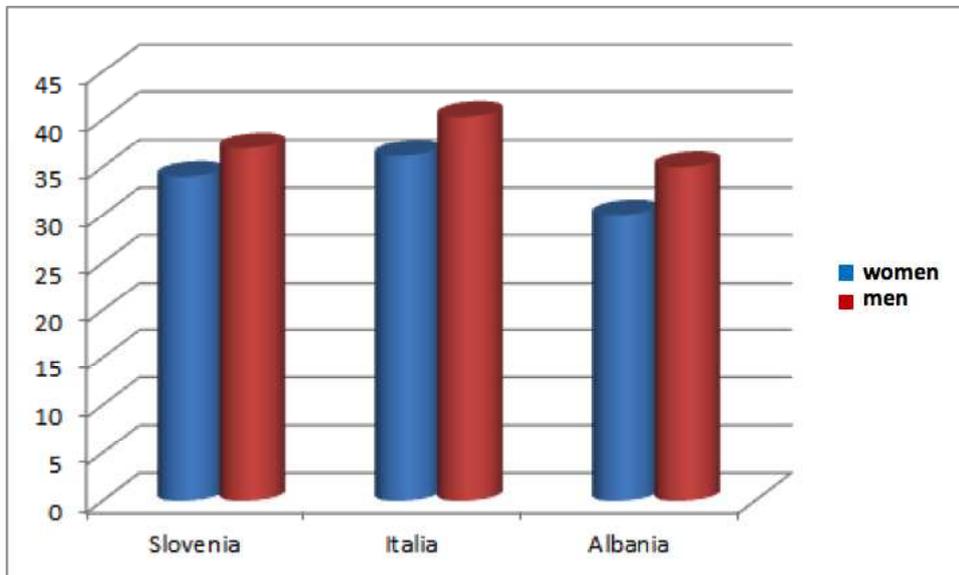
As regards the European situation, the data were taken from the (underestimating) European Register ESHRE 2005 and refer to 30 European countries, which report their activity in MAR<sup>37</sup>.

The analysis of the distribution of the centers of MAR in Europe presents a wide variability, as well as the cycles performed in each of them.

It goes without saying that the number of treatments carried out in European countries where reimbursement of services is expected, is increasing; this is so especially in Eastern European countries.

The average age of patients in the centers of the territories the project partners engaged in a cycle of MAR is 33 years for females and 37 for males.

### Average treatment age



Source: Data questionnaires

Below we analyze the responses to the questionnaire, separately analyzing them by

<sup>37</sup>

The registry guarantees minimal levels of safety for the patients, the donors of gametes, the fetuses, fairness, efficiency and high-standard treatments. Indeed, the new guidelines of the European Society for Human Reproduction and Embryology have set the standards for reproductive care, as based on these principles. These principles also aim at guaranteeing equal treatments for local versus foreign patients.



section and country. We begin with section three on the legislative aspects.

## **ITALY**

An analysis of the legislative aspects shows that in Italy the EU Directives have been adopted by the two legislative provisions D.Leg. 191/2007 and D.Leg. 16/2010. In addition, the questionnaire shows that in 2007 an Authority was created, with jurisdiction over licensing of centers for the Medically Assisted Procreation and inspections. In addition, the legislation provides for the possibility of granting permissions to both the public and private centers.

The state has also provided for the establishment of a register for treatment which is part of the Higher Institute of Health, to which, if you want to operate in the field of medically assisted procreation, it is compulsory to adhere. At least for now, there is no registry for donors.

The register of MAR treatments records specific treatments that we highlight in the table at the end of the section.

## **BOSNIA AND HERZEGOVINA**

The analysis of the legislative aspects shows that in Bosnia and Herzegovina the EU Directives have not been transposed. This involves, on the one hand, the absence of an Authority with jurisdiction over licensing of centers for the Medically Assisted Procreation and inspections, on the other hand the existence, caused by the absence of the authorization, of centers that may not be formally authorized. Both public and private centers can carry out MAR activity.

Among other things, the state has not yet provided for the establishment of a register for treatment in the field of medically assisted procreation, even if there are individual registers such as those of the individual hospitals. There is no register for donors.

As no record of the MAR treatments are possible, no specific treatments are highlighted in the table at the end of section.



**SLOVENIA**



Slovenia in 2007/08, as a Member State has implemented all the EU Directives concerning the Medically Assisted Procreation.

In addition, the questionnaire shows that an Authority was set up with the power of licensing centers for the Medically Assisted Procreation and of performing inspections. In addition, the legislation provides for the possibility to grant permissions only to public centers. Private centres are therefore absent.

The State has not provided for the establishment of a registry for treatment in the field of medically assisted procreation. At the same time, there is no registry for donors.

The registry of MAR treatments records specific treatments, that we highlight in the table at the end of the section

**ALBANIA**

The questionnaire shows that in 2002 Albania has adopted EU Directives on reproductive crops, and has established a competent Authority with jurisdiction over licensing of centers for the Medically Assisted Procreation and inspections. The legislation provides for the possibility to grant permissions only to private centers.

The state has not envisaged the establishment of a registry for treatment for those who want to operate in the field of medically assisted procreation. Registries are provided on a voluntary basis, organized by private clinical centers. At the same time, there is no registry for donors.

The absence of the registry for treatments MAR does not allow to describe, as shown in the table, specific treatments.

<i>List</i>	<i>IT</i>	<i>BO S</i>	<i>SL O</i>	<i>AL B</i>
<b>AID - Artificial insemination Donor sperm NO</b>			X	



<b>AIH - Artificial Insemination Husband sperm</b>			X	
<b>ART - Artificial (Assisted) Reproductive Technology (Treatment)</b>			X	
<b>ED - Embryo Donation</b>				
<b>FET - Frozen Embryo Transfer</b>	X		X	
<b>ICSI - IntraCytoplasmatic Sperm Injection</b>	X		X	
<b>IVF - In Vitro Fertilisation</b>	X		X	
<b>IVM - In Vitro Maturation</b>	X		X	
<b>MESA - Microsurgical Epididymal Sperm Aspiration</b>	X			
<b>NIVF - Natural Cycle In Vitro fertilization</b>	X		X	
<b>OD - Oocyte Donation</b>			X	
<b>PGD - Preimplantation Genetic Diagnosis</b>	X		X	
<b>PGS - Preimplantation Genetic Screening</b>				
<b>SET – Single Embryo Transfer</b>	X		X	
<b>SD – Sperm donation</b>			X	
<b>TESE – Testicular Sperm Extraction</b>	X			

Below we analyze the responses of the fourth section covering the specific legislation on medically assisted reproduction.

## ITALY

The standard specifies that rules on Medically Assisted Procreation are as in the law 40/2004. The state has also issued guidelines on best clinical and laboratory practices.



The techniques considered legal by the law are those listed in the table described at the end of the section. It should also be said that there are no restrictions in access to the MAR treatment.

At the same time it must be said that in Italy there is a national registry for the health of children conceived with techniques MAR. There are specialized departments of advanced care about in vitro fertilization, 74 of which are public and 10 private.

### **BOSNIA AND HERZEGOVINA**

In Bosnia and Herzegovina specific rules about Medically Assisted Procreation have been enacted. At the same time there are some guidelines on best clinical, laboratory and ethical practices.

The techniques considered legal by the law are those listed in the table described at the end of the section. It should also be said that in the country there are restrictions in access to the MAR treatment, such as: couples should be legally married, there is an age limit for women to be treated, there is a maximum number of cycles for immigrant patients.

In Bosnia and Herzegovina there is no national registry for the health of children conceived with MAR techniques, as well as there are no specialized departments of the advanced care inherent in vitro fertilization.

### **SLOVENIA**

In Slovenia there is a specific regulation containing rules on Medically Assisted Procreation, which also includes guidelines on standards.

The techniques considered legal by the law are those listed in the table described at the end of the section. The only limitation in access to MAR treatment, appears to be the decision of the Centre not to allow access to treatment.

At the same time it must be said that patients are expected to remain anonymous, in



order not to track donors and couples undergoing heterologous fertilization. It is also forbidden any kind of compensation for the donation, and the use of gametes / embryos after the death of the donors.

In Slovenia there is no national registry for the health of children conceived with techniques MAR, as well as there are no specialized departments of advanced care about in vitro fertilization.

### **ALBANIA**

In Albania there is a specific regulation, containing rules on Medically Assisted Procreation, which includes biological and clinical practices but does not provide specific guidelines.

The techniques considered legal by the law are those listed in the table described at the end of the section. It should also be said that in the country there are restrictions in access to the MAR treatment, such as: couples should be legally married, there is an age limit for women (50 years old) to be treated, while for men there is no explicit limit, there is a maximum number of cycles for patients outside the EU.

In the country, anonymity aimed at the non-traceability of donors and couples undergoing heterologous fertilization is not expected, while the legislation is not clear concerning the use of gametes / embryos after the death of patients.

In Albania there is no national registry for the health of children conceived with techniques MAR, while there are 2 departments specialized on advanced care about in vitro fertilization.

### **Allowed Procedures**

<i>List</i>	<i>IT</i>	<i>Bo s</i>	<i>SL O</i>	<i>AL B</i>
<b>AID - Artificial insemination Donor</b>			X	X



<b>sperm NO</b>				
<b>AIH - Artificial Insemination Husband sperm</b>	X	X	X	X
<b>ART - Artificial (Assisted) Reproductive Technology (Treatment)</b>	X	X	X	X
<b>ED - Embryo Donation</b>				X
<b>FET - Frozen Embryo Transfer</b>	X	X	X	X
<b>ICSI - IntraCytoplasmic Sperm Injection</b>	X	X	X	X
<b>IVF - In Vitro Fertilisation</b>	X	X	X	X
<b>IVM - In Vitro Maturation</b>	X	X	X	X
<b>MESA - Microsurgical Epididymal Sperm Aspiration</b>	X		X	X
<b>NIVF - Natural Cycle In Vitro fertilization</b>	X	X	X	X
<b>OD - Oocyte Donation</b>			X	X
<b>PGD - Preimplantation Genetic Diagnosis</b>	X		X	X
<b>PGS - Preimplantation Genetic Screening</b>				
<b>SET – Single Embryo Transfer</b>	X	X	X	
<b>SD – Sperm donation</b>			X	X
<b>TESE – Testicular Sperm Extraction</b>	X		X	X
<b>TESE - X Surrogacy</b>	X			X

Below we analyze the responses on the fifth section, as they concern reimbursements for patients who undergo MAR procedures.

## ITALY



In Italy reimbursements for patients who undergo the treatment of medically assisted procreation are not provided. Analogously, patients who undergo the treatment in other countries are not entitled to any refund.

It is allowed to donate eggs, sperm for scientific purposes.

### **BOSNIA AND HERZEGOVINA**

In Bosnia and Herzegovina reimbursements for patients who undergo the treatment of medically assisted procreation are not provided. Analogously, patients who undergo the treatment in other countries are not entitled to any refund.

It is allowed to donate embryos, eggs, sperm for scientific purposes.

### **SLOVENIA**

In Slovenia refund is complete for patients who undergo the treatment of medically assisted procreation, but with some limitations due to the age of the woman, the number of treatments and the number of embryos transplanted. Patients who choose to undergo the treatment in other countries, instead, have the right to reimbursement, only if the treatment is not available in Slovenia.

It is allowed to donate embryos, eggs, sperm for scientific purposes.

### **ALBANIA**

In Albania there is no reimbursement for patients who undergo the treatment of medically assisted procreation. As well as patients who undergo the treatment in other countries are not entitled to any refund.

It should be stressed that the country does not allow any donation, even for scientific purposes.

## **The results: the legislative aspects**

In this section we summarize the legislative aspects within the individual states of origin



of the project partners. The analysis is divided into two parts: the first takes into consideration the adoption of specific rules for the adoption of EU guidelines; the second highlights application aspects that are evident in the area.

With regard to the legal references related to the activities of MAR, we must start by Community legislation, which must be transposed by the Member States.

In this regard, the questionnaire shows a strong differentiation between the different territorial realities. Some of them (Member Countries and Albania) have transposed these directives, even upon making changes. The others, however, while providing specific legislation, have not yet transposed the EU Directives.

### **The results: the professional and training needs**

The content of the questionnaires and the observation of reality confronts us with evidence that individual countries need adequate training processes to enable all partners to meet EU guidelines relating to MAR. In addition, there is a need to explore the themes of regarding the optimal operation of a Centre of MAR, as well as reaching European quality standards (Directive 2004/23/EC). Moreover, it is considered very important to plan for benchmarking seminars between both among project partners and with other European territories with the most advanced legislation.

The training should cover the following professional skills within each Centre:

- ✓ medical specialists in obstetrics and gynecology;
- ✓ biologists / laboratory managers on topics such as cell cultures, the techniques of in vitro fertilization;
- ✓ biotechnologists;
- ✓ anesthesia for oocyte retrieval;
- ✓ psychologists and / or psychiatrists;
- ✓ genetic doctors, urologists and endocrinologists;
- ✓ nurses and / or midwives;
- ✓ support staff (administrative).



The ministries who have the responsibility of transposing EU guidelines may also be involved.

## Conclusions and critical comments

### Brief summary note

The need to adapt the knowledge and skills of health professionals in the development of medicine, technological and organizational innovation, as well as to changes in the demand for health, is urging many Centers MAR to promote programs for continuing education of its staff. The same World Health Organization, in recommending the activation of continuous training for health workers, reaffirms the strategic importance of continuous training and of job updating as key tools to keep skills and knowledge in line with technological progress and new knowledge.

It should also be stressed that each health professional is called, by the deontological rules that govern their work, to engage in continuous learning. Hence, the importance of continuing education for centers specialized in MAR in our cultural and professional contexts appears even more clear.

On the basis of the social and technological changes that have taken place in recent years, policy makers also need to update their knowledge in order to legislate with good knowledge of the facts.

Based on the findings from the survey, the need to prepare a training plan that takes into account adequately the training needs outlined above is obvious. This involves both on-site training and seminars. The proposal that we summarize in these conclusions should then be considered by all technical working group of the Future Medicine project.

The synthesis takes care to list some themes but without describing the organizational arrangements, method, strategies and implementation time used for the development of the training course.

The areas of expertise are particularly likely to be enhanced by training interventions are:



- ✓ family law in Community law;
- ✓ the European Convention for the Protection of Human Rights and Fundamental Freedoms;
- ✓ the Treaties, the court of Nice and the EU Directives in the field of assisted reproduction;
- ✓ ethics and bioethics in the policies of the European Union;
- ✓ social policies of the European Union;
- ✓ policies on health in the European Union;
- ✓ program 2013-2020 for health;
- ✓ legislation for access to medical care throughout the European Union and the European legislation on patients' rights in cross-border healthcare;

All issues can also be integrated with scientific issues related to medically assisted procreation. Managing committee will be identify which issues will be the subject of training activity and which, instead, should be covered by seminars, and appropriate time schedules.

### **The Questionnaire**

**See the Excel file separately provided.**