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# The law on artificial insemination: an italian anomaly

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**Summary.** The law on medically assisted procreation in Italy, from its entering into force, has undergone numerous amendments. This has been due to the fact that those citizens, directly affected by its imposed prohibitions, have not given in, bringing their requests before the courts, both nationally and internationally. Over the years, the courts through numerous rulings have significantly changed a law clearly incapable of protecting the rights of those involved. Currently Italy has an acceptable law on M.A.P. which is the result of the strong willing of citizens affected by problems of sterility or infertility. The aim of this paper is to present an historical summary of the troubled path which the issue, from every perspective, has faced and is still facing today. As well, it will document how, in Italy, the case-law and, therefore, the law's interpretation and application by the judges have contributed, in the end, to shaping a positive legislation. (www.actabiomedica.it)

**Key words:** human rights, law, legal system, medical law

## Introduction

The current Italian Law No. 40 of 19 February 2004 on artificial insemination (Medically Assisted Procreation or M.A.P.), has resulted from a long history of shifts in opinion in debates and institutional positions (the ministry and legislation), in the ethical sphere (National Bioethics Committee - N.B.C. - and Code of Medical Ethics - C.M.E.), as well as in the case-law, attempting to remedy a social disorder, due to the lack of a law, where common sense had been lost in its role in guiding medical behaviour and couples with fertility problems.

The fertilization of women already in advanced menopause, of single women, and the request for children from deceased husbands, or children from semen or eggs foreign to a couple, highlighted by the media and also following what was happening in other European countries, influenced public opinion into adopting, at times, markedly conflicting positions concerning this issue.

On the wave of a growing awareness of the issue, the legislators found themselves called upon to establish a uniform and complete legislation regarding the regulation of medically assisted procreation.

The aim of this paper is to present an historical summary of the troubled path which the issue, from every perspective, has faced and is still facing today. As well, it will document how, in Italy, the case-law and, therefore, the law's interpretation and application by the judges have contributed, in the end, to shaping a positive legislation.

## Law No. 40 of 19 February 2004 (Law on Medically Assisted Procreation)

The Italian M.A.P. Law No. 40 passed on 19 Febraury 2004, allowed the procedure only for sterility or infertility problems in the absence of any other effective treatment.

Heterogeneous adult couples, married or defacto, of a fertile age who were certified as being sterile or infertile by a doctor could access the programs. M.A.P. had to follow the principles of a step-by-step procedure where, firstly, a less invasive treatment was attempted;

the couple had to be informed of the ethical issues, the legal consequences and the associated health risks, providing their valid consent. Heterologous insemination was prohibited.

The Law forecasted that the Ministry for Health, after consulting the National Institute of Health and the National Health Council, would establish the guidelines for the treatment procedures, to be updated every 3 years.

The unborn child would acquire the status of a legitimate child or child recognized by the couple who had given their prior consent; denying paternity or maternity was prohibited; human embryo experimentation was prohibited, while clinical and experimental research was allowed for therapeutic and diagnostic purposes to safeguard the health and development of the embryo and when any other techniques were not available; the production of more than three embryos to be implanted at any one time was prohibited; cryopreservation was permitted only up to the implantation in the woman, to be carried out as soon as possible; embryo destruction and embryo reduction in multiple pregnancies was prohibited, except where foreseen under Law 194/1978; and the couple had to be informed on the number and, on express request, the health of the embryo to be tranferred *in utero*.

In June 2005, Italian citizens were called to the polls in order to repeal certain articles of Law No. 40 concerning the following questions:

- allowing scientific research on embryo cells;
- cancelling the obligation to fertilize only 3 oocytes, cancelling the obligation for *in utero* transfer of all the embryos including malformed ones, and removing the prohibition on embryo freezing;
- repealing the articles of Law 40 prohibiting genetically diseased carrier couples from applying for M.A.P. and pre-implantation diagnoses;
- repealing the articles of the law prohibiting sperm and egg cell donation, thus, also allowing couples, where one of the two was completely sterile, to become parents.

The referedum did not result in changing the law, as the turnout was very low, with only slightly more than 25% of citizens voting.

## Problems arising from the law, reaction from protected persons and the legal response

*1) Issue 1: Access to treatment only for sterile or infertile couples and the prohibition on pre-implantation diagnoses*

This resulted in fertile couples, but carriers of genetic or chromosomal pathologies, being denied access to artificial insemination procedures. This was a violation of art. 32 of the Constitution (safeguarding health as a fundamental right), in that it did not guarantee the health of the unborn, or it could even prevent a couple from planning a pregnancy, resulting in their giving up or turning, at a later time, to an abortion. This led to a marked decrease in requests for pre-implantation diagnoses in M.A.P. centres.

In referring to the said law, on 22 September 2007 and 17 December 2007, respectively, the Court of Cagliari and the Court of Florence recognized the right of sterile couples and carriers of genetically-transmitted diseases, who had been denied the possibility of re-implantation in clinics where they had previously applied, to a pre-implantation diagnosis. In this instance, on 22 September 2007, the Court of Cagliari, in a ruling, approved the request for pre-implantation diagnoses, at the same time raising the exception of constitutional illegitimacy under art. 13, Law 40/2004, affirming the priority of the woman's right to health as per art. 32 of the Constitution. Subsequently, the Court of Florence, with an order of 17 December 2007, approved the request of a couple, carriers of a serious genetic disease, to access pre-implantation diagnoses.

The reason, in both cases, was based on the fact that pre-implantation diagnoses were essential to providing the correct information for a valid consent and that the prohibition of the law was aimed only at clinical and experimental research and genetic engineering, and not pre-implantation diagnoses for procreative purposes.

The ethical principle underlying these rulings derived from the fact that the need to protect the woman's physical and mental health (art. 32 of the Constitution) should be first and foremost, overriding the protection of the unborn child.

The scientific community, following these decisions, responded with the Joint Paper from Italian

societies for reproduction, updating the guidelines of Law 40/2004 (28 September 2007). The experts asked to:

- foresee in the guidelines the possibility to implant more than three oocytes in order to avoid repeated hormonal therapy;
- cryopreserve the fertilized egg with two still clearly distinct pro-nuclei for later implantation if required;
- consider as cases of infertility also those linked to viral or genetically transmissible pathologies for the conceived, in compliance with the relevant court decisions;
- make every embryo diagnosis admissible in order to ascertain the possibility that, once implanted, it could result in a pregnancy which could alter the woman's physical and/or mental health, therefore, avoiding a forced embryo implantation and a later interruption of the pregnancy.

The Regional Administrative Court of Lazio (Sec. IIIc) with ruling no. 398 of 21 January 2008 declared the prohibition of pre-implantation diagnoses as forecasted in the 2004 guidelines illegal, as it was created *ex novo* and *contra legem*.

The underlying reason was that the guidelines allowed for only one diagnosis of an observational nature which resulted in assessing cell density and aggregation and any anomalies in the embryo's development, but not in identifying any genetic anomalies. This conflicted with the ethical principle concerning the right to be provided with accurate information.

Following this ruling, the institutions represented by the Ministry for Health, the National Health Council and the National Health Institute, issued new guidelines on M.A.P., with the Ministerial Decree 11 aprile 2008. These included some important changes to the previous guidelines, specifically:

- couples in which the man was a carrier of a sexually transmissible viral disease, and in particular HIV, or hepatitus B and C, could access M.A.P., as these conditions constituted infertility;
- each M.A.P. clinic had to guarantee the availability of psychological support for the couple, ensuring the services of a trained psychologist;
- the subparagraphs of the previous guidelines which restricted the possibility of an observational-type check were cancelled, in compliance with the Lazio Regional Court ruling no. 398/2008 published on 29 January 2008.

In September 2010, an Italian couple appealed (no. 54270/10) to the European Court of Human Rights. The apellants, both healthy carriers of cystic fibrosis, who already had a child born with cystic fibrosis and had already undergone an abortion after a prenatal diagnosis revealing that the foetus also had the same disease, claimed the right to a genetic pre-implantation diagnosis, even though they were fertile. The apellants invoked articles 8 and 14 of the "*Convention for the protection of human rights and fundamental freedoms*". The Court of Strasbourg (28 August 2012) ruled against the Italian law on medically assisted procreation, citing the right to private and family life as per art. 8 of the European Convention on Human Rights, based on an inconsistency existing between prohibiting the implantation of only healthy embryos and the possibility to interrupt a pregnancy at a later date.

Instead, in referring to art. 14, on the presumed discrimination against sterile or infertile couples or where the man is afflicted by a sexually transmitted viral disease (HIV or Hepatitus B or C) who can request pre-implantation diagnoses, the Court showed that the appeal was unfounded, as these groups of individuals are not treated differently from the apellants.

Recently, the Constitutional Court, with ruling no. 96 of 2015, expressed the same opinion declaring the constitutional illegitimacy "*of art. 1, subparagraphs I and II, and art. 4, subparagraph I, of Law No. 40 of 19 February 2004 (on medically assisted procreation), wherein access to medically assisted procreation techniques for fertile couples, but carriers of genetically transmissable diseases, is not permitted, satisfying the criteria of severity referred to in art. 6, subparagraph 1, point b, Law No. 194 of 22 May 1978 (regulations for the social protection of maternity and the voluntary interruption of pregnancy), established by the relevant public entities*".

*2) Issue 2: Restricting to three the number of embryos to avoid producing supernumerary embryos and to avoid "fetal reduction" in the case of multiple-birth pregancies*

Moreover, the prohibition of cryopreservation, only allowed for serious and certified *force majeure* rea-

sons where the woman's health was concerned; cryopreservation was allowed for embryos produced up to the transfer date, to be done as soon as possible.

The Lazio Regional Administrative Court, sec. IIIc, with ruling no. 398 of 21 January 2008, besides cancelling the guidelines referred to in the Ministerial Decree of 21 July 2004 declaring the prohibition of pre-implantation diagnoses illegal where it is stated *"that every test concerning the state of health of the embryos created in vitro, in accordance with art. 13, subparagraph 5, shall be purely observational"*, also highlighted the inequality of treatment for women who were no longer young or who, however, were not able to produce 3 good quality embryos at any one time. It also underlined the obvious conflict with art. 32 of the Constitution whereby, in accordance with the law, the woman would be forced to repeat treatment cycles, circumventing its step-by-step principle. Therefore, it raised the question of the constitutional legitimacy of art. 14.

In the same year, the Court of Florence, with Court order no. 323 of 12 July 2008, intervened for the first time, highlighting the need to guarantee as an absolute priority the protection of the right to health of the woman who was already a legal person, the unborn child as yet not being considered as such. Therefore, the question of the constitutional legitimacy of art. 14, subparagraphs 1 and 2, Law 40/2004 returned to the Constitutional Court, as being conflictual *"(...) in so far as they prohibit the cryopreservation of supernumerary embryos, the need for the creation of a maximum of three embryos, as well as the need for a single and simultaneous implantation of the embryos, which cannot, however, exceed three, and where they provide for the irrevocability of the woman's consent to the implantation in utero of the created embryos"*. Under a second Court Order, no. 382 of 26 August 2008, the Court of Florence also raised the question of constitutional legitimacy in relation to article 2 of the Constitution, sustaining that the use of invasive healthcare treatments of limited effectiveness constituted a violation of the human dignity of an individual.

The Constitutional Court, with ruling no. 151 of 8 May 2009, intervened on Law No. 40/2004. In deciding on the questions raised by the Lazio Regional Court and the Court of Florence, the Advisory Council gave an opinion on the constitutional legitimacy of art. 14, which was reworded with the following cancellation of any references relevant to the single and simultaneous implantation of a maximum of three embryos: *"Embryo production techniques, taking into consideration technical and scientific developments and as is forecasted in art. 7, subparagraph 3 (Three-year Guidelines), shall not produce a number of embryos more than that deemed strictly necessary"*.

It was the doctor, and no longer the legislator, who had to decide, case by case, on the number of embryos to be produced, taking into consideration the woman's health and age. The underlying reason for the decision was that the *"the protection of the embryo is not however absolute, but limited by the need to individuate the right balance between safeguarding procreation needs and the primary interest, namely, protecting the woman's health"*.

The amendments to Law No. 40 of 2004 have resulted in a better approach to the techniques and an increase in pregnancies following M.A.P..

*3) Issue 3: Prohibition on accessing heterologous insemination techniques, that is, the use of genetic material foreign to the couple*

This had prevented many couples, where one of the two had no possibility to donate their own gamete, from beginning a family.

The Constitutional Court with ruling no. 162 of 9 April 2014 declared the constitutional illegitimacy of art. 4, subparagraph 3, Law 40/2004, *"in so far as it establishes for the couple, as referred to in art. 5, subparagraph 1, of the said law, the prohibition to access heterologous medically assisted procreation techniques, if a pathology is diagnosed which is a cause of permanent and irreversible sterility or infertility, as well as under art. 9, subparagraphs 1 and 3, limited to the words «in violation of the prohibition under article 4, subparagraph 3" and art. 12, subparagraph 1, of the said law"*.

The Advisory Council underlined that the impossibility to begin a family with one's partner, negatively and markedly affected the couple's well-being. The reason underlying this decision was that, in the hypothesis of "disability" caused by irreversible sterility, preventing the adoption of avant-garde therapeutic practices, was nothing but an unacceptable restriction on an individual's right to health. The reason for this

decision could be found in the fact that the technique "*did not carry any risks for the donor's health other than the normal risks involved in any type of therapeutic practice*".

Moreover, the Constitutional Court highlighted a further irrationality in the law – it created an unjustified and different treatment for couples affected by the more serious pathologies, as, depending on their economic means, they could be denied exercising their fundamental right. That is, couples lacking the necessary economic resources could be denied access to this treatment when such treatment was only available in other countries. The Court considered that medically assisted procreation involved *"various constitutional needs*" and, consequently, Law No. 40/2004 affected many interests in this category.

These, as a whole, needed to be balanced ensuring a minimum level of legislative protection for each, with, in fact, the Constitutional Court already affirming that the same *"protection of the embryos is not, however, absolute, but limited to the need to identify the right balance between safeguarding the needs of procreation»*.

Indeed, prohibiting heterologous insemination had been introduced into Italian law under Law No. 40/2004. Prior to this, the use of heterologous insemination techniques had been prohibited in National Health Service structures, while they had been allowed without any restrictions in private centres operating in compliance with circulars drawn up by the Ministry for Health.

It is clear how Law No. 40 of 2004 was slowly *"crumbling away"* under accusations of being unconstitutional.

Following the last ruling of the Advisory Council, the Minister for Health, Lorenzin, following the decision of the Council of Ministers, acknowledged the need that it should be, as per normal procedure, the Parliament which intervened, taking into account the obvious ethical aspects arising from the issue.

Therefore, in anticipation of a law being debated and approved, the autonomous Conference of Regions and Provinces convened on 4 September 2014, approved a guideline document to standardize the heterologous insemination procedures for all of Italy.

The paper drawn up included a series of agreed upon fundamental points:

- that heterologous insemination would be free of charge or on payment of a voucher;
- that the recipient women would be no more than 43 years old and thus, be of a potentially fertile age;
- that between donors and recipients there would be a *"reasonable compatibility";*
- for both the male and female donors a maximum ceiling of 10 births for each was forecasted. The female donor had to be between 20 and 35 years and the male donor between 18 and 40;
- that accurate tests and clinical exams would be conducted for the donors and a register established;
- that the male or femal donor would remain anonymous: *"… The clinical data of the donor may be made available to the healthcare personnel only in special cases…"*.

After the publication of the paper, each region has been proceeding at different rates and the situation is continually evolving, both for the application of the procedure and for covering the costs.

Notably, the Tuscany Region was the first to adopt an *ad hoc* resolution. Emilia Romagna, Liguria, Piedmont, Umbria and Veneto are ready to follow and in the near future also the other regions will be adopting resolutions on the issue.

Recently, the Ministerial Decree of July 1th 2015 established the 2015 Guidelines replacing the previous have been enacted. These have been revised, not only in relation to the technical and scientific developments in the field, but also in relation to the decisions of the Constitutional Court n. 151/2009 and 162/2014.

Among the main changes: to have access to heterologous fertilization techniques, when it employs both male and female gametes donated by individuals other than members of the recipient couple, a careful clinical assessment of the risk-benefit of the treatment is needed, and particular attention has to be given to obstetric complications, to neonatology potential impact and any risks for the health of the mother and newborn. The access is allowed to couples in which one of the individuals is a carrier of sexually transmitted viral diseases for HIV, HBV or HCV. The medical records have to be compiled in more detail by describing the M.A.P. procedures, the decision about the number of

embryos to be generated, and the embryos to be cryopreserved.

## Conclusion

The law on M.A.P. in Italy, from its entering into force, has undergone numerous amendments. This has been due to the fact that those citizens, directly affected by its imposed prohibitions, have not given in, bringing their requests before the courts, both nationally and internationally. Over the years, the courts through numerous rulings have significantly changed a law clearly incapable of protecting the rights of those involved.

Currently Italy has an acceptable law on M.A.P. which is the result of the strong willing of citizens affected by problems of sterility or infertility.

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