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MEDICALLY ASSISTED PROCREATION: EMERGING PROBLEMS IN ITALY

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Abstract
In Italy, medically assisted procreation is governed by Law 40/2004. The said law has been subject to several changes over the past ten years, which have redesigned the face of it so as to make it an example of re-writing a legal text. Even today, many problems still need to be seen to that require a rethinking of the family model, parenthood, and the existence of a right to procreative freedom. The various currents of feminism have welcomed the advent of new reproductive technologies differently. Intended to broaden women’s rights, these new technologies have also opened up new forms of subjection and exploitation.

Keywords
Medically assisted procreation, new technologies, exploitation.

Resumen
En Italia la procreación médicamente asistida se rige por la Ley 40 de 2004. Esta ley ha sido sujeto de múltiples cambios en los últimos diez años, que han rediseñado su
apariencia hasta convertirla en una especie de referente de cómo se reescribe un texto legal. Incluso, hoy en día, muchos problemas deben ser vistos como un replanteamiento del modelo familiar, la paternidad y la existencia de un derecho a la libertad procreativa. Diferentes corrientes del feminismo han acogido el advenimiento de nuevas tecnologías reproductivas de manera diversa, ya que, si bien supuestamente fueron creadas para ampliar los derechos de las mujeres, también han dado lugar a nuevas formas de explotación y sometimiento.

**Palabras clave**

Procreación asistida, nuevas tecnologías, explotación, maternidad subrogada, libertad procreativa.
1. As is well-known, medically assisted procreation is a relatively recent practice: the first experiments date back to the late 1960s, but only in 1978 the first artificially inseminated child, Louise Brown, was born in England.¹

There has been no legislation in Italy for a long time: the difficulty of regulating this practice from a purely legal point of view, besides its ideological aspects, arises from the multiple problems stemming from the proliferation of subjects involved in the reproductive process. Subjects that bring a potential conflict of interest between them (biological parents, the embryo, the future child, any sperm or egg donors, doctors). This gap in legislation was overdue for over twenty years and only in 2004 did Law 40 come about (the “Medically Assisted Reproductive Law”), and finally passed by the Chamber after five hours of debate, with 277 votes in favor, 222 against, and 3 abstentions.

The very rigid system of the law, with a strong repression, caused more problems, and just a year later, in April 2005, the referendum campaign aimed at declaring the unconstitutionality of the entire law was started. However, the Constitutional Court² rejected the overall referendum on the basis of the assertion that Law 40 must be considered constitutionally necessary, as it provides the first organic regulation ensuring a minimum level of protection for a number of situations of significant constitutional interest. Furthermore, it contained four partial referendums on the most controversial points of the law, such as the possibility of access to medically assisted procreation not only by sterile couples but also to those with genetically transmissible pathologies, the limits to experimental research and the prohibition of heterologous fertilization. On June 12th and 13th, 2005, a referendum was held and failed due to lack of quorum.³

Law 40 has been subject to several changes over the past ten years or so, which have redesigned the face of it so as to make it an example of re-writing a legal text.⁴

In the initial formulation, it was severely detrimental to women’s health: a “bad bad law”, as it was defined⁵, reducing the woman’s body to a mere container of the conceived, sacrificing her right to health (I refer in particular to Article 14 banning the production of more than three embryos and the consequent obligation of a single and simultaneous implant) and Article 13 (on the prohibition of pre-implantation).

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² Cost, 13/01/2015 no. 45, in the Gazzetta Ufficiale 02/02/2005 no. 5.
The articles of the failed referendum were then brought before the Constitutional Court. By ruling 151 of the 8\textsuperscript{th} May 2009\footnote{In G.U. 13/05/2009 no. 19.}, the Court declared the constitutional illegality of Article 14, stating that the provision of the law is in contravention of article 32 of the Constitution, as it affects the right to women’s health. If the first attempt at implantation is unsuccessful then a second painful and invasive ovarian stimulation is required, aimed at the formation of new embryos for a second implant. The Court also notes the unreasonableness of Article 14, which provides for the same treatment for all women without taking into account the specific situations which must be assessed case by case in the medical/patient relationship. The Court, therefore, reiterated the principle underlined in Article 14, namely banning the creation of a number of embryos exceeding the necessary level, but considered it reasonable to entrust the physician with a case-by-case determination of how many embryos to produce and implant in relation to the individual women’s health conditions.

Subsequently, with two sentences in 2015, no. 96 of the 5\textsuperscript{th} June 2015\footnote{In G.U. 10/06/2015 no. 23.} and no. 229 of 11\textsuperscript{th} November 2015\footnote{In G.U. 18/11/2015 no. 46.} respectively, the Court accepted, with the former, that fertile couples carrying genetic diseases could access medically assisted procreation (the previous Article 1 only allowed this to couples suffering from infertility or sterility) and, secondly, the selection of embryos if they were suffering from serious transmissible diseases, i.e. pathologies that meet the severity criteria for abortion in virtue of Law 194 of 1978 (“Rules for the Social Protection of Maternity and Voluntary Termination of Pregnancy”). The Court has once again intended to protect the health of women who would otherwise have to resort to abortion after the implant: in fact, if the law allows for the voluntary termination of pregnancy in order to prevent compromising the psycho-physical integrity of a woman by the prospect of generating a severely ill child, it seems unreasonable to impose the implantation of an embryo with a serious anomaly on a woman, and then force her to abort it.

The European Court of Human Rights in Strasbourg pronounced on the case of \textit{Costa and Pavan} c. Italy (August 28\textsuperscript{th}, 2012)\footnote{Appeal no. 54270/10.} and noted the inconsistency of Italian law, which offers stronger protection to the embryo than to the fetus when it bans couples carrying genetic diseases to access medically assisted procreation and to select embryos carrying no disease, but then allows for abortion once a pregnancy begins with a fetus bearing that illness.
2. In 2014, with judgment no. 162 of the 9th April\(^{10}\), the Constitutional Court also ruled that medically assisted procreation of a heterologous type was unlawful\(^{11}\) (provided for in Article 4, paragraph 3, of Law 40). It should be noted that in Italy since the late 1970s, when medically assisted procreation spread, until 2004 (the year in which Law 40 came into force) heterologous fertilization was practiced, but regulated by ministerial decrees. One particular decree was the Degan of 1985, which provided that the donor had to be anonymous and that the donation was to be made without payment. From 2004 to 2014 the ban then came into place.

The ruling of the Constitutional Court of 2014 was preceded by an intervention by the European Court of Human Rights in Strasbourg\(^{12}\), which in 2010 condemned Austria for the absolute ban –provided by the law of that country as was the case in Italy too– of the donation of eggs, as it was considered incompatible with the principles laid down in the ECHR (European Convention on Human Rights of 1950) in article 8 on respect for the right to private and family life and article 14 on the principle of equality.

In February 2011, the Grand Chamber in Strasbourg reformulated this decision, believing that the prohibition by Austrian law did not go beyond the margin of appreciation granted to the European states. In particular, it stated that this ban was an expression of a non-censurable balance between the right to parenthood and the need to preserve certainty in family relationships, with particular reference to the possible conflict between genetic mother and biological mother, and the interest of the individual to know their genetic origins.

In 2014, the Italian Constitutional Court based the declaration of illegitimacy of medically assisted heterologous procreation on the following points:

- The Constitution includes fundamental and general freedom of self-determination (Articles 2, 3, and 31), AND the choice to become a parent and to form a family is one of these expressions. In particular, Article 31 gives the Republic the task of facilitating the formation of families by means of economic and other measures. Law 40 is to be seen as follows: it is explicitly intended to “remove the causes of infertility or sterility”. But heterologist prohibition is to be considered unreasonable in light of the purpose of the law itself, as it prevents completely sterile subjects accessing medically assisted procreation.

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11. As the renowned gynecologist Carlo Flamigni emphasized on several occasions, the term “heterologous” makes it possible to think of reproductive meetings between subjects of different species. From the scientific point of view, it would be more appropriate to define it as “exogamic reproduction”; i.e. with eggs from total strangers.
techniques to form a family that needs donor eggs. In other words, irrelevance lies in the fact that the law guarantees access to assisted medical procreation to those who are ill but denies it to those with more serious illnesses.

-In addition, the Constitution guarantees the right to health (Art. 32), traditionally being psychophysical well-being. The inability to form a family with children can adversely affect the health of the couple.

Once the freedom of self-determination in family matters (Articles 2, 3 and 31) and the right to a couple’s health (Art. 32) have been clarified, the Court states that, in order to impose prohibitions or limitations on the rights of persons, then equivalent rank rights that would be lost need to be individuated. In the case of heterologic fertilization, what are the interests/rights that would be damaged? Possible traumas from non-natural parenting and the possible compression of the right of the offspring to know his or her genetic origins. But such profiles, referring to possible situations that have not been demonstrated, are not as such as to prevail over the above-mentioned rights (self-determination and health).

Therefore, the rules prohibiting heterologous fertilization lead to a disparity of treatment: at first glance, with reference to the severity of the dysfunction of the couple and, under another profile, with reference to economic abilities. Those with economic means may resort to treatment abroad where medically assisted heterosexual procreation is a permitted practice.13

In light of all this, the Court ruled that the prohibition of heterology was unethical for unreasonable disproportion, as “the censured rules do not respect the least possible sacrifice of other constitutionally protected interests and values and instead make a clear and irreversible injury to some of the them” (self-determination and health).

As a result of this ruling, some have found a regulatory vacuum and, therefore, the need for new intervention by the legislator. However, the Court itself pointed out, in the final part of the judgment, that there is no vacuum, since Law 40 acknowledges the legitimacy of medically assisted heterosexual procreation in many countries, it had already provided for Article 9 to regulate the state of the child’s birth: “Whenever medically assisted heterosexual procreation techniques are used, the spouse or cohabitant whose consent can only be obtained by means of concluding acts cannot exercise the act of rejecting the paternity”; that “the mother of a baby resulting from the application of medically assisted procreation techniques cannot declare the will not to be named”;

13. See, in particular, A. Borini, C. Flamigni, Fecondazione e(s)terologa, L’Asino d’oro, Roma, 2012.
that “in the case of heterologous techniques, the egg donor does not acquire any paren-
tal legal relationship with the baby and cannot claim any right or obligation to do so”.

So, in the opinion of the Court, there is no gap in the subjective requirements of
the provisions of Article 5: “access to medically assisted procreation techniques may be
granted to married or cohabiting heterosexual adults of a potentially fertile age, who
are both living”.

Lastly, there is no problem with regard to authorized structures, which remain those
provided for in Articles 10 and 11, that is to say, public and private facilities authorized
by the regions and registered in a special register.

Finally, we call upon:

  the definition of quality and safety standards for the donation, procurement, control,
  processing, conserving, storage and distribution of human tissues and cells” with ref-
  erence to the gratuity and willingness of the donations; the modalities of consent; the
  anonymity of the donor; health care; etc.

- The law of no. 184 dated May 4, 1983, regarding adoptions, and amendments made
  by Legislative Decree 154 of 2013, with particular reference to the issue of genetic identity.

3. On July 1, 2015, the Ministry of Health, in the light of technical-scientific de-
velopments and judgments of the Constitutional Court, issued a decree updating the
guidelines of Law 40 and substituting those of 2008, largely inspired by the document
of State-region conference approved in September 2014, following the judgment of the
Constitutional Court.14

With reference to the heterology, it is to be pointed out that the donation must be
anonymous in the sense that it should not be possible for the donor to trace the receiv-
ing pair and vice versa. Furthermore, it must be free of charge, with the exclusion of the
reimbursement of expenses. It has been highlighted that it is not possible to choose the
phenotypic characteristics of the donor in order to avoid unlawful eugenic selections
but that the medically assisted procreation centre should reasonably ensure the compat-
ibility of the donor’s main features with those of the receiving pair, so as to avoid that
the child’s appearance is not too dissimilar to that of the parents.

The problems of implementing the heterologous discipline in Italy are still numerous, beginning with the number of male donors and especially female ones (in this regard an adequate information campaign is lacking), which makes it necessary to import eggs from abroad.

Two years after the ruling of the Constitutional Court, the Italian Fertility Society (SIFE) issued some very worrying data: there were just a dozen female donors (against the 500/600 that would be needed each year), one hundred or so female donors through eggsharing, i.e. women in treatment for medically assisted procreation who give part of their oocytes. One of the reasons for these numbers is to be found in the fact that, as has been said, the donation in Italy is entirely free, whereas in other countries it is an entirely different story (e.g. in Spain where a law provides for a fee of about 1000 euros). This creates a clear controversy: paid donation is forbidden, but oocytes can be obtained from other countries at a price.¹⁵

Only since this year (March 2017) the heterology services have been included in the National Health Service’s LEA (Essential Support Levels), which should avoid large territorial differences concerning the possibility of access and reimbursement and the continuation of the so-called procreative tourism, both from region to region (until March only in three regions –Tuscany, Emilia-Romagna, and Friuli– access was operational with redeemability), as well as towards foreign countries.

Besides these practical problems, I would like to emphasize three open questions of great bioethical importance.

The first question concerns Article 13 (still in force) of Law 40, which prohibits any experimentation on human embryos, except for therapeutic and diagnostic purposes aimed at protecting the health and the development of the embryo itself. The prohibition also affects the cryo-preserved supernumerary embryos produced before the entry into force of Law 40 and after the Constitutional Court ruling of 2009, which eliminated the limit of three embryos to be produced and implanted. Consequently, even the latter cannot be donated for research. The provision of Article 13 has been the subject of judgment before the European Court of Human Rights (Case Parrillo c. Italy, 27 August 2015).¹⁶ Adelina Parrillo, in 2002, before Law 40 entered into force, along with her companion Stefano Rolla, had decided to access medically assisted procreation techniques in order to produce embryos to be implanted at a later date.

However, in 2003 she lost her companion who was killed in Nassiriya, and the widow gave up on the idea of transferring the embryos, but expressed the desire to donate them to scientific research. Her request was refused by the healthcare facility where the embryos were kept. This refusal was motivated by the fact that Law 40 under Law 13 prohibited any embryo research. So Mrs. Parrillo decided to resort directly to the European Court of Human Rights, arguing that the prohibition stated in Article 13 violates Article 1 of Protocol No 1.1, annexed to the text of the European Convention on Human Rights (“Protection of property”), Article 8 (“Right to respect for private and family life”), and Article 10 (“Freedom of expression” where scientific freedom can be considered an aspect). The Grand Chamber on 27 August 2015 declares that the application is inadmissible: with respect to Article 1, Protocol 1, the Court emphasizes that the scope of the rule is strictly of an economic-capital nature and cannot therefore refer to the case in question. With respect to Article 8, while recognizing that the embryos contain genetic material belonging to the applicant and are therefore to be considered as constituting genetic and biological identity, the Court considers that this does not directly affect respect for private and family life. This also takes into account that there is no evidence of will in the same sense from the companion. Finally, in Article 10, the Court holds that the alleged violation should have been submitted by a researcher, who is the holder of the right to freedom of expression, in the sense of the right to scientific freedom, and not by others.

Article 13 of Law 40 also issued the Constitutional Court with Judgment no. 84 dated 22 March 2016 following a lawsuit filed at the Law Court of Florence, to which a couple had turned to order that their nine cryopreserved embryos held by an assisted fertilization center be sent to medical and scientific research. The Consult, explicitly referring to the ruling of the Court of Strasbourg, emphasizes the intangibility of legislative choice to safeguard the dignity of the embryo at the expense of freedom of scientific research and considers that only the legislator “as the interpreter of the will of the community” can be called to translate the balancing of basic values into conflict, taking into account the orientations and instances rooted in social consciousness at the given moment. This ruling, therefore, sends the legislator a warning to decide on the fate of human embryos in perpetual cryopreservation that could be used in scientific research or even—may I add—“adopted” because of the low number of male sperm donors/female egg donors.

17. In G.U. 20/04/2016 no. 16.
The second question, however, concerns the anonymity of either donor provided in the 2015 guidelines. This is a more general topic involving other institutions such as the adoption and anonymity of the mother who chooses, as envisaged in Italy, to give birth to a hospital without being identified.

In 2011, therefore, before the heterologist prohibition was dropped in Italy, the National Committee for Bioethics, took note of the 2010 Recommendation of the Council of Europe’s Bioethics Steering Committee to the States which prohibited the heterology from drafting protective rules of the identity rights to the newborn, expressed itself with an opinion (“Knowing Their Biological Origins in Medically Assisted Heterologist Procreation”) that can be summarized in the following points:

-Parents are recommended to tell their children how they were conceived using appropriate ways, so as to prevent any genetic testing from revealing the secret later on and causing unpredictable reactions.

-The facility where the medically assisted procreation has been performed must keep appropriate registers containing the genetic data of the male donor/female donor necessary for any diagnostic/therapeutic treatment of the child in the future.

With regard to the right of the child to know its origins, by accessing the biological data of both donors, some have, on the one hand, emphasized the importance of comprehensive data (both genetic and personal information) of who gave the eggs, arguing that every individual has the right to know the truth, and if this was prevented he or she would be a victim of violence. Others, on the other hand, have argued the need to preserve anonymity, arguing that the bond with the donor is biological and not relational, and therefore does not add anything to the child’s background, and would risk family balance.

From a legal point of view, with reference in particular to the aforementioned institution of the mother’s anonymity, the Italian constitutional court expressed the right to confidentiality of women in 2005 as well as the European Court of Human Rights of Strasbourg in 2012, with the judgment of Godelli c. Italy. The Court of Strasbourg considered that the prohibition of access provided for in Italian law violated Article 8 of the European Convention on Human Rights and that Italy did not seek to establish a

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balance between the rights of the parties concerned (the privacy of the woman and the right to the personal identity of the child). By analogy, these arguments may also apply to the case of medically assisted heterozygous procreation.

The third question concerns gestation for others or surrogate maternity\(^{21}\), which is a type of medically assisted procreation that is prohibited in Italy. As previously stated, Law 40, even after its re-writing, recognizes access to homologous or heterologous assisted procreation techniques only to “adult heterosexual couples that are married or cohabiting, potentially fertile, and both living”.

Cases of gestation for others are slowly becoming more common in Italy. The original Decree on Civil Unions (which became Law No. 76 on May 20\(^{th}\), 2016) provided for the possibility of so-called *stepchild adoption*, i.e. the possibility of recognition of the parental bond to those who did not contribute biologically to the birth of the child, but this part was then excluded when it came to approving the decree. In the absence of legislation, two different roads have been taken:

- In some cases, the possibility of transcribing the birth of a child “obtained from surrogate maternity” in the registers of the Italian registry has been allowed in a state that disciplines it if there is a genetic bond of some sort.
- In the case, however, of a surrogate child with no biological bond to the contracting couple, in the interest of the minor, the state of abandonment is to be declared and therefore he or she can be adopted.

This second orientation is also reflected in the recent judgment of the European Court of Human Rights in Strasbourg of 24 January 2017 in the case of *Paradiso and Campanelli c. Italy*.\(^ {22}\)

A married Italian couple went to Russia to satisfy their desire of a child through a maternity surrogacy agreement (which was however concealed by the Russian authorities at the time of the birth of the child). Back in Italy, they requested that the birth be registered in Italy, which was rejected, given the offense of false attestations and the complete absence of a genetic bond. The Juvenile Court of Campobasso, therefore, initiated proceedings for the declaration of adoptability of the child. The spouses appealed

\(^{21}\). To indicate that form of pregnancy when a woman, with or without consideration, carries a pregnancy for others with the intent to entrust the baby to intentional parents without claiming any rights to the child, the preferred terminology is “gestation for others” in as neutral as “surrogate maternity”, clearly disreputable (the term “surrogate” refers to something that pretends to be authentic and is not) or “uterus to rent”, where the use of a part for everything is obscured by the subjectivity of the woman.

\(^{22}\). Appeal no. 25358/2012.
against the Italian State to the European Court of Human Rights for violation of article 8 of the European Convention on Human Rights (right to respect for private and family life). In the first instance, the Court accepted the appeal, but the Grand Chambre issued a second sentence, completely subverting the previous decision. It supported this second decision by stating that there was no biological bond and, above all, their relationship had been very brief (six months), and consequently did not constitute a solid family relationship. For these reasons, the Court considered the ruling of the Italian judges to be reasonable, as the question was ethically sensitive, with respect to which the States should enjoy a broad margin of appreciation.

Various openings can be found in the ruling of the Court of Trento of the 23rd February 2017, by which the Court maintained that the refusal of the Civil Registrar to transcribe a foreign judgment recognizing dual male parenthood to a child born abroad, for being contrary to public order, was illegal. The Court argued that the failure to recognize the status filiationis in relation to the non-biological father would cause an obvious injury to the child. Furthermore, no rights would be recognized to him. It is argued that the protection of this principle goes beyond any reference to the prohibition of gestation for others as “the recognition of the deformity of the fertilization practice by virtue of which children were born, compared to those considered legitimate by the current rules of medically assisted procreation and should not result in the denial of the status filiationis legitimately acquired abroad”.

Besides the specific problems affecting Italy, the issue of medically assisted procreation requires wider reflection with regard to the family model and parenting and whether or not there is a right to freedom of procreation.23

As pointed out by the European Court of Human Rights with regard to the applicability of Article 8 of the Convention when talking about the family model, not only to spouses, but also to heterosexual or homosexual couples that cohabit more uxorio:

The State, in choosing means to protect the family and ensure the respect for family life provided for in Article 8, must necessarily take into account the evolution of society and change in the perception of social issues and civil status and relations, and include the fact that there is not just one way or choice to lead family or private life.24

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As for parenting, it is necessary to realize that the certainty enshrined in the ancient saying *mater semper certa* (or rather “the mother of the child is always known”) seems to crumble nowadays and the reference figures are multiple: the genetic mother (giving the fertilized egg), the biological mother (who lives the gestation), the social mother (who takes on the responsibility of the newborn), the paternal father, the biological father (the donor), and therefore the rights/duties of these different figures need to be balanced.

Finally, as regards the right to procreative freedom, this is to be included in the context of the so-called “procreative revolution.” Following the rapid development of new reproductive technologies, biology is no longer a destiny: contraception allows you to choose when/how to reproduce or not to reproduce at all (so-called negative procreative rights), as well as choose how to reproduce. It ranges, for example, to freezing your eggs to use them at a time in life that is more suitable for you, to the procreation for sterile or infertile couples with transmissible genetic diseases, to the procreation with donor eggs and surrogate mothers (so-called positive procreative rights).

The decision to have a child—as the Italian Constitutional Court cites in the above-mentioned ruling—“concerning the most intimate and intangible sphere of the human person, cannot be compulsory unless it fails other constitutional values”. Self-determination in life and body, citing Stefano Rodotà, represents the most intense and extreme point of existential freedom.

The different currents of feminism have greeted the advent of new technologies in the field of reproduction very differently. The ability of such techniques has been argued. On the one hand, they broaden the rights and freedom of choice and self-determination of women; on the other hand, they open new frontiers to the subjection and exploitation of women’s bodies.

Under the latter profile, the most controversial theme is the so-called gestation for others or surrogacy pregnancies. As we have seen in Italy, and in most European countries, this practice is banned. Some countries only recognize the altruistic form (e.g. UK,

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Greece, Belgium, many US states), few also recognize the commercial form (e.g. California, Russia, Ukraine)\(^\text{28}\).

The policy of the European states, contrary to marketing, is reflected in various international legislation: Article 21 of the Oviedo Convention on Human Rights and Medicine states that “the human body and its parts should not be as such forms of profit”. Article 3 of the Charter of Fundamental Rights of the European Union provides the same “prohibition on making the human body and its parts as such a source of financial gain”. The EC Directive 2004/23, referred to, as we have seen, the Italian Constitutional Court in the 2014 judgment, Article 12 prohibits the sale of human tissue, allowing only the payment of compensation strictly limited to making good the expenses and the problems resulting from the donation. In light of this directive, some countries, as already stated, regulate the altruistic-solidarity form of egg donation, comparing it to the donation of blood or organs.

The discordance of standardization has prompted the Hague Conference Council, since 2010, to find uniform solutions to issues of international law and to address the issue, and has commissioned a group of experts to advance proposals for common solutions. The report prepared in February 2017 states that, given the complexity of the phenomenon of transnational gestation and the various legislative approaches of the states, “it is not yet possible to reach a definitive conclusion on the actual possibility of identifying and applying common rules of international law concerning recognition of parental responsibility”.

While requiring further discussions and considerations, the Council has identified two main objectives. The first one is to ensure the certainty and stability of the legal status of surrogate children for others, which must be acknowledged by all States, and the second to ensure that gestation for others is conducted in the respect of human rights and the well-being of all persons involved in the proceedings.