



## A properly reasoned refusal by the courts to authorise access to experimental treatment was neither arbitrary nor discriminatory

In its decision in the case of [Durisotto v. Italy](#) (application no. 62804/13) the European Court of Human Rights has by a majority declared the application inadmissible.

The case concerned the refusal by the courts to authorise the applicant's daughter to undergo compassionate therapy (experimental treatment known as the "Stamina" method) to treat her degenerative cerebral illness. The therapy was undergoing clinical trials and, under a legislative decree, was subjected to restrictive access criteria.

The Court held that the prohibition on access to this therapy, imposed by the court in application of legislative decree no. 24/2013, pursued the legitimate aim of protecting health and was proportionate to that aim. Sufficient reasons had been given for the court's decision, and it had not been arbitrary. Indeed, the therapeutic value of the "Stamina" method had, to date, not yet been proven scientifically. Nor could the Court conclude that the justice system's refusal to grant her permission had been discriminatory.

The decision is final.

### Principal facts

The applicant, Nivio Durisotto, is an Italian national who was born in 1950 and lives in Udine (Italy). He lodged his application in his capacity as the legal guardian of his daughter, Ms M.D., who was born in 1975 and has been suffering since adolescence from a degenerative cerebral illness.

On 8 April 2013 Mr Durisotto applied to a court, asking it to order Brescia Hospital to administer stem cells to his daughter using a treatment known as the "Stamina" method. The court provisionally granted his request, considering that there were no grounds for delaying administration of the requested treatment.

On 3 May 2013 Brescia Hospital asked that Mr Durisotto's request be dismissed, and submitted that the legal conditions had not been satisfied. In particular, Ms M.D. had not begun the treatment prior to the date on which Legislative Decree no. 24/2013 entered into force, namely 27 March 2013, as required by that decree, which governed patient access to the method in question. By a decision of 11 July 2013, the court rescinded its previous decision and dismissed the applicant's request.

On 30 August 2013 the court dismissed the applicant's claim. It noted that Legislative Decree no. 24/2013 had ordered clinical testing of the "Stamina" method for a period of 18 months from 1 July 2013 and reiterated that the public health service guaranteed access to medicines or therapies only where their validity and effectiveness had been tested and approved by scientific medical bodies. According to the court, Ms M.D.'s situation did not correspond to one of the authorisation criterion set out in the legislative decree which would allow for access to the treatment.

### Complaints, procedure and composition of the Court

The application was lodged with the European Court of Human Rights on 28 September 2013.

Relying on Articles 2 (right to life), 8 (right to respect for private life) and 14 (prohibition of discrimination), the applicant alleged that there had been a violation of his daughter's right to life and health on account of the fact that it was impossible for her to obtain the compassionate therapy known as "Stamina". He alleged that Legislative Decree no. 24/2013 had introduced discrimination in access to care between persons who had already begun treatment prior to the entry into force of the decree and those who – like his daughter – were not in that situation.

Relying on Articles 6 § 1 (right to a fair hearing within a reasonable time) and 14, he complained about the fact that, in the area of access to urgent treatment methods, the Italian legislative system provided for the possibility to lodge an urgent request and to contest the court's decision by a complaint, but that it allowed no appeal against a possible dismissal of such a complaint.

The decision was given by a Chamber of seven, composed as follows:

Işıl Karakaş (Turkey), *President*,  
Guido Raimondi (Italy),  
Nebojša Vučinić (Montenegro),  
Helen Keller (Switzerland),  
Paul Lemmens (Belgium),  
Egidijus Kūris (Lithuania),  
Robert Spano (Iceland), *Judges*,

and also Abel Campos, *Deputy Section Registrar*.

## Decision of the Court

### Article 8

The Court reiterated that in cases concerning prohibitions on access to compassionate care in respect of persons suffering from serious illnesses, the member States enjoyed a wide margin of appreciation.

In the present case, under Legislative Decree no. 24/2013 only courses of the so-called "Stamina" treatment which had been commenced prior to the entry into force of the legislative decree could be carried through to completion, in addition to courses of treatment authorised by a court. Mr Durisotto's request had been rejected on the basis of that law.

The Court further noted that a scientific committee set up by the Ministry of Health had issued a negative opinion on the therapeutic method in issue. The scientific value of this therapy had not therefore been established. The Court reiterated that it was not up to the international court to substitute itself for the competent domestic authorities in determining the level of acceptable risk for patients wishing to have access to compassionate therapy in the context of experimental treatment.

It followed that the interference in the right to respect for Ms M.D.'s private life, represented by the refusal to grant the request for medical therapy, could be considered as necessary in a democratic society. The complaint under Article 8 concerning the prohibition on Ms M.D.'s access to the compassionate treatment requested by her father had therefore to be rejected as manifestly unfounded.

### Article 14 taken together with Article 8

With regard to the judicial decisions which had authorised access to the compassionate treatment for certain individuals, and which were cited by Mr Durisotto, the Court noted, firstly, that several of the cases in question concerned situations which differed from that of Ms M.D. In certain cases, the

treatment had begun on dates prior to the entry into force of the legislative decree, and in others the courts had, on an exceptional basis, authorised access to the treatment.

The Court reiterated in this connection that in order for an issue to arise under Article 14 it was not enough that there was a difference in treatment of persons in relevantly similar situations, but that the impugned difference in treatment had to be discriminatory. A difference in treatment was discriminatory if it had no objective and reasonable justification, which meant that it did not pursue a legitimate aim or that there was no reasonable proportionality between the means employed and the aim sought to be realised. Even supposing that Ms M.D. was in a comparable situation to that of the persons who had received exceptional judicial permission to undergo treatment, the Court could not conclude that the justice system's refusal to grant her permission had been discriminatory.

The prohibition on access to the "Stamina" method, imposed by the court in application of Legislative Decree no. 24/2013, pursued the legitimate aim of protecting health and was proportionate to that aim. The court's decision had been properly reasoned and was not arbitrary. In addition, the therapeutic value of the "Stamina" method had, to date, not yet been proven scientifically. The fact that certain courts had authorised access to this treatment for persons in a similar state of health to Ms M.D. was not sufficient to amount to a breach of Article 14 taken in conjunction with Article 8 of the Convention. This part of the application had to be rejected as manifestly ill-founded.

#### Article 6 § 1

The Court reiterated that the Convention did not as such guarantee a right to appeal proceedings in civil cases. This part of the application had therefore to be rejected as incompatible with the provisions of the Convention.

*The decision is available only in French.*

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**The European Court of Human Rights** was set up in Strasbourg by the Council of Europe Member States in 1959 to deal with alleged violations of the 1950 European Convention on Human Rights.