Corte costituzionale

JUDGMENT NO. 438 OF 2008

GIOVANNI MARIA FLICK, President
MARIA RITA SAULLE, Author of the Judgment

JUDGMENT NO. 438 YEAR 2008

In this case the Court considered a direct application by the office of the Prime Minister against regulations issued by Piedmont Region setting out requirements relating to informed consent from a parent or guardian for the administration of psychoactive drugs to minors, as well as the provision of information regarding possible alternative treatment. The Court struck down the contested regulations on the grounds that they purported to regulate matters directly touching on a fundamental principle in the area of healthcare, over which competence was reserved to the state legislature, and were not limited to the issue of detailed ancillary regulations.

THE CONSTITUTIONAL COURT

Composed of: President: Giovanni Maria FLICK; Judges: Francesco AMIRANTE, Ugo DE SIERVO, Paolo MADDALENA, Alfio FINOCCHIARO, Alfonso QUARANTA, Franco GALLO, Luigi MAZZELLA, Gaetano SILVESTRI, Sabino CASSESE, Maria Rita SAULLE, Giuseppe TESAURO, Paolo Maria NAPOLITANO, Giuseppe FRIGO, Alessandro CRISCUOLO,

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 3 of Piedmont Region law No. 21 of 6 November 2007 (Provisions governing the use of psychotropic substances on children and adolescents), commenced pursuant to the application by the President of the Council of Ministers, served on 7 January 2008, filed in the Court Registry on 15 January 2008 and registered as No. 3 in the Register of Appeals 2008.

Considering the entry of appearance by Piedmont Region;

having heard the judge rapporteur Maria Rita Saulle in the public hearing of 18 November 2008;

having heard the *Avvocato dello Stato* Danilo Del Gaizo for the President of the Council of Ministers and Gabriele Pafundi, barrister, for Piedmont Region.

The facts of the case

1. – By appeal served on 7 January 2008 and filed on 15 January, the President of the Council of Ministers, represented and advised by the *Avvocatura Generale dello Stato*, raised with reference to Articles 2, 32 and 117(2)(m) and (3) of the Constitution, the question of the constitutionality of Article 3 of Piedmont Region law No. 21 of 6 November 2007 (Provisions governing the use of psychotropic substances on children and adolescents).

The contested Article 3(1) provides that: "Children and adolescents up to the age of 18 years may only be treated with psychotropic substances, including in particular psychostimulant, antipsychotic, psychoanaleptic, anti-depressant and hypnotic drugs in the region when the parents or guardians express their written, free, informed, current and manifest consent".

Article 3(2) charges the Regional Council with the task of drawing up a form for informed consent, by which the general practitioner, paediatrician, psychiatrist or child neuropsychiatrist provide the information regarding the presumed advantages of the therapy, the side effects of the recommended drug, possible alternative treatments and the procedures for its administration.

Article 3(3) then charges the Council with the identification of means and procedures for promoting the access to alternative or supplementary therapies to the treatments mentioned under sub-section 1.

Finally, Article 3(4) lays down the procedures by which consent to the administration must be given by the parent or guardian concerned.

In the opinion of the applicant, in rendering the treatments mentioned in sub-section 1 subject to the compulsory written consent of the minor's parents or guardians, the provisions mentioned above exceed the shared legislative competence of the region over

healthcare, since the above consent is not required under national legislation for the prescription of narcotic or psychotropic drugs and, in particular, is not contemplated under presidential decree No. 309 of 9 October 1990 (Consolidated law governing narcotic and psychotropic substances and the prevention, treatment and rehabilitation of the various states of drug addiction).

In fact, the applicant considers that the requirement for informed consent is a fundamental principle in the area of “healthcare” and, accordingly, that the stipulation of the situations in which such consent is required is a matter for the state legislature, which in effect has provided for it only in specific cases, such as for example for the clinical trials on humans of medicinal products still pending market authorisation, or for the study of new therapeutic indications for drugs already on the market, or for the donation and receipt of blood and blood components.

Therefore, in rendering the access to specific therapeutic treatment subject to the consent of the patient in situations not contemplated under national legislation and in the absence of any confirmation based on the current state of scientific knowledge, the regional legislature is claimed to have introduced a limit on the ability to prescribe a broad range of medicinal products, subjecting the decision of the doctor to the discretionary judgment of the parents or guardians, with the resulting infringement of the right to healthcare protected under Article 32 of the Constitution, and of the essential levels of service regarding that right, the regulation of which is reserved exclusively to the state under the terms of Article 117(2)(m) of the Constitution.

On this point, the state representative refers to judgment No. 338 of 2003, in which the Court asserted that “to establish the boundary between permitted therapies and non permitted therapies on the basis of scientific and experimental results is a decision which touches directly and necessarily on the fundamental principles in this area of law, 'which is situated at the intersection between two fundamental rights of persons suffering from illnesses: that to be treated effectively, according to the canons of science and the medical state of the art; and that to be respected as a person, in particular with regard to one's

physical and mental integrity', […] the protection of which cannot fail to be given under conditions of fundamental equality throughout the country".

After having noted that the challenges set out above also apply to the provisions contained in sub-section 3 of the contested Article, with regard to sub-section 4 the applicant argues that it breaches Article 2(i) of legislative decree No. 211 of 24 June 2003 (Implementation of directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for clinical [*sic.*] use), which specifies the individuals entitled to give informed consent.

2. – On 31 January 2008 Piedmont Region entered an appearance, requesting that the application be rejected.

As a preliminary matter, the Region observes that no reasons are given in the application regarding the alleged violation of Article 2 of the Constitution and that the challenge to Article 3(3) of the regional law is generic in that it is limited to asserting that the said provision "is subject to the same challenges" brought against the other contested provisions.

On the merits, as regards the alleged violation of the fundamental principles in the area of healthcare, the Region observes that the state legislation governing informed consent is of limited scope since it refers to specific medical activities. Therefore, these laws cannot be elevated to the status of fundamental principles, nor is it possible to infer from them the principle that informed consent may be required only in situations governed by state laws.

The Region argues, by contrast, that the fundamental principles in the area of healthcare are those "characterised by the implementation of quality guidelines for medical assistance which satisfy the requirements of effective and appropriate assistance whilst ensuring respect for the dignity and freedom of the human person".

In particular, according to the Region's representative, there was no violation of Articles 2 and 32 of the Constitution since the contested provisions guarantee the voluntary nature of medical treatment in a humane manner through the actual provision of informed consent to the treatment methods which may be used, possible alternative choices regarding different therapeutic procedures, and the specific risks and advantages associated with the

various techniques and treatments which may be followed, without this entailing any restriction of the autonomy and responsibility of doctors in choosing the best therapy to administer on the basis of scientific knowledge.

As regards the alleged violation of the right to healthcare, the Region notes that the full knowledge and awareness and [provision of] adequate information concerning the most appropriate therapies is intended precisely in order to protect this right.

Finally, there was no violation of Article 117(2)(m) of the Constitution, since the provisions governing informed consent do not relate to medical assistance to be provided on a uniform basis throughout the country.

3. – Shortly before the public hearing, Piedmont Region filed a written statement in which, in addition to restating the arguments already set out in its entry of appearance, it notes that the applicant does not take into account the most recent resolutions of the Italian Pharmaceuticals Agency [*Agenzia Italiana del Farmaco*], which suggested rendering the administration of psychoactive drugs to children subject to the requirement of the signature in advance of an informed consent form entirely similar to that contemplated under the contested provisions, as well as under other regional laws pending approval which contain specific provisions regulating informed consent.

The Region goes on to argue that, by guaranteeing the right to healthcare through the informed access by minors to various therapies, the contested provision operates in accordance with the provisions contained in Article 5 of the United Nations Universal Declaration of Human Rights of 1948 and Article 33 of the United Nations Convention on the Rights of the Child, ratified and implemented in Italy by law No. 176 of 27 May 1991.

Conclusions on points of law

1. – The President of the Council of Ministers challenges Article 3 of Piedmont Region law No. 21 of 6 November 2007 (Provisions governing the use of psychotropic substances on children and adolescents) on the grounds that it violates Articles 2, 32 and 117(2)(m) and (3) of the Constitution.

2. – As a preliminary matter, the Court rejects the objections raised by Piedmont Region that the application is inadmissible.

2.1 – As regards the claim that insufficient reasons are given regarding the alleged violation of Article 2 of the Constitution, it it sufficient to observe that the application refers to this principle in close conjunction with Article 32 of the Constitution when arguing that the contested legislation violates the patient's right to healthcare understood as a fundamental right of the person.

2.2 – As far as the alleged generic nature of the challenge to Article 3(3) is concerned, the fact that in relation to that provision the applicant refers to the arguments already used against the other sub-sections of the same Article appears to be sufficient in order to enable the Court to identify the precise scope of the challenges against it: this is due to the absolute homogeneity and consequential nature of the various provisions contained in Article 3.

3. – The question is well founded on the merits.

The contested provision on the one hand provides that children and adolescents may only be treated in Piedmont Region with psychotropic substances when the parents or guardians express their written, free, informed, current and manifest consent; on the other hand, it charges the Regional Council with the task of regulating the procedures for the issue of the said consent.

In the opinion of the applicant, the provisions referred to violate Article 117(3) of the Constitution, since the informed consent to medical treatment is a fundamental principle in the area of healthcare and therefore the regulation of it is reserved to the state legislature.

The state representative goes on to argue that, by rendering the ability of doctors to administer specific drugs to the requirement that the patient's consent be obtained, the contested provision places a limit on the right to healthcare and, more generally, the receipt of medical assistance, thereby violating Articles 32 and 117(2)(m) of the Constitution.

4. – In this regard, it is important to point out that informed consent, understood as an expression of the informed acceptance of the medical treatment proposed by the doctor, has the status of a full-scale right of the person and is grounded in the principles expressed in Article 2 of the Constitution, which protects and promotes fundamental rights, and Articles

13 and 32 of the Constitution which provide, respectively, that "personal freedom is inviolable" and that "nobody may be forcefully submitted to medical treatment except as provided by law".

Moreover, numerous international law provisions stipulate the requirement for the informed consent of the patient to medical treatment.

In particular, Article 24 of the Convention on the Rights of the Child, signed in New York on 20 November 1989, ratified and implemented by law No. 176 of 27 May 1991, stipulates that the states "recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health", going on to provide that "all segments of society, in particular parents and children, are informed ...of child health and nutrition".

Article 5 of the Convention on Human Rights and Biomedicine signed in Oviedo on 4 April 1997, ratified by Italy by law No. 145 of 28 March 2001 (although the instrument of ratification has not yet been deposited), provides that "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it"; Article 3 of the Charter of Fundamental Rights of the European Union, proclaimed in Nice on December 2000, provides moreover that "everyone has the right to respect for his or her physical and mental integrity" and that in the fields of medicine and biology, amongst other things, in particular "the free and informed consent of the person concerned, according to the procedures laid down by law" must be respected.

The need for the patient to be put in a position to gain knowledge of his course of therapy can also be inferred from various national laws governing specific medical activities: for example, Article 3 of law No. 219 of 21 October 2005 (New provisions governing transfusions and the national production of blood derivatives), Article 6 of law No. 40 of 19 February 2004 (Provisions governing medically assisted procreation), as well as Article 33 of law No. 833 of 23 December 1978 (Establishment of the national health service), which provides that treatment as a rule be voluntary and that nobody may be forcefully submitted to medical treatment unless provided for by law.

The fact that informed consent is grounded in Articles 2, 13 and 32 of the Constitution gives prominence to its role as a synthesis of two fundamental rights of the person – the right to self determination and the right to healthcare – since, whilst it is the case that every person has the right to receive medical treatment, all persons also have the right to receive appropriate information regarding the nature and possible developments of the course of therapy to which they may be subject, as well as any alternative therapies; this information must be as comprehensive as possible, precisely in order to guarantee a free and informed choice by the patient and, therefore, his very personal freedom, in accordance with Article 32(2) of the Constitution.

It follows from the above that informed consent must be regarded as a fundamental principle in the area of healthcare, the substantive regulation of which is reserved to the state legislature. The provisions under review must therefore be declared unconstitutional, since Piedmont Region did not thereby limit itself to enacting detailed provisions governing the procedures for the expression of such consent. Indeed, where the contested Article 3(1) identifies the subjects entitled to provide informed consent (parents or guardians), as well as the procedures according to which it must be given (written, free, informed, current and manifest), it regulates aspects of primary significance of this figure in the area of law concerned, without however any similar provision having been enacted by the state legislature.

Since the other sub-sections of Article 3 are closely related to the provisions contained in sub-section 1, they breach the constitutional provisions cited and the Court therefore declares that they are unconstitutional.

on those grounds

THE CONSTITUTIONAL COURT

declares that Article 3 of Piedmont Region law No. 21 of 6 November 2007 (Provisions governing the use of psychotropic substances on children and adolescents) is unconstitutional.

Decided in Rome, at the seat of the Constitutional Court, *Palazzo della Consulta*, on 15 December 2008.

Signed:

Giovanni Maria FLICK, President

Maria Rita SAULLE, Author of the Judgment

Giuseppe DI PAOLA, Registrar

Filed in the Court Registry on 23 December 2008.

The Director of the Registry

Signed: DI PAOLA