



Corte costituzionale



JUDGMENT NO. 253 OF 2009

Francesco AMIRANTE, President

Maria Rita SAULLE, Author of the Judgment

JUDGMENT NO. 253 YEAR 2009

In this case the Court considered a challenge by the President of the Council of Ministers to a Trento Province law requiring doctors to obtain written informed consent from parents before administering psychotropic substances to children (cf. No. 438 of 2008, relating to similar provisions enacted by Piedmont Region). The Court accepted the application, striking down the contested provisions on the same grounds as in its previous judgment.

THE CONSTITUTIONAL COURT

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

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 4 of Autonomous Province of Trento law No. 4 of 6 May 2008 (Provisions governing the use of psychotropic substances on children and adolescents), commenced by the President of the Council of Ministers by application served on 17-21 July 2008, filed in the Registry on 25 July 2008 and registered as No. 38 in the Register of Applications 2008.

Considering the entry of appearance by the Autonomous Province of Trento;

having heard the Judge Rapporteur Maria Rita Saulle in the public hearing of 7 July 2009;

having heard the *Avvocato dello Stato* Carlo Sica for the President of the Council of Ministers and counsel Franco Mastragostino for the Autonomous Province of Trento.

The facts of the case

1. – By application served on 17-21 July 2008 and filed on 25 July 2008, the President of the Council of Ministers, represented and advised by the *Avvocatura Generale dello Stato*, raised with reference to Article 117(3) of the Constitution as well as Article 9(10) of presidential decree No. 71 of 31 August 1972 (Approval of the consolidated text of constitutional laws concerning the Special Statute for Trentino-Alto Adige), a question concerning the constitutionality of Article 4 of Autonomous Province of Trento law No. 4 of 6 May 2008 (Provisions governing the use of psychotropic substances on children and adolescents).

The contested Article 4 renders the treatment of children and adolescents with psychotropic substances subject to the written, free, informed, current and manifest consent of the parents, notwithstanding the obligation on the attending physician to inform the minor and take account of his wishes, obtaining his consent (sub-section 1).

Sub-section 2 authorises the Provincial Board for Health Services to draw up a form for informed consent.

Sub-section 3 then entrusts the Province with the task of identifying instruments to favour access to alternative therapies to the treatments referred to under sub-section 1.

Finally, sub-section 4 provides that the consent in written form be attached to every prescription of a drug containing psychotropic substances.

In the opinion of the Applicant, the provisions referred to above fall outwith the legislative competence of the Province over hygiene and health, provided for pursuant to Article 9(10) of presidential decree No. 670 of 1972, as well as over the protection of health pursuant to Article 117(3) of the Constitution, which can be relied on in this case “in the light of the equivalence clause laid down by Article 10 of constitutional law No. 3 of 2001”.

In particular, the legislation under examination is stated to violate the constitutional principles indicated on the grounds that it does not comply with the provisions of state

legislation, which provides for informed consent only for specific therapeutic treatments, which do not include those involving the administration of psychotropic substances.

In this way, in the opinion of the *Avvocatura Generale*, the principle by which the practice of medicine is free and may not be controlled has also been violated, since the contested legislation replaces, through the provision for informed consent, the evaluations which the doctor must make with the wishes of the parents or guardian of the patient who, notwithstanding their lack of the necessary knowledge, choose the treatment to which the latter must be subjected.

The state representative observes in fact that the practice of medicine must comply exclusively with the choices made by the state legislature on the basis of technical and scientific evaluations carried out by the appropriate bodies, which make it possible for identical healthcare treatment to be received throughout the country – choices which include informed consent, as a fundamental principle in matters relating to the protection of health.

2. – The Autonomous Province of Trento entered an appearance, requesting that the question be ruled inadmissible or groundless.

3. – Shortly before the hearing, the Autonomous Province of Trento filed a written statement in which, after having argued that the purpose of the contested legislation is that of avoiding the abuse of psychotropic substances through their administration to children and adolescents, it considers the contested provision to be lawful on the grounds that it is a manifestation of its own shared legislative competence over hygiene and health, according to the provisions of Article 9(10) of the local government Statute.

In particular, the Province argues that the informed consent does not place any limit on access to the various healthcare treatments, the regulation of which is reserved to the state legislature on the basis of progress in medical science; however, as an expression of a right of the person, the intention of informed consent is to secure more conscious access to particular therapeutic practices. This consciousness is all the more necessary in cases involving the administration of psychotropic substances to children and adolescents.

Therefore, according to the Respondent, informed consent – as a right strictly pertinent to the specific individual – not only does not prejudice the right to the protection of health but, on the contrary, in fact furthers it by providing conscious access to the individual therapy, and is grounded in various legislative sources including, first and foremost, Article 32 of the Constitution which stipulates that there shall be free access to all medical treatment, except as provided for by the limits imposed by specific statutory provisions.

On this point, again in the opinion of the Province, the National Health Plan 2006–2008 which the regions and autonomous provinces must implement is of significance. In stating as an objective the broadest possible participation of the citizen in therapeutic choices, this plan regards informed consent as an instrument already present within our legal order which must be further promoted. For this reason, the contested legislation, which seeks to achieve precisely the aforementioned goal, cannot be considered unconstitutional.

Finally, the Province observes that, with regard to treatment for attention deficit hyperactivity disorder, the Italian Pharmaceuticals Agency [*Agenzia Italiana del Farmaco*] already makes provision for informed consent, which means that the contested provision is limited to specifying in detail the procedures for obtaining that consent.

In particular, the contested provision is stated to be limited to enacting detailed arrangements, without impinging upon the fundamental core of informed consent as may be inferred from the legislative sources referred to and, in particular, from Article 32 of the Constitution which, in classifying it as a principle with constitutional status, requires local legislatures to implement it.

The Respondent concludes, arguing that Article 4 could violate the constitutional principles relied on only insofar as it provides that consent must be given in writing.

Conclusions on points of law

1. – The President of the Council of Ministers challenges Article 4 of Autonomous Province of Trento law No. 4 of 6 May 2008 (Provisions governing the use of psychotropic

substances on children and adolescents), due to violation of Article 117(3) of the Constitution, as well as Article 9(10) of presidential decree No. 670 of 31 August 1972 (Approval of the consolidated text of constitutional laws concerning the Special Statute for Trentino-Alto Adige).

Sub-section 1 of the contested provision provides that the treatment of children and adolescents with psychotropic substances shall be subject to the written, free, informed, current and manifest consent of the parents, notwithstanding the obligation on the attending physician to inform the minor and take account of his wishes, obtaining his consent.

The following sub-sections provide that the Provincial Board for Health Services shall draw up a form for informed consent and that the Province shall identify appropriate instruments to favour access to alternative therapies to those referred to under sub-section 1, also providing that the consent in written form be attached to every prescription of a drug containing psychotropic substances.

In the opinion of the Applicant, the provisions referred to above fall outwith the legislative competence over hygiene and health conferred on the Province pursuant to Article 9(10) of presidential decree No. 670 of 1972, as well as over the protection of health pursuant to Article 117(3) of the Constitution, which can be relied on in this case “in the light of the equivalence clause laid down by Article 10 of constitutional law No. 3 of 2001”.

2. – The question is well founded.

As this Court already asserted in judgment No. 438 of 2008 – in which it declared unconstitutional Article 3 of Piedmont Region law No. 21 of 6 November 2007 (Provisions governing the use of psychotropic substances on children and adolescents), which contained legislation highly similar to that under examination – informed consent has the status of a fundamental principle in matters concerning the protection of health by virtue of its role as a synthesis of two fundamental rights of the person: the right to self-determination and the right to healthcare.

It follows from this that the regional legislature cannot enact legislation regulating aspects concerning the individuals that are entitled to provide their informed consent, as

well as the forms for its provision, since they do not amount to detailed arrangements relating to the principle under examination, but concern its very fundamental structure which, as such, is reserved to the competence of the state legislature.

The arguments adopted in the judgment referred to may be used in full also with reference to the provision at issue in these proceedings since, in conferring shared legislative competence over hygiene and health on the Province of Trento, Article 9 of the local government Statute of Trentino-Alto Adige does not expand the sphere of legislative competence of the same compared to that of regions governed by ordinary statute.

In fact, in specifying the limits under which the aforementioned competence may be exercised, Article 9 refers to Article 5 of the Statute, which expressly provides that the provincial legislature must, *inter alia*, respect the “principles laid down by laws of the state”.

The Court therefore finds that Article 4(1) of the law in question is unconstitutional since, in specifying the individuals who may consent to the treatment of children and adolescents with psychotropic substances as well as the forms for its provision, the Province thereby exceeded the limits of its own legislature competence.

Given their inseparable connection with sub-section 1, the following sub-sections also violate the constitutional principles referred to, and must therefore also be declared unconstitutional.

ON THOSE GROUNDS

THE CONSTITUTIONAL COURT

declares that Article 4 of Autonomous Province of Trento law No. 4 of 6 May 2008 (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 23 July 2009.

Signed:

Francesco AMIRANTE, President

Maria Rita SAULLE, Author of the Judgment

Giuseppe DI PAOLA, Registrar

Filed in the Court Registry on 30 July 2009.

The Director of the Registry

Signed: DI PAOLA