medstra-online.de case note 3/2015

Access to an experimental treatment according to the right to respect for private life

Durisotto v. Italy (ECHR May 6th 2014, appl. no. 62804/13) – access to experimental treatment: personal autonomy versus the protection of health (Article 8 ECHR, right to respect for private life)

Dave van Toor LLM BSc, Univ. Bielefeld

1. The facts (paragraphs 1-3)

The admissibility decision of the second Chamber of the ECHR in the case of Durisotto is worth mentioning because of two reasons. First, the Court has to examine for the second time in two years a complaint because a State refuses to comply with a request to grant excess to an *experimental* therapeutic method (Durisotto) and a not registered medicine (ECHR November 13th 2012, appl. nos. 47039/11 & 358/12, Hristozov and others v. Bulgaria). Secondly, the case is interesting because the Court uses the notions of personal autonomy and quality of life, which are core concepts in health law, in balancing the right to respect for private life versus the right of the State to interfere with the right of privacy to pursue the legitimate aim of the protection of health (to prohibit potentially dangerous pharmaceuticals and health methods). The applicant in Durisotto is the father and legal guardian of his daughter (born 1975) who had been suffering since adolescence from a rare, genetic degenerative cerebral illness (metachromatic leukodystrophy). The applicant complains about violation of Articles 2, 8 and 14 (right to life, right to respect for privacy and prohibition of discrimination) because several courts and hospitals did not allow his daughter access to an experimental method (called the Stamina method) to treat the metachromatic leukodystrophy.

2. Relevant domestic law (paragraph 12-24)

The Italian Medicines Agency had closed down the Stamina operations in August 2012 on safety grounds. In March 2013, the government issued a Legislative Degree (no. 24/2013) allowing patients to continue Stamina treatment if they had already begun treatment prior to the decision to shut down operations in August 2012. On 11 September 2013, an expert committee appointed by the Health Ministry to examine the Stamina method, concluded that there was no scientific evidence to indicate that the Stamina method might be beneficial for patients with metachromatic leukodystrophy and issued a warning about the safety of the Stamina method. With encouragement from the president of the Stamina foundation, some patients appealed to courts for the right to treatment with the method. Some judges ruled that the treatment should be given on compassionate grounds, while others — including the judge in the Durisotto case — ruled that compassionate therapy was

not justified because there was no scientific evidence of efficacy. Durisotto brought his appeal to the European Court of Human Rights on 28 September 2013, a month after losing his case in Italy.

3. Violation of Article 2 and Article 8 in combination with Article 14 of the Convention (paragraph 42-50)

The Court doesn't handle the complaint about violation of the right to life, but without any argumentation. Most likely because the daughter still lives so the right to life is not violated (yet), due to the refusal to the Stamina method. (However, this leaves an option for the applicant to file another complaint in the near future.) The complaint about the violation of right to privacy in combination with the prohibition of discrimination is rejected because the complaint is, according to the Court, manifestly ill-founded (Article 35 (3) ECHR). The complaint raises the question about access to the treatment for other metachromatic leukodystrophy patients, but not for the applicants daughter. The Court observers firstly that the cases with which the applicant compares his daughters case are not of a similar nature. A difference in treatment is only discriminatory if the decision is not based on objective and reasonable justification. Access to the Stamina method in Italy is only allowed if the treatment started before August 2012, when the Ministry issued a warning about the method. The applicant's daughter did not start treatment before the Degree prohibiting treatment with the Stamina method, in contrast to some other patients. Secondly, the Court observes that "*the fact that some national courts have authorized access to this therapy to other persons in a state of allegedly similar to the applicant's daughter health is not severe enough to characterize a breach of Article 14 of the Convention taken together with Article 8 of the Convention* (translation DvT, paragraph 49)."

4. Interference with Article 8 (1) of the Convention (paragraph 31-33)

As regards to the complaint about the violation of the right to respect for privacy, the Court firstly notes that the inability of the applicant's daughter to access the Stamina therapy clearly calls for an inquiry in terms of section 8 of the Convention. Access to treatment falls within the scope of the right to respect for her private life.[1] The interpretation regarding the notion of 'private life' is underpinned by notions of personal autonomy and quality of life.[2]

[1] See inter alia ECHR February 6th 2001, appl. no. 44599/98 (Bensaid v. the United Kingdom) and ECHR April 30th 2009, appl. no. 13444/04 (Glor v. Switzerland) and ECHR September 12th 2012, appl. no. 10593/08 (Nada v. Switzerland).

[2] See also ECHR April 29th 2002, 2346/02, 7 (Pretty v. the United Kingdom) and ECHR November 13th 2012, appl. nos. 47039/11 & 358/12 (Hristozov and others v. Bulgaria).

The right to respect for privacy contains for the most important part respect for personal autonomy about (the quality of) their own lives. In other words, citizens should be autonomous in two senses of the concept 'autonomy', firstly in the sense of independent choice and secondly that the choice can be based on their own preferences (autonomy as agency or deliberate autonomy). Personal autonomy is then further divided in 'personal identity'[3] and 'personal development'[4]. To decide autonomously about (quality of) life issues, a person has (1) to develop personal preferences and a personality and (2) should be given space to express their preferences. An essential object of Article 8 is to protect the individual against arbitrary interference by the public authorities in making choices in life.[5] In the case of Durisotto the complaints are raised in specific about the, in view of the applicant, arbitrary interference of the Italian Courts to forbid access to the Stamina method on basis of personal preferences to improve the quality of life for his daughter.

5. Justification of the interference under Article 8 (2) of the Convention (paragraph 34-41)

The right to respect for private life can be restricted when the restriction is 'in accordance with the law', pursued 'a legitimate aim' and 'is necessary in a democratic society' (Article 8 (2) ECHR). In the present case, the Court considers that the interference was prescribed by law, namely the Legislative Decree 24/2013 (mentioned above) and pursued a legitimate aim, namely in protecting the health of individuals against experimental and possible dangerous medical treatment. As regards to the necessity of the Law, the question arises whether a fair balance has been struck between the competing interests of the individual and the community.

In this context, the Court recalls that in case of denial of access to compassionate care given to those affected by serious diseases people, the discretion of the Member States is ample. The Court assesses the reasonableness of restrictions of fundamental rights, including the right to respect for privacy, with some reluctance. States have, in establishing legitimate breaches of the right to respect for privacy, a margin of appreciation.[6] However, the width of

---

[3] See inter alia ECHR July 11th 2002, appl. no. 28957/95 (Christine Goodwin v. the United Kingdom) and ECHR March 15th 2012, appl. no. 4149/04 & 41029/04 (Aksu v. Turkey).

[4] See inter alia ECHR February 6th 2001, appl. no. 44599/98 (Bensaid v. the United Kingdom) and ECHR June 12th 2003, appl. no. 35968/97 (Van Kuck v. Germany) and ECHR January 12th 2010, appl. no. 4158/05 (Gillan & Quinton v. the United Kingdom) and ECHR July 17th 2012, appl. no. 2913/06 (Munjaz v. hthe United Kingdom).

[5] See inter alia ECHR December 4th 2008, appl. nos. 30562/04 & 30566/04 (S. & Marper v. the United Kingdom) and ECHR December 13th 2012, appl. no. 39630/09 (El-Masri v. the Former Yugoslavian Republic of Macedonia) and ECHR November 12th 2013, appl. no. 5786/08 (Söderman v. Sweden).

[6] D.J. Harris, M. O'Boyle, E.P. Bates & C.M. Buckley, *Harris, O'Boyle & Warbrick: Law of the European Convention on Human Rights*, Oxford: Oxford University Press 2009, p. 11 and S. Greer, 'The Interpretation of the European Convention on Human Rights: Universal Principle or Margin of Appreciation?', *UCL Human Rights Review* 2010, 3, p. 2.

the margin of appreciation is not always equal for each theme.[7] As a supranational body, the ECHR has to deal with complaints from Member States with very different legal and economic systems and socio-cultural societies. The authorities of the Member States themselves are often better legitimized and equipped than the ECHR to balance the interests at issue. This is the so called 'better placed' argument or 'better rationale-position'.[8] Themes with a wide margin for Member States include the overall political policy,[9] the economic-political choices,[10] spatial planning[11] and the establishment of an educational[12] and, for this matter of great importance, health care system[13]. The Court considers in Durisotto as follows: "*it is not the international judge to substitute for competent authorities to determine the acceptable level of risk by patients seeking access to compassionate care in the context of an experimental therapy* […] *The interference in the right of the applicant's daughter to respect for his private life may be thus considered necessary in a democratic society* (translation DvT, paragraph 40-41)." In other words, the ECHR does not feel himself well placed to make a judgment about national choices to allow or prohibit certain treatments and therefore ruled that Italy has acted within its margin of appreciation.

According to the Durisotto case (and also the previously cited case of Hristozov (in paragraphs 125-127) can be concluded that the interests of the protection health against unregistered medicines (Hristozov) or experimental treatments (Durisotto) are more important than personal autonomy and quality of life. Secondly, the margin of appreciation that a State is due to choose, create and maintain the health system as he sees fit, is very wide.[14]

---

[7] D.J. Harris, M. O'Boyle, E.P. Bates & C.M. Buckley, *Harris, O'Boyle & Warbrick: Law of the European Convention on Human Rights*, Oxford: Oxford University Press 2009, p. 13.

[8] I. de la Rasilla del Moral, 'The Increasingly Marginal Appreciation of the Margin-of-Appreciation Doctrine', *GLJ* 2006, 6, p. 618.

[9] ECHR May 20th 2014, appl. no. 4241/12, r (McDonald v. the United Kingdom).

[10] ECHR July 16th 2014, appl. no. 60642/08 (Alisic and others v. Bosnia, Croatia, Serbia, Slovenia and the Former Yugoslavian Republic of Macedonia).

[11] ECHR April 24th 2012, appl. no. 25446/06 (Yordanova and others v. Bulgaria).

[12] ECHR June 12th 2014, appl. no. 56030/07 (Fernández Martínez v. Spain).

[13] ECHR May 20th 2014, appl. no. 4241/12 (McDonald v. the United Kingdom).

[14] "*In view of the authorities' broad margin of appreciation in this domain, the Court considers that regulatory solution did not fell foul of Article 8. It is not for an international court to determine in place of the competent national authorities the acceptable level of risk in such circumstances. The salient question in terms of Article 8 is not whether a different solution might have struck a fairer balance, but whether, in striking the balance at the point at which they did, the Bulgarian authorities exceeded the wide margin of appreciation afforded to them (see, mutatis mutandis, Evans, § 91, and S.H. and Others v. Austria, § 106, both cited above). In view of the considerations set out above, the Court is unable to find that they did.*" ECHR November 13th 2012, appl. nos. 47039/11 & 358/12 (Hristozov and others v. Bulgaria).