

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FIRST SECTION

DECISION

Application no. 17101/17
Lucyna Agata SMOLARKIEWICZ and Marek SMOLARKIEWICZ
against Poland

The European Court of Human Rights (First Section), sitting on 10 January 2023 as a Committee composed of:

Lətif Hüseynov*, President*,
Krzysztof Wojtyczek,
Erik Wennerström*, judges*,

and Liv Tigerstedt, *Deputy Section Registrar,*

Having regard to:

the application (no. 17101/17) against the Republic of Poland lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") on 23 February 2017 by two Polish nationals, Ms Lucyna Agata Smolarkiewicz and Mr Marek Smolarkiewicz, who were born in 1969 and 1968 respectively and live in Kórnik ("the applicants"), and who were represented by Ms P.D. Kieszkowska-Knapik, a lawyer practising in Warszawa;

the decision to give notice of the application to the Polish Government ("the Government"), represented by their Agent, Mr J. Sobczak of the Ministry of Foreign Affairs;

the parties' observations;

Having deliberated, decides as follows:

SUBJECT MATTER OF THE CASE

1. The present application was lodged by parents whose son had died following the decision of the panel of experts on ultra-rare diseases to discontinue financing of their son's treatment with a very expensive drug.

2. The applicants' son, M., was born in 1996. In 2001 he was diagnosed with mucopolysaccharidosis type II ("MPS II"), a rare genetic disorder also known as Hunter syndrome.

3. In 2009 M. was included in a programme run by the National Health Fund (*Narodowy Fundusz Zdrowia* – "the NHF") relating to the treatment of MPS II and was prescribed an enzyme replacement therapy involving a drug called Elaprase.

4. M.'s treatment was monitored by the Panel of Experts on Ultra-Rare Diseases (*Zespół Koordynacyjny do spraw Chorób Ultrarzadkich* – "the Panel"). His condition was reviewed every six months by this group of experts and on each occasion detailed reports were prepared.

5. In their reports of 15 November 2010, 27 February 2012, 3 September 2012 and 5 March 2013 the experts stated that M. had tolerated Elaprase well and that no adverse effects had been observed. They also noted several beneficial effects. However, in subsequent reports prepared in March and August 2014, it was observed that the positive changes in M.'s condition had been less significant than previously described. In a report of February 2015 positive changes were again noted, as well as the lack of deterioration of his neurological functions.

6. In a letter of 14 May 2015, headed "certificate" (*zaświadczenie*), the Panel informed the hospital treating M. that it had decided to discontinue the enzyme replacement therapy which he had been undergoing. The experts briefly stated that the treatment with Elaprase had not had any beneficial impact on M.'s health.

7. The doctor in charge of the boy's treatment complained about that decision. She argued that M.'s neurological and mental-health functions had improved as a result of the treatment with Elaprase. She further submitted, relying on results of clinical research, that discontinuation of the enzyme replacement therapy would most probably cause a significant deterioration in M.'s condition and, in consequence, his death.

8. On 14 July 2015 the Panel confirmed its decision to discontinue the treatment in respect of the applicants' son. The experts noted that some of the improvements in M.'s physical condition could have been natural physical developments linked to growing up and going through puberty. They stated that as Elaprase does not penetrate the brain it could not have caused any improvement in M.'s neurological condition. They concluded, referring to medical opinions, that the enzyme replacement therapy had not caused any significant change in M.'s condition.

9. On 14 August 2015 the applicants applied on their son's behalf to the NHF in order to confirm his entitlement to health care financed from public funds.

10. In reply, on 16 September 2015 the Head of the Wielkopolska Regional Branch of the NHF (*Dyrektor Wielkopolskiego Oddziału Wojewódzkiego NFZ*) informed the applicants that their son was entitled to care provided by the national health service. However, decisions regarding specialised therapy, including whether he was to be included in the enzyme replacement therapy programme, were to be taken by the Panel.

11. Upon appeal by the applicants, on 15 January 2016 the Head of the Department of Drug Management of the NHF (*Dyrektor Departamentu Gospodarki Lekami NFZ*) informed the applicants that no administrative decision in their case had been issued, and therefore their appeal was unfounded. The letter of 16 September 2015 had merely contained information about their son's general situation as regards national healthcare.

12. The applicants lodged an appeal with the Warsaw Regional Administrative Court (*Wojewódzki Sąd Administracyjny*) which, in a decision (*postanowienie*) of 16 August 2016, rejected the applicants' appeal as inadmissible in law. The court held that the letter of 15 January 2016 did not constitute an administrative decision and therefore could not be challenged before an administrative court. The decision was served on the applicants' lawyer on 25 August 2016.

13. The applicants' son died on 3 September 2016.

14. The applicants submitted that they had not lodged a cassation appeal with the Supreme Administrative Court (*Naczelny Sąd Administracyjny*) because their son had died during the period allowed for appealing.

15. The applicants complained under the procedural limb of Article 2 and under Article 13 of the Convention about the organisational and procedural shortcomings in the functioning of the Panel which had made the decision to discontinue the financing of their son's treatment.

THE COURT'S ASSESSMENT

16. The Government raised several preliminary objections. They argued that the application was incompatible *ratione materiae* with the Convention, and that the applicants had lodged their application after the expiry of the six-month time-limit, which, in their view, should be calculated from the decision of the Panel, that is, 14 July 2015. They also argued that the applicants had not exhausted domestic remedies because they had failed to lodge a cassation appeal against the decision of the Warsaw Administrative Court of 16 August 2016, had failed to appeal against the Panel's ruling and had not availed themselves of a civil or disciplinary action against the doctors concerned.

17. The Court does not find it necessary to rule on all of the Government's preliminary objections since it considers that in any event the application is inadmissible for failure to comply with the six-month requirement.

18. The gist of the applicants' complaint is the discontinuance of financing the treatment of their son. The relevant ruling was made by the Panel on 14 May 2015 and confirmed on 14 July 2015 (see paragraphs 6 and 8 above).

19. According to the Court's case-law, where it is clear from the outset that the applicant has no effective remedy, the six-month period runs from the date on which the act complained of took place or the date on which the

applicant was directly affected by or became aware of such an act or had knowledge of its adverse effects (*Varnava and Others v. Turkey* [GC], nos. 16064/90 and 8 others, § 175, ECHR 2009, and *Aydarov and Others v. Bulgaria* (dec.) no. 33585/15, § 90, 2 October 2018). Where an applicant avails himself or herself of an apparently existing remedy and only subsequently becomes aware of circumstances which render the remedy ineffective, it may be appropriate to take the start of the six-month period from the date when the applicant first became or ought to have become aware of those circumstances (*Varnava and Others*, cited above, §§ 157-158, and *Jeronovičs v. Latvia* [GC], no. 44898/10, § 75, 5 July 2016).

20. The Court considers that in the present case it was or should have been clear to the applicants at the outset that no administrative decision was issued in their case and that no appeal was available in law to challenge the Panel's conclusion to discontinue the treatment. At the very latest, this should have been apparent to them when they received the reply, dated 16 September 2015, from the Head of the Wielkopolska Regional Branch of the NHF (see paragraph 11 above). Therefore, their attempts to have administrative proceedings introduced cannot be considered as extending the time-limit to lodge their application with this Court.

21. The applicants applied to the Court on 23 February 2017, thus after the expiry of the six-month time-limit calculated either from 14 July 2015, the date on which the Panel's ruling became known to them, or 16 September 2015, the date of the letter by the Head of the Wielkopolska Regional Branch of the NHF. It follows that the application is inadmissible and must be rejected in accordance with Article 35 §§ 1 and 4 of the Convention.

For these reasons, the Court, unanimously,

Declares the application inadmissible.

Done in English and notified in writing on 2 February 2023.

Liv Tigerstedt Deputy Registrar	Lətif Hüseynov President