Alternative medical treatments and compassionate use

25 September 2019 | Contributed by Preslmayr Attorneys at Law

Healthcare & Life Sciences, Austria

- **Facts**
- **First-instance and appeal decisions**
- **Supreme Administrative Court decision**
- **Comment**

Patients who are beyond treatment under the standards of conventional medicine often seek help from alternative medical treatments; however, these methods pose not only medical risks for patients, but also legal risks for doctors.

Facts

A surgeon with qualifications in vascular, heart and thorax surgery treated seriously ill patients using an innovative method. The patients suffered from morbus Parkinson, multiple sclerosis, various forms of myatrophy and paralysis, traumatic spinal cord injuries, macular degenerations or psychiatric impairments such as autism. All of the patients were beyond treatment under the standards of conventional medicine. The surgeon treated them with stem cell therapy.

First-instance and appeal decisions

In April 2014 the Viennese Administrative Authority fined the surgeon under Section 49(1) of the Act on the Medical Profession for failing to observe patient welfare – namely, for not evaluating the side effects and counterindications of using stem cell therapy to treat the abovementioned conditions.

In July 2015 the Viennese Administrative Tribunal**(1)** partly confirmed this decision. The tribunal ruled that potential health risks cannot be withheld from patients.

Supreme Administrative Court decision

On appeal, the Supreme Administrative Court**(2)** overruled the Viennese Administrative Tribunal's decision. The court held that the administrative tribunal had accused the surgeon of regularly using autologous stem cell therapy as a new treatment, even though clinical studies had yet to determine its benefits and risks.

According to the court, stem cells fall within the definition of medicinal products under Section 1 of the Medicinal Products Act.**(3)** The court could therefore revert to the doctrine and precedents on the off-label use of medicinal products. In its view, the tribunal had not shown that the treatment was clearly prohibited. Further, without a prohibition on the off-label use of medicinal products with marketing authorisation, such a prohibition cannot be based on the Medicinal Products Act. Therefore, an infringement of "compliance with existing rules according to sec 49 (1) Act on the Medical Profession" was not obvious.

The use of medicinal products or treatments that have not been clinically evaluated in terms of benefit-risk ratio for certain (new) indications is referred to as 'compassionate use'. The Declaration of Helsinki on ethical principles for medical research involving human subjects states as follows:

> *Unproven interventions in clinical practice*
>
> *37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.*

According to legal literature, compassionate use is a deviation from medical standards in special treatment situations, either because the standard is unhelpful or no standard for the special treatment is available. Unlike clinical studies, it refers to individual cases and not to a clinical sample.

Under Section 49(1) of the Medical Profession Act physicians must observe the rules of medical science; however, these rules are only guidelines with respect to patient welfare insofar as it is possible to go beyond conventional medicine. Therefore, Section 49(1) does not prohibit compassionate use for patients who are beyond therapy under conventional medicine if they are comprehensively informed and the compassionate use makes objective sense.**(4)**

There is no legal definition of 'compassionate use' and no Supreme Court precedents in this regard. On 13 February 1956 the German Federal Court ruled**(5)** that a method of treatment is a clinical study and not a compassionate use if the method is applied not primarily in the interests of treating a patient, but in the interest of scientific research. A new method of treatment may be applied if the responsible medical evaluation and comparison of the expected benefits and risks of the new method with the standard treatment under consideration justify its application.**(6)**

New methods may be used only on patients who are fully informed that said methods imply unknown risks. Further, patients must be able to evaluate and consent to (or not) said risks.**(7)**

In the case at hand, all of the surgeon's patients were beyond treatment such that, according to the medical standard, no successful cure could be expected at the time of the treatment.

The Viennese Administrative Tribunal failed to establish that the applied treatment had posed a danger to the patients; rather, it stated only that health risks cannot be excluded without clinical studies. The tribunal reproached the applicant for integrating the method of treatment into regular clinical operations. Compassionate use that is legitimate in individual cases becomes illegitimate if it is adopted in regular clinical operations, as it becomes a regular treatment with an unverified method. This further implies that the person administering the treatment has applied it in multiple cases. It is unclear whether the application of a new therapy on a larger number of patients excludes the qualification of the treatment as compassionate use.

Insofar as the Viennese Administrative Tribunal questioned the surgeon's claim to have evaluated the risks of stem cell therapy in each case, the tribunal lacked evidence to evaluate the types of risk that would prohibit compassionate use. Further, the tribunal failed to establish the circumstances and specific patient information that would prohibit compassionate use. Therefore, the Supreme Administrative Court set aside the Viennese Administrative Tribunal's decision.

Comment

The Supreme Administrative Court's decision appears to favour a liberal approach to new therapies and compassionate use and enhances the possibilities for developing new therapies and alternative medicines in future. However, patient welfare remains paramount for qualifying a new method as compassionate use.

For further information on this topic please contact Rainer Herzig at Preslmayr Attorneys at Law by telephone (+43 1 533 16 95) or email (herzig@preslmayr.at). The Preslmayr Attorneys at Law website can be accessed at www.preslmayr.at.

Endnotes

(1) VGW-001/047/26739/2014-28.

(2) 24 April 2019, RA 2015/11/0113.

(3) Kopecky, *Stammzellenforschung in Österreich*, 2008, 269.

(4) Resch and Wallner, *Handbuch Medizinrecht* (second edition), 2015, 222.

(5) III ZR 175/54.

(6) German Federal Court of Justice, 13 June 2006, VI ZR 323/04.

(7) German Federal Court of Justice, 13 June 2006, VI ZR 323/04 and Federal Court of Justice, 27 March 2007, VI ZR 55/05.

Rainer Herzig