

Balancing the right to reimbursement of medication and obligation of vaccination with other rights and freedom in the Supreme Administrative Court's (Poland) case law

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Introduction

▶ **The Constitution of the Republic of Poland of 2nd April, 1997** (published in Law Journal No. 78, item 483)

▶ Art. 68

1. **Everyone shall have the right to have his health protected.**
2. **Equal access to health care services, financed from public funds, shall be ensured by public authorities to citizens, irrespective of their material situation. The conditions for, and scope of, the provision of services shall be established by statute.**
3. **Public authorities shall ensure special health care to children, pregnant women, handicapped people and persons of advanced age.**
4. **Public authorities shall combat epidemic illnesses and prevent the negative health consequences of degradation of the environment.**
5. **Public authorities shall support the development of physical culture, particularly amongst children and young persons.**

I. Reimbursement of medications case law

- ▶ The legal vacuum in the system of medicines reimbursement until 2017:
- ▶ the Act of 12 May 2011 on Reimbursement of Medications, Foodstuffs Intended for Particular Nutritional Uses, and Medical Devices (Law Journal of 2015 item 345 with further amendments)

Art. 39 sec. 1

- ▶ „ A medication without market authorisation in the Republic of Poland, imported in accordance with the conditions and procedure provided for in Article 4 of Act of 6 September 2001 - Pharmaceutical Law as well as a foodstuff intended for particular nutritional uses referred to in Article 29a of Act of 25 August 2006 on Food and Nutrition Safety may be issued after the beneficiary settles the flat-rate payment referred to in Article 6.2 (2) for a unit package, provided that the minister responsible for health has granted consent to reimburse such products.”

The judgement of the Supreme Administrative Court of 21 of February 2017, II GSK 4768/16

- ▶ Facts: A minor K. M. suffered from a TRAPS syndrome. He applied to the Minister of Health for a consent to reimburse a specific medicine on the basis of art. 39 sec. 1 of the Act on Reimbursement of Medications.
- ▶ The Minister of Health granted a consent to import the medicine **but he refused to reimburse the medicine**, stating that it was approved for trade on the territory of Poland (got a market authorisation).

The judgement of the Supreme Administrative Court of 21 of February 2017, II GSK 4768/16*

The Court held that:

- ▶ *Article 39(1) of the Act on Reimbursement applies not only to a medicine without marketing authorisation, but by reference to Article 4 (9) of the Pharmaceutical Act in conjunction with Article 68(1) and (2) of the Constitution of the Republic of Poland, it also applies to a medicine with marketing authorisation if the conditions stipulated in Article 4(9) of the Pharmaceutical Act.*

- ▶ Art. 4(9) of Pharmaceutical Act:

The minister in charge of health [...] may, in the event of a natural disaster or other **threat to human or animal life or health**, **grant permission to import** from abroad, in accordance with the conditions set forth in paragraphs 2 and 3, a medicinal product that simultaneously:

- 1) holds an authorization referred to in Article 3 (1) or (2),
- 2) is authorized for marketing in the country from which it is imported,
- 3) is unavailable on the territory of the Republic of Poland

- provided that there is no medicinal product available in the territory of the Republic of Poland containing same or the same active substances, the same strength and form as the imported medicinal product.

* and also in the judgements of: 6th October 2016, II GSK 2765/16; 6th December 2017, II GSK 2805/17 and others

„*In dubio pro vita humana*”

- ▶ All possible doubts concerning the protection of the human life should be resolved in a favour of this protection - “in dubio pro vita humana” - the judgements: of 21 of February 2017, II GSK 4768/16; of 6th October 2016, II GSK 2765/16; of 6th December 2017, II GSK 2805/17 and others
- ▶ Protection of health is closely related to the protection of life, and the right to life (art. 2 CFR) and human dignity (art. 1 CFR). The right to health is primarily the right to preserve life and protect it when it is threatened.
- ▶ This interpretation takes account of a situation in which, in the exercise of its **right to economic freedom**, no trader is interested in marketing the medicinal product in question or in submitting an application for reimbursement.
- ▶ **Article 35 CFR with conjunction with art. 1 and 2 of CFR prevailed in the proces of interpretation of the national law**
 - ▶ *Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.*

II. An obligation of vaccination case law

- ▶ Art. 5 sec. 1 (2b) of the Act of 5 December 2008 on prevention and control of infections and contagious diseases in humans (Law Journal 2020 item 1845):
 - ▶ *Persons residing in the territory of the Republic of Poland are obliged, under the terms of the Act, to receive a preventive vaccination.*
- ▶ **REGULATION OF THE MINISTER OF HEALTH of 18 August 2011 on mandatory preventive vaccination (Law Journal 2018 item 753) which specifies i.a.:**
 - ▶ *the list of communicable diseases covered by the obligation of preventive vaccination and*
 - ▶ *persons or groups of persons obliged to undergo obligatory protective vaccinations against infectious diseases, age and other circumstances constituting the premise for imposing the obligation of protective vaccinations on these persons.*

The Supreme Administrative Court judgements on vaccination obligation (1/3)

- ▶ The necessity to carry out the obligation to subject a minor to obligatory preventive vaccinations does not contradict Article 8 paragraph 1, Article 31 paragraph 2, Article 47 of the Constitution of the Republic of Poland and **Article 8 paragraph 1 of the Convention for the Protection of Human Rights and Fundamental Freedoms**. On the contrary, Article 68 Section 4 of the Constitution imposes an obligation on public authorities to combat epidemic diseases and prevent adverse health effects of environmental degradation. This obligation does not conflict with respect for the private and family life of the individual, and therefore the matter concerning preventive vaccination is not in any way connected with the sphere of individual privacy.
- ▶ *The Supreme Administrative Court's judgement of 19 December 2018, II OSK 2546/18*

The Supreme Administrative Court judgements on vaccination obligation (2/3)

- ▶ Regulations on compulsory preventive vaccination in the Polish legal system does not infringe Articles 8(2) and 31(2) of the Polish Constitution and Article 8(1) of the Convention for the Protection of Human Rights and Fundamental Freedoms, including in particular the right to respect for private and family life, the principle of direct application of the provisions of the Constitution and the principle that a person's freedom is subject to legal protection.
- ▶ **the principle of proportionality** - limitations on the exercise of freedoms and rights may be established by statute when they are necessary to protect **health** or the freedoms and rights of other persons (art. 31 sec. 3 of the Polish Constitution). **Compulsory vaccination falls within the scope of this principle.**
- ▶ *The Supreme Administrative Court's judgement of 26 February 2020, II OSK 873/18*

The Supreme Administrative Court judgements on vaccination obligation (3/3)

- ▶ There is a clash between two individual and general interests, which requires **the principle of proportionality** to be taken into account.
- ▶ The obligation to vaccinate stems directly from the law (a condition of the principle of proportionality)
- ▶ An appropriate mechanism prior to vaccination, i.e. a qualifying examination to determine whether there are any contraindications to vaccination in a given individual case prevents a violation of human rights, freedoms and dignity.

- ▶ *The Supreme Administrative Court's judgement of 17 October 2018, II OSK 2524/16*

The latest ECHR judgement - CASE OF VAVŘIČKA AND OTHERS v. THE CZECH REPUBLIC (appl. No. 47621/13 and 5 others)

- ▶ no violation of Article 8 (right to respect for private life) of the European Convention on Human Rights
- ▶ The measures complained of by the applicants, assessed in the context of the national system, had been in a **reasonable relationship of proportionality** to the legitimate aims pursued by the Czech State (to protect against diseases which could pose a serious risk to health) through the vaccination duty.