

Administrative Liability for Vaccination with an Age-Inappropriate SARS-CoV-2 Vaccine: Latvian Experience

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Abstract

The duty of ensuring epidemiological safety, including the duty to ensure vaccination against SARS-CoV-2 to people, is included in the framework of the national constitutional rights. The healthcare institutions providing vaccination and medical practitioners performing vaccination are one of the key assets of the national health care system, to whom the duty in the field of public health and protection of lives that is a part of human rights have been delegated. Violation of the epidemiological safety requirements in the Republic of Latvia, if it may cause a risk to human health, is subject to a fine. In this study, the authors have analysed the administrative offence cases, in which administrative liability has been imposed on medical institutions for performing vaccination with age-inappropriate vaccine, explain separation of administrative liability from criminal liability in such cases, reveal compensation mechanisms in the event of consequences, when inappropriate vaccination has caused harm to persons' life or health. The results of the research show that no appropriate security measures have been introduced in the medical institutions to prevent or avoid administrative offences in particular cases, as the result medical institutions were subject to first-time application of administrative liability. Besides, there are lack sufficiently secure system for the examination and registration of patients in the medical institutions. The minor patients were unsecured and have been vaccinated with an inappropriate vaccine, because a specific (non appropriate) vaccine has been requested by the minors' parents or the minors themselves.

Keywords

administrative liability – medical practitioner – SARS-CoV-2 – patient – vaccination

1 Introduction

The purpose of the vaccines against Covid-19 infection is to protect people from disease, which is caused by the new coronavirus SARS-CoV-2, by promoting protective response of the body. The current Covid-19 infection pandemic caused by the coronavirus disease is a global crisis with devastating effects on human health, social processes and the economy. Covid-19 infection may cause severe disease and even death of people of all age groups, including those having no other diseases. Moreover, its long-term effects on human health are currently unknown. Vaccination against Covid-19 infection is necessary to protect everyone from this disease.¹

The main objective of the Covid-19 vaccination strategy in the Republic of Latvia is to ensure continuous functioning of the health care system, to reduce the burden of mortality and morbidity on the health care system and to achieve collective immunity (from the informative report “On the Implementation of Covid-19 Vaccination Strategy” considered at the sitting of the Cabinet of Ministers on December 1, 2020). The rate of spread of Covid-19 infection is related to the extent of the restrictions, the overall morbidity in the countries, which are visited often by the nationals, and possible virus mutations. In turn, the share of persons to be vaccinated is also closely related to the wish of persons to be vaccinated. In order to achieve the objectives of Covid-19 vaccination, it is crucial that the society is involved in the vaccination process.²

In accordance with the case-law of the European Court of Human Rights, vaccination of children is generally considered to be an integral part of public health policy, moreover, it follows from Articles 2 (Right to life) and Article 8 (Right to respect for private and family life) of the European Convention for the Protection of Human Rights and Fundamental Freedoms that the states have a positive obligation to take measures to protect human life.³

1 J. Bordāns, *Informatīvais ziņojums “Iespējamie vakcinēšanās pret Covid-19 infekciju motivējošie līdzekļi” (Possible motivating agents for vaccination against Covid-19 infection)*, available online at tap.mk.gov.lv/doc/2021_04/TM_InfoZin_vakcin_motivac_260.972.docx.

2 *Ibid.*

3 *Vavříčka v. the Czech Republic* (Application No 47621/13 and 5 others), ECHR (2021), available online at <https://hudoc.echr.coe.int/fre#%7B%22itemid%22:%5B%22001-209039%22%5D%7D>).

The obligation to ensure epidemiological safety, including the obligation to ensure vaccination of individuals against COVID-19, falls within the scope of the national constitutional values. The medical institutions providing vaccination and medical practitioners performing vaccination are one of the key assets of the national health care system, which have been delegated the duty in the field of public health and protection of lives that is a part of human rights. The Covid-19 infection pandemic is a global crisis with devastating effects on human health, social processes and the economy. In such circumstances, it is not permissible for medical institutions to allow offences, which are posing or may pose additional risks and endangerment to the health and life of persons and which could have been prevented.

2 Methodology

General scientific research methods are used in this study. To solve the research problems and meet research goals, descriptive research as type of quantitative research was selected. The content of the legislation, legal literature and scientific articles are analysed. Case Study Method is used to describe situation in vaccination cases from the perspective of administrative liability.

The data from the responsible institution are collected to annualize the legal and practical situation in vaccination with an age-inappropriate SARS-CoV-2 vaccines. The analytical method is used to explain the cause and effect of complex legal phenomena in administrative liability cases related to an age-inappropriate SARS-CoV-2 vaccines. Analytical research is used to make the interpretation of methods to examine cases, legal regulations and other forms of law to seek out, construct or reconstruct rules and principles and to draw conclusions. An empirical research method is used to reflect and analyse the Health Inspectorate statistics on administrative liability cases adopted in the age-inappropriate SARS-CoV-2 vaccination.⁴

4 The statistics are obtained from the archives of the Health Inspectorate, Republic of Latvia. In the Republic of Latvia, the Health Inspectorate is an institution of direct administration subordinate to the Minister of Health. The purpose of the inspectorate is to fulfil functions of public administration in the supervision and control of the health sector, in order to ensure compliance with the regulatory requirements in the said area, as well as their implementation, for quality and highly-qualified healthcare, as well as in order to ensure a safe and healthy living environment. Regulation of the Cabinet of Ministers No. 309 "Regulations of the Health Inspectorate" 9 July 2019, available online at <https://likumi.lv/ta/id/308072-veselibas-inspekcijas-nolikums> Article 1. and 2.

Various methods of interpretation of legal norms are used in the research. The grammatical (philological) method of interpretation is used to clarify the meaning of legal norms from a linguistic point of view. The historical method of interpretation has been used to clarify the meaning of legal provisions in the light of the circumstances on the basis of which they were created. The systemic method of interpretation has been used to clarify the meaning of legal provisions in relation to other legal provisions.

The teleological method of interpretation (meaning and purpose) is used to ascertain the meaning of the provisions on the basis of a useful and equitable aim to be attained by the relevant provisions.⁵ Methodological approach is used to conduct the study — the Latvian legal system, laws and regulation are characterized by openness to international law, therefore the process of analysing particular national norms should be observed as broad interpretation.

In accordance with Section 89 of the *Satversme* (Constitution) of the Republic of Latvia, Latvia recognises and protects fundamental human rights in accordance with the Constitution, laws and international treaties binding on Latvia. In applying laws and regulations in the Republic of Latvia, the following hierarchy of legal force of external laws and regulations shall be observed: (1) *Satversme* (Constitution); (2) laws; (3) Cabinet of Ministers Regulations; (4) binding municipal regulations.⁶ In this particular case, the procedure for vaccination with Covid-19 in Latvia is regulated by the law and Cabinet of Ministers regulations. The author analyses all the laws and regulations that regulate the Covid-19 vaccination procedure and the application of penalties for incorrect vaccination. At the same time, the author analyses the Covid-19 vaccination manual, since according to the Cabinet of Ministers' regulations, vaccination should be carried out in accordance with this manual.

5 Administrative Procedure Law: law of the Republic of Latvia, Paragraph 1 of Section 17. *Latvijas Vēstnesis*, 164, 14 November 2001; *Latvijas Republikas Saeimas un Ministru Kabineta Ziņotājs*, 23, 13 December 2001, adopted 25 October 2001. Entered in effect 1 February 2004, available online at <https://likumi.lv/ta/id/55567-administrativa-procesa-likums>.

6 The Constitution of the Republic of Latvia. The Law. Section 89. *Latvijas Vēstnesis*, 43, 1 July 1993; *Latvijas Republikas Saeimas un Ministru Kabineta Ziņotājs*, 6, 31 March 1994; 141, 30 June 1922; 29 April 1993, available online at <https://likumi.lv/ta/en/en/id/57980>.

3 Legal Framework for Vaccination Against Covid-19

In the Republic of Latvia, the procedures for vaccination are regulated by the Epidemiological Safety Law⁷ and the Cabinet of Ministers Regulation No. 662 of 28 September 2021 “Epidemiological Safety Measures for the Containment of the Spread of COVID-19 Infection” (hereinafter Regulation No. 662).⁸ Until the entry into force of Regulation No. 662, the Cabinet of Ministers Regulation No. 360 of 9 June 2020 “Epidemiological Safety Measures for the Containment of the Spread of COVID-19 Infection” (hereinafter Regulation No. 360) was in force.⁹

In accordance with Section 1 clause 8 of the Epidemiological Safety Law, epidemiological safety is the system of prophylactic, also hygienic, counter-epidemic, medical treatment and organisational conditions and measures the objective of which is to reduce the threat to public health caused by infectious diseases and the harmful effects of environmental factors affecting health.¹⁰ Pursuant to Section 1 clause 30 of the Epidemiological Safety Law, vaccination (shot) is a specific prophylactic measure for the purpose of inducing or maintaining the insusceptibility of an organism to an infectious disease by injecting a vaccine. In accordance with Section 3 (1) clause 3 of the Epidemiological Safety Law, the epidemiological safety includes the provision of immunobiological preparations and the vaccination of the population.¹¹

Both Regulation No. 662 and Regulation No. 360 provide that the vaccination must be performed in accordance with the Covid-19 vaccination guidebook published on the website of the State Agency of Medicines.¹²

The established vaccination procedure sets the obligation for the medical institution to ensure the assessment of the state of health of a person to be vaccinated before the vaccination, as well as identification and documentation of a possible postponement or cancellation of the vaccination. Therefore,

7 Epidemiological Safety Law. Latvijas Vēstnesis, 342/345, 30.12.1997, available online at <https://likumi.lv/ta/en/en/id/52951-epidemiological-safety-law>.

8 Regulation of the Cabinet of Ministers No 662 “Epidemiological Safety Measures for the Containment of the Spread of COVID-19 Infection” 28 September 2021, available online at <https://likumi.lv/ta/en/en/id/326513-epidemiological-safety-measures-for-the-containment-of-the-spread-of-covid-19-infection>.

9 Regulation No. 360.

10 *Supra* note 7, part 8.

11 *Ibid.*, part 30.

12 Regulation No. 662, Section 203; Regulation No. 360, Section 62.

based on the person's age, the medical institution is obliged to decide whether to postpone or cancel vaccination.

In accordance with the Covid-19 vaccination guidebook published on the website of the State Agency of Medicines, only Pfizer-BioNTech Comirnaty and Moderna Spikevax vaccines are intended to be used for the minors. Covid-19 Vaccine Janssen,¹³ should only be used for adults from 18 years of age.¹⁴ It is unambiguously clear from the abovementioned that COVID-19 Vaccine Janssen is not intended for vaccination of minors, as the safety and efficacy of this vaccine has not been scientifically tested with regard to minors and the vaccines have not been registered with the European Medicines Agency for this age group. Therefore, Covid-19 vaccination must be performed with an age-appropriate vaccine. This means that, if, for example, COVID-19 Vaccine Janssen is intended for active immunization for the prevention of SARS-CoV-2-induced Covid-19 infection in persons from 18 years of age, it must not be used for persons, who are 17 or under.

4 Legal Framework for Vaccination Against Covid-19 in the Field of Administrative Liability

There are cases established in the Republic of Latvia, where minors were vaccinated with COVID-19 Vaccine Janssen, a practice not in accordance with the Covid-19 vaccination guidebook. This was due to the following circumstances:

- no appropriate security measures were implemented in medical institutions to prevent or avoid administrative offences;
- no sufficiently secure system for the examination and registration of patients was introduced in the medical institutions, where vaccination and registration of patients was performed by different persons, and, as a result, mistakes were made, as the medical practitioner performing the vaccination was not required to check personal identification documents;

13 Vaccine Janssen. *Summary of product characteristics. COVID-19 Vaccine Janssen* — EMEA/H/C/005737 — IB/0024/G (12 October 2021), available online at <https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen>. According to section 4.1 of Annex 1 to the SPC for COVID-19 Vaccine Janssen (Therapeutic indications), Covid-19 Vaccine Janssen is indicated for the active immunization of SARS-CoV-2-induced Covid-19 infection in persons from 18 years of age. According to section 4.2 of the SPC, the safety and efficacy of COVID-19 Vaccine Janssen in children and adolescents (below 18 years of age) have not been established.

14 *Vaccination guide — information material for vaccinators*, available online at <https://www.vmnvd.gov.lv/lv/vakcinacijas-rokasgramata-informativais-materials-vakcinacijas-veicejiem>.

- in some cases, an age-inappropriate vaccine was administered due to the mistake of the medical practitioner by mixing up the vaccines;
- in some cases, minor patients have been vaccinated with an age-inappropriate vaccine as vaccination with a specific vaccine has been requested by the minors' parents or the minors themselves.

It should be noted that according to Section 1 of the Medical Treatment Law, vaccination is considered to be treatment. The law provides that medical treatment is professional and individual prophylaxis, diagnosis and medical treatment of diseases, medical rehabilitation and care of patients. It means that vaccination process is a part of medical treatment and the rights of minor patients must be viewed from the medical treatment perspective.¹⁵ The rights of minor patients are set forth in Section 13 of the Law on the Rights of Patients. According to the said Section, in the Republic of Latvia medical treatment of a minor patient (up to the age of 14 years) shall be permissible if his or her lawful representative is informed thereof and has given his or her consent. The minor patient has the right to be heard and according to his or her age and maturity to participate in taking the decision related to the medical treatment. There is no such right given to the patients to make the decision on vaccination. Nevertheless, medical treatment of a minor patient (from the age of 14) shall be permissible, if his or her consent has been received. There can be a correlation with the rights to agree to vaccination in general or to choose the vaccine, but in that case the Civil Law of the Republic of Latvia must be extended as well. According to Section 177 of the Civil Law, until reaching the age of majority (18 years of age), a child is under the custody of his or her parents. The custody is the rights and duties of parents to care for the child and his or her property and to represent the child in his or her personal and property relations. That means that despite the fact that a minor patient has the right to consent to the treatment, the general law, such as the Civil Law, shall be taken into account.

It shall be noted that according to Section 13 (3) of the Law on the Rights of Patients, if a minor patient (from the age of 14) refuses to give his or her consent to medical treatment, but the physicians deem that the medical treatment is in the interests of this patient, the consent to the medical treatment shall be given by the lawful representative of the minor patient.¹⁶ In general,

15 Medical Treatment Law. *Latvijas Vēstnesis*, 167/168, 1 July 1997; *Latvijas Republikas Saeimas un Ministru Kabineta Ziņotājs*, 15, 7 August 1997, available online at <https://likumi.lv/ta/en/en/id/44108-medical-treatment-law>.

16 Law on the Rights of Patients. *Latvijas Vēstnesis*, 205, 30 December 2009, available online at <https://likumi.lv/ta/en/en/id/203008-law-on-the-rights-of-patients>, Section 13.

minors under the age of 14 have the lack of cognitive capacity and are generally under the parent's care, even in decision-making process regarding vaccination. Factors, such as social pressure, emotional regulation, communication, influence minors and at the same time affect their decisions (consideration of the choices). Therefore, the existing regulation requires parental permission and presumes that parents know and will act in the best interest of their children. In the context of vaccination, some older minors may possess a more accurate understanding of the risks or positive aspects of vaccination than their guardians. Nevertheless, by the age of 14, minors are generally able to act as adults and the respect of the child's autonomy must increase even in health care situations, especially if the decision affects public interests.¹⁷ It means that taking part in decision-making process in such cases as vaccination is important for identification of whether the decision of a minor complies with the best interests of the minor and the public interests.¹⁸

Therefore, the rights of minor patients to consent to the vaccination and at the same time to agree on particular medical treatment and participate in decision-making process related to health issues is regulated on the national level, but there are still some gaps and shortcomings related to general principles and general laws on parental rights. The balance between parental rights and the rights of minor patients shall still be established to clearly understand the motivation on decision-making process in health care.

Nevertheless, to ensure the best interests of children, as well as patients in general, it is important to provide a mechanism that could help to avoid unsafety processes in vaccination as well.¹⁹ Patient safety is one of the priorities in nowadays. The safe treatment process gives framework of organized activities that creates cultures, processes, procedures, behaviours in health care that consistently mitigates the risks, reduces the occurrence of avoidable harm, errors etc.²⁰

Administrative liability for vaccination against Covid-19 with an age-inappropriate vaccine is applicable in accordance with Section 37⁵ of the

17 L. Morgan, J.L. Schwartz and D.A. Sisti, 'COVID-19 Vaccination of Minors Without Parental Consent: Respecting Emerging Autonomy and Advancing Public Health' *JAMA Pediatrics* 175(10) (2021) 995–996. DOI: 10.1001/jamapediatrics.2021.1855.

18 N. Shevzov-Zebrun and A. Caplan, 'Parental consent for vaccination of minors against COVID-19', *Vaccine* 39(44) (2021) 6451–6453. DOI: 10.1016/j.vaccine.2021.09.049.

19 A. Slavinska, E. Grigoroviča, K. Palkova, N. Jansone-Ratinika, M. Silis, O. Sabeļņikovs and A. Pētersons, 'Prasmju monitorings veselības aprūpes studiju virziena studijās — pacientu drošībai un veselības aprūpes kvalitātei', *Society. Integration. Education/Sabiedriba Integrācija. Izglītība* 1 (2021) 611–630. DOI: 10.17770/sie2021vol1.6448.

20 World Health Organization, *Patient Safety* (2021), available online at <https://www.who.int/news-room/fact-sheets/detail/patient-safety>.

Epidemiological Safety Law, which provides that a fine from two to four hundred units of fine shall be imposed on a natural person, a fine from twenty-eight to one thousand units of fine shall be imposed on a legal person for the violation of the epidemiological safety requirements, if it may cause risk to human health.²¹ Section 5.6 of the Cabinet of Ministers Regulation No. 309 of July 9, 2019 “Regulations of the Health Inspectorate” provides that in the cases specified in external regulatory enactments, the Health Inspectorate is entitled to carry out proceedings of administrative offences.²² Proceedings of administrative offences regarding the violations specified in Section 37⁵ of the Epidemiological Safety Law are carried out by the Health Inspectorate.²³ In the Republic of Latvia, the Health Inspectorate is an institution of direct administration subordinate to the Minister of Health. The purpose of the inspectorate is to fulfil functions of public administration in the supervision and control of the health sector, in order to ensure compliance with the regulatory requirements in the said area, as well as their implementation, for quality and highly-qualified healthcare, as well as in order to ensure a safe and healthy living environment.²⁴

Given that the medical institutions are responsible for complete organisation of vaccination procedure, safety of patients in the institutions and provision of safe services, as well as that Section 37⁵ of the Epidemiological Safety Law allows to impose administrative liability on legal persons, administrative fines were imposed on the medical institutions.

In the Republic of Latvia, the procedure for administrative offence proceedings is regulated by the Law on Administrative Liability.²⁵

5 Statistics and Methodology for Determination of the Fine Amount at First Instance at the Health Inspectorate

The administrative offence cases regarding certain offences are examined at first instance by an official of the Pharmacy Department.

21 *Supra* note 7, Section 37⁵.

22 Regulation of the Cabinet of Ministers No. 309 “Regulations of the Health Inspectorate”, 9 July 2019, available online at <https://likumi.lv/ta/id/308072-veselibas-inspekcijas-nolikums>, Article 5.6.

23 *Supra* note 7, Section 37⁶.

24 *Supra* note 22, Articles 1 and 2.

25 Law on Administrative Liability. Latvijas Vēstnesis, 225, 14 November 2018. OP number: 2018/225.1, available online at <https://likumi.lv/ta/en/en/id/303007-law-on-administrative-liability>.

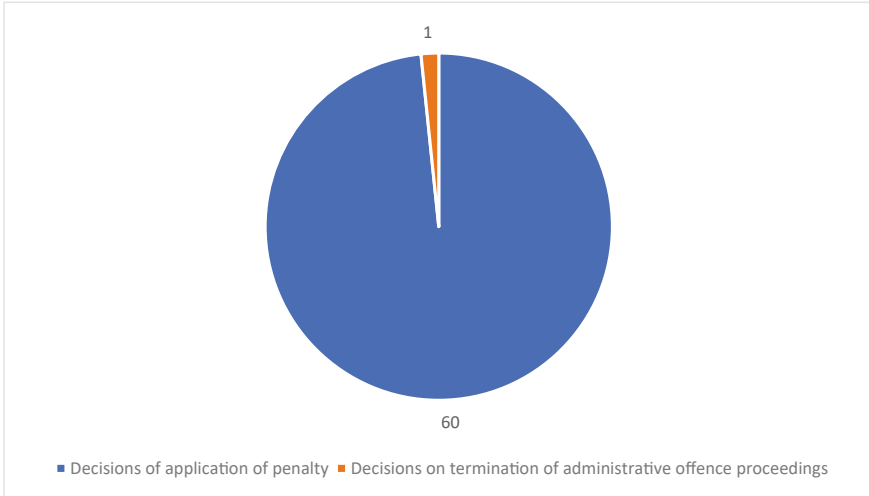


FIGURE 1 Categorisation of 61 administrative offence cases at first instance regarding vaccination of persons with an age-inappropriate Covid-19 vaccine

A total of 61 administrative offence cases were initiated and examined (Figure 1).²⁶ In one administrative offence case a decision has been taken to terminate the proceedings (the initially established offence was not confirmed, as an error was made when entering the information in the health system E-veselība).

5.1 Amounts of Fines at First Instance at the Health Inspectorate

In accordance with Section 37⁵ of the Epidemiological Safety Law, which provides that, a fine from 28 to 1000 fine units shall be imposed on a legal person for the violation of the epidemiological safety requirements, if it may cause risk to human health (Figure 2),²⁷ the Health Inspectorate determined the administrative fines at first instance in the order indicated below:

26 The statistics are obtained from the archives of the Health Inspectorate, Republic of Latvia. In the Republic of Latvia, the Health Inspectorate is an institution of direct administration subordinate to the Minister of Health. The purpose of the inspectorate is to fulfil functions of public administration in the supervision and control of the health sector, in order to ensure compliance with the regulatory requirements in the said area, as well as their implementation, for quality and highly-qualified healthcare, as well as in order to ensure a safe and healthy living environment. Regulation of the Cabinet of Ministers No. 309, Articles 1 and 2.

27 *Supra* note 7, Section 37⁵.

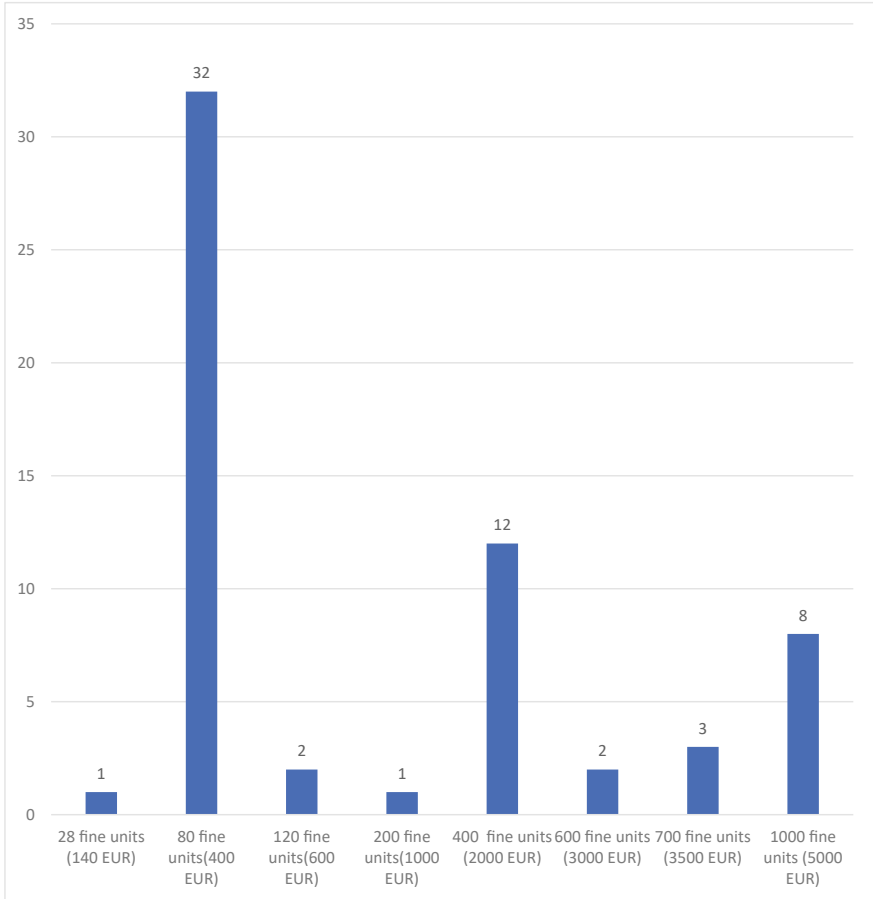


FIGURE 2 Amount of administrative fines imposed at first instance on the medical institutions for vaccination of persons with an age-inappropriate Covid-19 vaccine (1 fine unit = 5 EUR)

1. practices of general practitioners are subject to an administrative fine of:
 - 1.1 80 units of fine for vaccination of one person with inappropriate vaccine;
 - 1.2 120 units of fine for vaccination of two or more persons with inappropriate vaccine.
2. medical institutions (associations of health centres, polyclinics, regional hospitals) are subject to an administrative fine of (Figure 3):
 - 2.1 400 units of fine for vaccination of one person with inappropriate vaccine;

- 2.2 600 units of fine for vaccination of two or more persons with inappropriate vaccine.
3. establishing repeated cases of vaccination of persons against Covid-19 with an age-inappropriate vaccine, the decision on the imposition of the maximum amount of the fine is taken.

The amount of fine for vaccination of persons with an inappropriate vaccine in points 1 and 2 is based on the consideration that medical institutions may endanger a larger circle of patients compared to the practices of general practitioners, thus, the risk of violation is higher.

At the same time, the nature of the committed offence, the personality of the person to be held liable (in case of a legal person — its reputation), financial situation, circumstances of committing the offence, and mitigating and aggravating circumstances are taken into consideration in the determination of the amount of fine.²⁸

In accordance with Section 20 of the Law on Administrative Liability of the Republic of Latvia, the following circumstances mitigate liability for an administrative offence:

- (1) a person to be held liable has confessed and regretted the act committed;
- (2) a person to be held liable has voluntarily compensated for loss or eliminated the caused damage;
- (3) an offence has been committed under the influence of extreme mental agitation or due to serious personal or family circumstances;
- (4) a person to be held liable has voluntarily applied prior to disclosing of the committed offence;
- (5) an offence has been committed as a result of unlawful or immoral behaviour of the victim;
- (6) an offence has been committed by a pregnant woman or a woman who takes care of a child under 1 year of age.

Other circumstances may also be recognised as mitigating.²⁹

In accordance with Section 21 of the Law on Administrative Liability of the Republic of Latvia the following circumstances aggravate liability for an administrative offence:

- (1) an unlawful action is continued, regardless of a request of an authorised official to cease it;
- (2) a person of legal age has involved a minor in the committing of an offence;
- (3) an offence has been committed during a natural disaster or in other exceptional circumstances;

²⁸ *Supra* note 25, Section 19.

²⁹ *Ibid.*, Section 20.

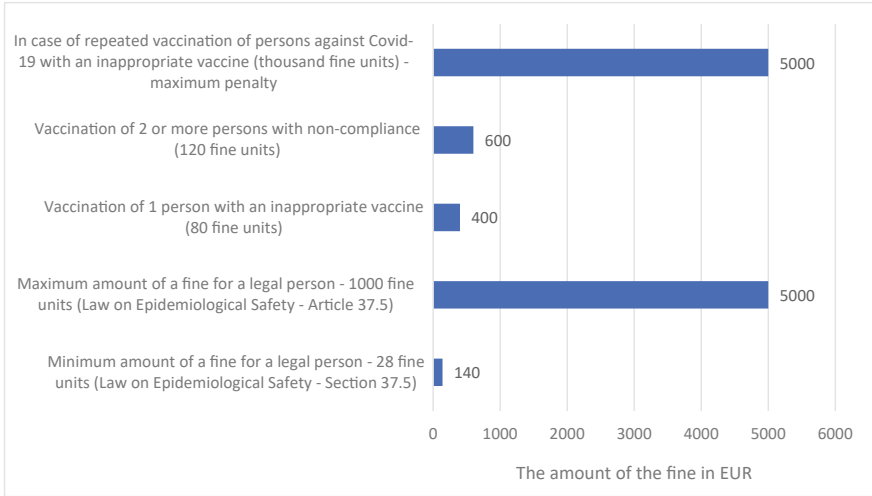


FIGURE 3 Methodology for the amount of administrative fines imposed at first instance on the medical institutions for the vaccination of persons with an age-inappropriate Covid-19 vaccine (1 fine unit = 5 EUR)

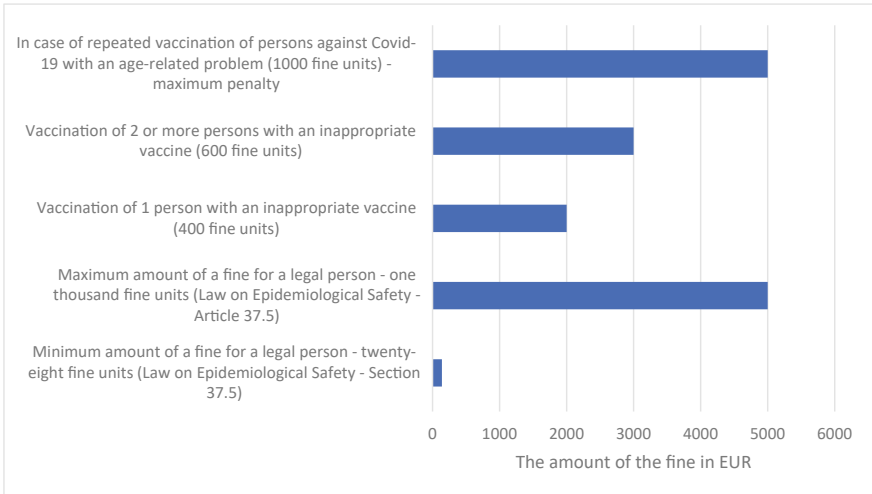


FIGURE 4 Methodology for the amount of administrative fines imposed at first instance on medical institutions (associations of health centers, polyclinics, regional hospitals) for vaccination of persons with an age-inappropriate Covid-19

- (4) an offence has been committed under the influence of alcohol, narcotic or other intoxicating substances or while intoxicated;
- (5) committing of an offence has been motivated by hatred against distinctive features of a person, such as race, religious beliefs, nationality or other clearly obvious distinctive features of the person;
- (6) an offence has been committed by a group of persons.³⁰

5.2 *Amounts of Fines at the Appeal Stage at the Health Inspectorate*

Section 172 (1) of the Administrative Liability Law stipulates that a higher official (head of the Inspectorate) shall examine a complaint and ascertain the circumstances of an administrative offence case on the basis of evidence in the relevant case.³¹

A total of 14 out of 61 decisions were appealed (Figure 5). A higher official examining an administrative offence case may take the following decision:

1. to leave the decision unchanged, but to reject the complaint;
2. to set aside the decision and terminate administrative offence proceedings;
3. to set aside the decision fully or partially, take a new decision by which a person is found guilty of committing an administrative offence, and apply a penalty;
4. to amend a measure of penalty within the framework provided for in a legal provision which stipulates liability for the established administrative offence.³²

In this particular case at the appeal stage, it has been established that:

1. a lawful basis for setting aside a decision and termination of the administrative offence proceedings may be, for example, the case when the administrative offence is incorrectly imposed on the wrong subject of the administrative offence, or it is established that the administrative offence was not committed, as well as in other similar cases, when obvious irregularities are established in the initial decision.
2. the amount of fine may be reduced, if the mitigating circumstances specified in Section 20 of the Law on Administrative Liability are established, for example, the medical institution has confessed and regrets the act committed and has carried out active measures to prevent recurrence of offence and is able to submit to the Health Inspectorate specific

³⁰ *Ibid.*, Section 21.

³¹ *Ibid.*, note 25, Section 172 (1).

³² Law on Administrative Liability. Latvijas Vēstnesis, 225, 14.11.2018.OP number: 2018/225.1, available online at <https://likumi.lv/ta/en/en/id/303007-law-on-administrative-liability> Section 173 (1).

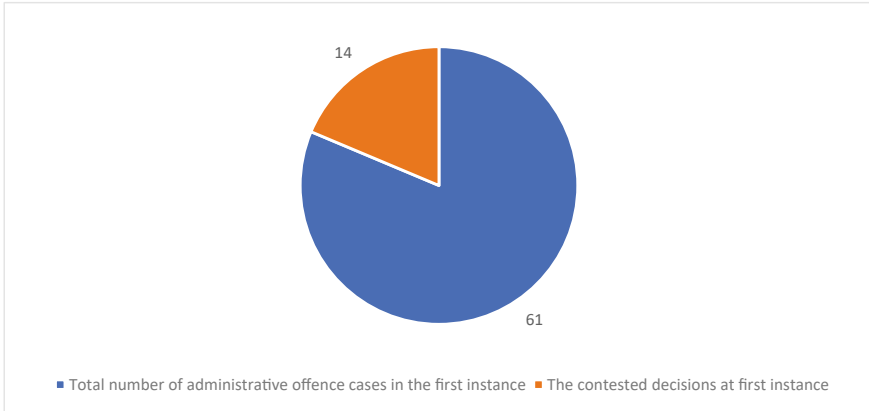


FIGURE 5 Categorisation of 14 administrative offence cases at second instance regarding vaccination of persons with an age-inappropriate Covid-19 vaccine

evidences of what improvements have been made in the medical institution. Therefore, if the mitigating circumstances specified in Section 20 of the Law on Administrative Liability are established, the fine is reduced.

3. if only the aggravating circumstances specified in Section 20 of the Law on Administrative Liability and no mitigating circumstances are established, for example, offences continue to be committed in the medical institution, despite the fact that a decision has been previously made to impose a penalty for vaccination of minors with an age-inappropriate vaccine and the commitment is not regretted, a higher official acknowledges that there are no grounds to amend or cancel the fine.

The examples, where mitigating circumstances were taken into account, are cases where medical institutions confessed the act committed and took steps to prevent the harmful effects of the offense and not to allow such errors in the future. For instance, has taken measures to ensure a high-quality vaccination process:

- (1) all personnel involved in the vaccination process was trained in accordance with the Covid-19 vaccination guidebook;
- (2) contracts with employees involved in the vaccination process included the obligation to comply with the regulatory enactments applicable to organization of health care, provision of services and ensuring the quality of services;
- (3) all employees are provided with free access to the latest updated edition of Covid-19 vaccination guidebook;
- (4) changes has been made to the vaccination process to improve it and to prevent the harmful effects of the offence on the health of persons that may have occurred.

In this particular case the following decisions were taken at the appeal stage (Figure 6), with 2 proceedings out of 14 decisions taken (Figure 7).

5.3 Results of Legal Proceedings

In one case, the court found the Health Inspectorate’s actions justified. But the other proceedings at first instance are still ongoing.

The Court, which found the Health Inspectorate’s actions justified, held that the senior official of the Health Inspectorate, when examining the complaint on the imposition of a penalty, had found that the complainant had established vaccination of minors with an age-inappropriate vaccine against Covid-19 and had acted to prevent the harmful consequences of the violation and to prevent such errors in the future, that the Complainant had taken the necessary actions to reduce the occurrence of human error in the vaccination process. The above circumstances are considered to be relevant for the reduction of the fine to a fine of EUR 2000.00 or 400 penalty units. The Court also found that

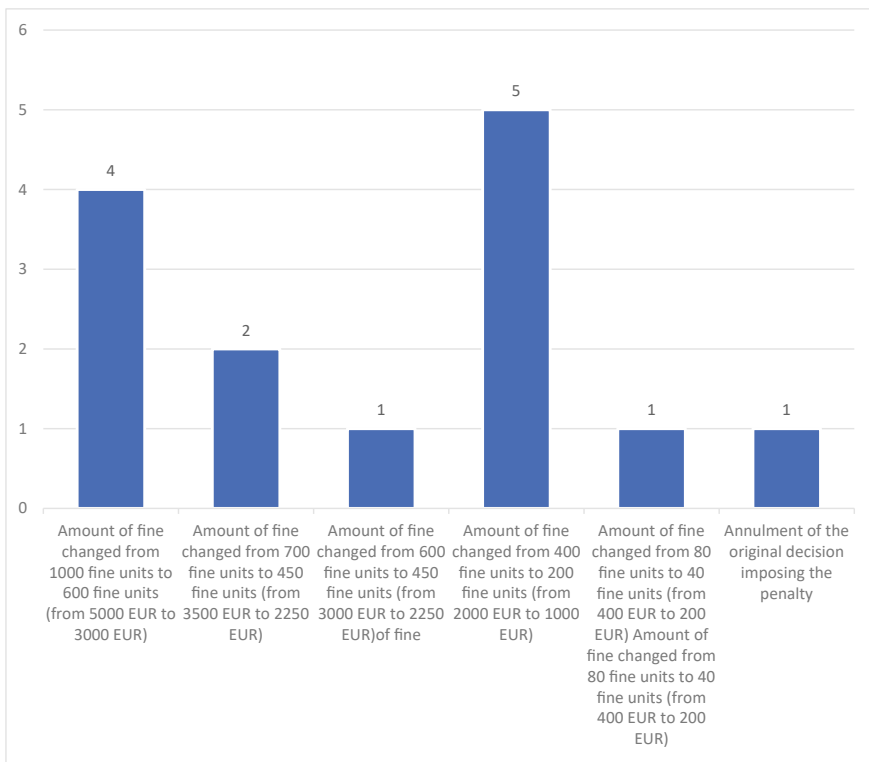


FIGURE 6 Decisions taken at second instance on the medical institutions for the vaccination of persons with an inappropriate Covid-19 vaccine, taking into account mitigating and aggravating circumstances

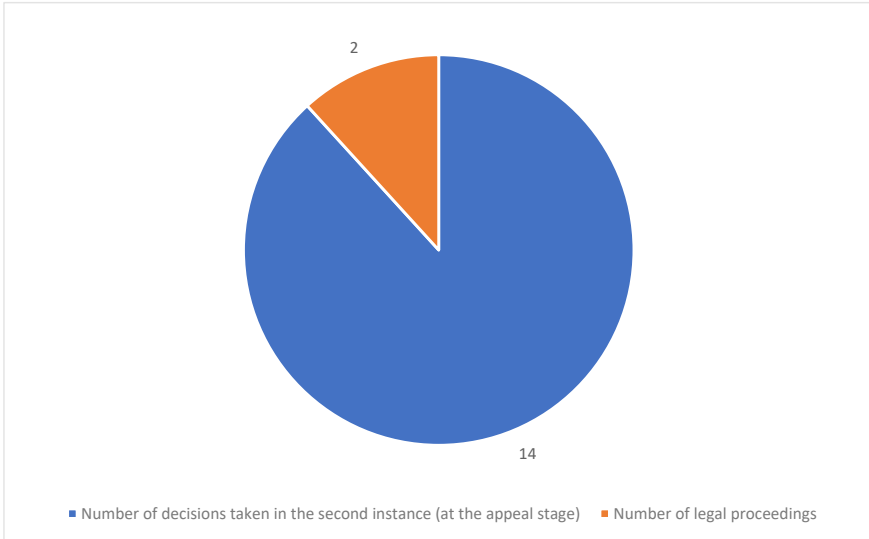


FIGURE 7 Number of legal proceedings

the senior official of the Health Inspectorate had taken into account the seriousness and danger of the infringement, as well as the existence of repeated cases of minors vaccinated with vaccines not appropriate for their age. The senior official rightly stated that it could not reduce the amount of the fine any further, with which the Court agrees.

The Court held that it shared the view of the senior official that the infringement was of a serious nature and that the obligation to ensure epidemiological safety fell within the scope of the State's constitutional values, since it was a means of exercising the right to health of individuals, which is part of human rights. In the context of the spread of Covid-19, the medical establishments providing vaccination and the medical practitioners providing vaccination are one of the most important components of the healthcare system to which the duty to protect public health and life has been delegated. The Covid-19 pandemic is a global crisis with devastating impacts on human health, social processes and the economy. In such circumstances, it is not permissible for medical establishments, by negligent performance of their duties, to create a risk to a person's health which, in the Court's view, could have been prevented by a penalty of a disciplinary nature. The Court observes that, in adopting its decision, the senior official has assessed the reasonableness and proportionality of the penalty initially imposed for the administrative offence committed, has taken into account all the arguments and considerations raised in the initial complaint, and has provided an assessment of the applicable legal provisions and the reasons for reducing the penalty from 1000 penalty units

to 400 penalty units, which the Court considers to be in accordance with the objective of the administrative penalty and does not find grounds either for reducing the penalty or for dismissing the case.³³ The judgment has not been appealed and has entered into force.

6 Compensation Mechanisms in the Event of Consequences, If Harm Has Been Caused to the Life or Health of a Person Due to Inappropriate Vaccination

When preparing an administrative offence case for examination, the Health Inspectorate, in accordance with Section 125 (1) clause 4 of the Law on Administrative Liability, shall decide an issue regarding a victim.³⁴ According to Section 43 (1) of the Law on Administrative Liability, a victim may be a natural person who has suffered loss or non-material damage as a result of an administrative offence and with regard to whom an official or a higher official has taken the relevant decision to grant the status of the victim.³⁵

According to Section 43 (3) and Section 44 (2) of the Law on Administrative Liability, the lawful representative of the vaccinated person may exercise the victim's rights voluntarily and within the scope chosen by him or her. Failure to exercise the rights shall not delay the progress of administrative offence proceedings. A victim — the vaccinated person — shall fulfil his or her obligations in person as far as the administrative offence case requires personal fulfilment of obligations.³⁶

Given that the vaccinated person has not reached the age of majority, in accordance with Section 55 (1) of the Law on Administrative Liability, a minor in the administrative offence case may be represented in the order of priority by:

- 1) one of his or her lawful representatives (parents, guardians, foster family, a person authorised by a child care institution);
- 2) one of his or her grandparents;
- 3) his or her brother or sister who is of legal age;
- 4) a representative of an authority for the protection of the rights of children.³⁷

33 Judgement of Riga City Latgale District court of 17 June, 2022 in case No. 1A/22/408.

34 *Supra* note 25, Section 125. (4).

35 *Ibid.*, Section 43.panta (1).

36 *Ibid.*, Section 43 (3) and Section 44 (2).

37 *Ibid.*, Section 55 (1).

If the lawful representative is not able to fully represent the interests of a minor, in accordance with Section 55 (2) of the Law on Administrative Liability, an official, a higher official is entitled to summon another representative by taking into consideration the possibilities and willingness of specific persons to truly protect the interests of the minor and following the order of priority specified in paragraph one of this Section.³⁸

A person who has suffered damage as a result of an administrative offence has the right to request compensation for damage from the person who has committed the offence in accordance with the procedures laid down by the Civil Procedure Law.³⁹

Up to now, no cases have been identified in Latvia when a person has exercised the specified rights affecting the use of the compensation mechanism. There is also no information available, which proves that any adverse consequences have occurred to the health of any minor in order to establish that harm has been caused.

7 Conclusions

The authors of the study established that no appropriate security measures have been introduced in the medical institutions to prevent or avoid administrative offences. It must be noted, that as the result in all cases the medical institutions were subject to first-time application of administrative liability. Analysing the cases of administrative offences, the authors found that no sufficiently secure system for the examination and registration of patients have been introduced in the medical institutions.

Mistakes were made in medical institutions where vaccination and registration of patients was performed by different persons. The medical practitioner performing the vaccination was not strictly obliged to check personal identification documents. In addition, in some cases, inappropriate vaccine was administered due to the mistake of the medical practitioner by mixing up the vaccines.

In other cases, minor patients have been vaccinated with an inappropriate vaccine as vaccination with a specific vaccine has been requested by the minors' parents or the minors themselves. In the authors' opinion, in order to eliminate the identified deficiencies, a number of measures are required, also aimed at the special protection of the documents of minor patients during

³⁸ *Ibid.*

³⁹ *Ibid.*, Section 34 (2).

vaccination. For example, by providing the questionnaire form in a different colour, writing the name of the vaccine on the card in a bright colour, performing repeated verification of personal data, as well as considering not only the year of birth, but also the date and month of birth, using vaccines from one manufacturer in one vaccination stream. It must be noted that patients safety plays a huge role even in vaccination process.

It is important to provide strong, clear, and visible attention to safety through implementation of nonpunitive systems for reporting and analysing errors within the organization.