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THE DISTINCTIVE NATURE OF COVID-19 VACCINES: COMPENSATION FOR POTENTIAL DAMAGES UNDER THE LEGAL FRAMEWORK OF LITHUANIAN STATE IN THE CONTEXT OF GLOBAL EXAMPLES

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The article analyzes *legal mechanisms of compensation for damages caused by side effects of COVID-19 vaccines in Lithuania. In particular, draft amendments to the Law on the Rights of Patients and Compensation of the Damage to their Health registered by the Parliament of the Republic of Lithuania in 2021 are evaluated and arguments for the need for further improvement are provided herein. In order to comprehensively assess*

the nature of the side effects that may be a substantiated cause for damages, pharmaceutical analysis and evaluation of COVID-19 vaccines eligible in Lithuania are analyzed. Analysis of the legal framework and proposals are construed mainly in light of the assessment of global examples. Following throughout evaluation of the question at hand, it is the opinion of the authors of the article that the product liability mechanism is not appropriate in the context of the vaccination program applied in Lithuania and instead „a no-fault compensation model" shall be adopted that would be funded by a separate (non) State institute/fund in Lithuania.

Keywords: *COVID-19 pandemic; vaccines; Constitution; vaccination; side effects; damage compensation, no-fault model.*

COVID-19 VAKCINŲ IŠSKIRTINUMAS: KOMPENSACIJA UŽ GALIMAI PATIRTA ŽALĄ PAGAL LIETUVOS VALSTYBĖS TEISINĮ POBŪDĮ GLOBALIŲ PAVYZDŽIŲ KONTEKSTE

Straipsnyje analizuojama *teisiniai žalos atlyginimo mechanizmai dėl COVID-19 vakcinų sukeltos žalos, pasireiškusios dėl šalutinio poveikio, Lietuvoje. Konkrečiai – analizuojami Pacientų teisių ir žalos atlyginimo įstatymo pakeitimo pasiūlymai, įregistruoti Lietuvos Respublikos Seimo 2021 m., bei teikiami argumentai dėl poreikio tobulinti šiuos pasiūlymus toliau. Siekiant išsamiai įvertinti šalutinius poveikius, kurie galėtų būti pagrindas reikalauti žalos atlyginimo, pristatoma Lietuvoje teisėtai naudojamų COVID-19 vakcinų šalutinių poveikių farmacinė analizė. Teisinių mechanizmų ir pasiūlymų vertinimas atliekamas labiausiai atsižvelgiant į pavyzdžius, naudojamus globaliai. Plačiai išanalizavus klausimą, šio straipsnio autoriai pirmiausiai laikosi pozicijos, kad produktų saugos teisinis mechanizmas šiuo atveju nėra tinkamas, atsižvelgiant į vakcinavimo programą, kuri taikoma Lietuvoje, vietoje to kad žalos, sukeltos COVID-19 vakcinų šalutinių poveikių, atlyginimas turėtų būti taikomas pagal žalos be kaltės modelį, finansuojamą iš atskiro Valstybes instituto/fondo.*

Raktiniai žodžiai: *COVID-19 pandemija; vakcinos; Konstitucija; vakcinacija; šalutiniai poveikiai; žalos atlyginimas, „žalos be kaltės" modelis.*

Introduction

„The pandemic provides us with a window of opportunity, where the government could introduce a COVID-specific scheme, and potentially expand it to include other vaccinations"
Shevaun Drislane

Ordinarily, it takes scientists about 10 years to develop a vaccine. However, the pharmaceutical industry has worked toward emergency approval of COVID-19 vac-

cines just in a matter of months (Van Tassel et al., 2021). Indeed, it is to be mentioned that the latter procedure was not done from the scratch – the research was performed using data on similar coronaviruses called SARS and MERS (Cassata, 2021).

Nowadays vaccination is considered as one of the public health's greatest achievements. However, a major ethical dilemma still lies in the balance between personal autonomy and choice *versus* protection of the entire population at risk (El Amin et al., 2012).

In any case, the expedient procedure that was employed for the registration of COVID-19 vaccines triggered a certain level of doubts from people about the quality, side effects (adverse reaction) and effectiveness of COVID-19 vaccines. Consequently, policymakers and rules enforcers experienced challenges in regard to facilitating the global administration of COVID19 vaccines and preventing concerns about compensation for damages caused by side effects of the vaccine (Congressional Research Service, 2021).

And what is known about the side effects (adverse reactions) of COVID-19 vaccines that are often referred to by people hesitant or refusing to have a vaccine? Up to 1 March 2022, the European Centre for Disease Prevention and Control (ECDC) estimated a total of 876,708,597 doses of COVID-19 vaccines administered in EU/EEA countries, it constitutes that at least one dose was received by 85.5% (316,963,728) of the adult population over 18 years and full vaccination is completed by 82.8%. According to the European Medicines Agency (EMA) reports, up to 30 January 2022, 1,018,250 (0.7% of all administered doses) suspected adverse reactions after COVID-19 vaccination were reported to EudraVigilance.

The number of reported cases does not seem to be very high. One may claim, that a vaccine is no different from any medicinal product, since every medicinal product may have adverse reactions, they are usually introduced to a patient using the medicinal product through a leaflet of such product, thus the patient is properly informed and could make a decision whether to administer the product or not. There is no special treatment of compensation of damages caused by side effects of a medicinal product, therefore no special mechanism is needed for evaluation of damages caused by side effects of the COVID-19 vaccine, one may add. However, it shall be noted that pandemic situation and requirements imposed on people to be vaccinated in order to be engaged in certain activities, social events or simply performing one's work duties are not the same as those for consuming other medicinal products.

Lithuanian Government adopted rules requiring to be vaccinated in order to be able to work certain professional activities (thus the refusal of the vaccine can incur significant consequences upon that person) and since the number of reported cases is not that high maybe in Lithuania, patients could benefit from a more simplified procedure for compensation of damages in case of side effects (adverse reactions)?

In general, under the legal system of Lithuania, as long as a specific legal mechanism of compensation for damages caused by vaccines has not been adopted, general rules on product liability apply. That means currently, people of Lithuania who suffered adverse reactions can claim compensation for damages by commencing a product liability case or litigation against the state, healthcare professionals and/or the manufacturer of the vaccine before a court of Lithuania. This implies that the patient is faced with extremely difficult, time-consuming and costly court proceedings which would require to prove all circumstances of general civil liability. Until no amendments are adopted to the existing laws, a person may not benefit from an existing special simplified procedure under the Law on the Rights of Patients and Compensation of the Damage to their Health (1996) that applies for damages caused to a person's health in the event of provision of healthcare services. This special compensation mechanism is called a „no-fault" procedure and under existing regulation, it explicitly excludes damages caused due to side effects (adverse reactions) of a medicinal product.

Consequently, in today's reality, all potential vaccine recipients, and especially people in high-risk communities, face a dilemma: should they risk becoming infected or risk having a vaccine side-effect without sufficient access to compensation? This dilemma is exacerbated when it comes to compulsory vaccination or the voluntary consent of people to be vaccinated in the name of public health.

The purpose of the article – to analyze and evaluate legal mechanisms of compensation for damages caused by side effects of COVID-19 vaccines in Lithuania. Accordingly, **the tasks** are as follows:

1. To evaluate the possible mandatory nature of vaccination in foreign and Lithuanian contexts;
2. To define the current no-fault compensation model, to evaluate the possibilities of compensation for damage caused by vaccines in Lithuania;
3. To provide analysis of the side effects that may be a substantiated cause for damages;
4. To assess draft amendments to the Law on the Rights of Patients and Compensation of the Damage to their Health and present arguments for the need for further improvement.

The object of the research – legal documents that establish indemnification mechanisms in Lithuania and pharmaceutical information related to COVID-19 vaccines.

The **article is relevant** since the vaccination process is still ongoing in Lithuania. People still do not have access to adequate redress for the possible side effects of vaccines. Such regulation is still not possible under the laws of the Republic of Lithuania, although vaccination has been going on for more than two years. The draft amendment to the law registered by the Parliament only a couple of months ago is still in the process of being adopted and it is not clear when it will enter into force (if it enters into force).

The **following methods** were applied when conducting the research: **comparative analysis** helped to understand different positions on vaccines and vaccination process; **legal document analysis** was used to analyze the provisions of current law in the context of patient compensation for damages and to assess the national regulations of other countries; **systemic analysis** was applied when evaluating the case-law of the European Court of Human Rights, the Constitutional Court of the Republic of Lithuania and the Supreme Court of Lithuania; **empirical analysis** of case-law was applied in order to better comprehend the concept of and the grounds of restricting the privacy under the case-law of the Lithuanian Constitutional Court and the ECHR; the **linguistic method** was applied in order to evaluate the relevant terms applicable to the research, to systematically interpret them.

1. Peculiarity of COVID-19 vaccines: (non)compulsory vaccination and compensation for damages

Contemporary forms of mandatory vaccination compel vaccination by direct or indirect threats of imposing restrictions in cases of non-compliance (Gravagna et al., 2020). Typically, mandatory vaccination policies permit a limited number of exceptions recognized by legitimate authorities (e.g., medical contraindications) (WHO, 2021). Despite its name, mandatory vaccination is not truly compulsory, i.e., force or threat of criminal sanction are not used in cases of non-compliance. Still, mandatory vaccination policies limit individual choice in non-trivial ways by making vaccination a condition of, for example, attending school or working in particular industries or settings, like health care.

On 2020 December 27 vaccination against COVID-19 has started in Lithuania, as in the entire European Union (Order of the Ministry of Health, 2020). It should be noted that the pivotal clinical trials of all COVID-19 vaccines have not been completed. For example, Pfizer/BioNTech: Comirnaty is due to submit a report on the Comirnaty pivotal clinical trial to the European Medicines Agency in December 2023. In the European Union, they are conditionally registered, i. e. in the absence of all the data normally required. As a result, their long-term effects, such as the risk of cancer, risk of autoimmune diseases, risk of birth defects, fertility, are unknown (European Medicines Agency, 2020).

Nonetheless, with almost a year and a half since vaccination began, different examples of practice in the context of compulsory vaccination appeared. Under these conditions, some countries have only tried to contain the virus and apply it for a short period of time, while others have only applied compulsory vaccination to workers in certain countries. Consequently, some of the countries already had existing or newly introduced mechanisms of compensation for damages caused by adverse effects of COVID-19 mandatory vaccination, others – not. These are analyzed further below.

1.1. Examples of other countries

In high-income countries, few existing compensation mechanisms incorporate side effects of the COVID-19 vaccines, based on the declared health emergency states and the incentives of a wide vaccination campaign. In other cases, the existing no-fault compensation programs for routine immunization do not incorporate COVID-19 vaccination adverse events (D'Errico S., et al., 2021):

- **Austria** – COVID-19 vaccination is (or have been) fully mandatory. Austrian law provides a system of public law on the basis of which compensation is paid under the Vaccine Damage Act (Bundesgesetz vom, 1973). The state pays compensation if certain vaccines have caused damage to a person's health. Compensation is granted on an application for social insurance to the state under the Vaccine Injury Act. The claim is being processed administratively. Vaccinations from COVID-19 have been included in the Recommended Vaccination Regulation.
- **Canada** – In August 2021, the Canadian government announced it would require COVID-19 vaccination for federal public service employees and members of the military. As of June 2021, the Canadian government started a national vaccine damage compensation. The program is essentially designed for people who experienced **severe** reactions to an approved COVID-19 vaccine (Public Health Agency, 2021). Thus, it provides financial support only to those who have experienced a serious and/or permanent injury after receiving a Health Canada-authorized COVID-19 vaccine in Canada on or after 8 December 2020. This support includes income replacement, payment for injuries, death benefits (including funeral expenses), and other eligible costs, such as uncovered medical expenses. The amount of financial support provided will be determined on a case-by-case basis, but compensation will be retroactive from the date of the injury or person's death.
- **France** – COVID-19 vaccination is not mandatory, but the French government has recommended COVID-19 vaccinations for certain categories of individuals. The existing compensation program includes compensation for injuries that are related only to compulsory vaccinations. There is officially no special procedure for compensation of damages resulting from recommended non-compulsory vaccinations. Therefore, any person who has suffered an injury and/or any damage as a result of the COVID-19 French vaccination program is eligible for compensation pursuant to the general principles of French civil law, since this vaccine is non-compulsory (République Française Decree, 2020).
- **Germany** – COVID-19 vaccination is not mandatory in Germany, and the compensations are covered under existing legislation. Germain no-fault compensation program applies to everyone: to compulsory vaccination and to non-compulsory vaccinations as long as the vaccination is publicly recommended by

the Government of Germany. Therefore, a nofault compensation program that also applies to COVID-19 vaccines as long as they are officially recommended by the Government as stated in Section 60 of the German Infection Protection Act (Infektionsschutzgesetz, 2020). The compensation size officially is a flatrate scheme influenced by various factors, depending primarily on the individual degree of injury/damage.

- **South Africa** – COVID-19 vaccination is based on free will in South Africa. On 24 February 2021, it was announced that the government would set up a legal base of a nofault compensation model (Mboweni, 2021). The actual legal framework surrounding this compensation fund has not yet been released officially. However, the Health Minister of South Africa stated in January 2021 that any person who voluntarily chooses to get the vaccine will be required to sign an indemnity waiver, indemnifying the individual from any liability stemming from any potential risk and harm caused by the COVID-19 vaccine. In addition, the WHO created the vaccine injury compensation program, which is a no-fault compensation system that are available to 92 low and middle-income countries, including South Africa (WHO, 2021).
- **South Korea** – Vaccination against COVID-19 is voluntarily in South Korea. The South Korean Disease Control and Prevention Agency stated that in the future they will expand compensation coverage for those suffering from **severe** side effects injury and or damage after getting a COVID-19 vaccine (Lee and Kim, 2021). The compensation will provide up to 10 million KRW for the medical expenses caused by vaccines.

1.2. Peculiarity of COVID-19 vaccination in Lithuania

Paragraph 1 of Article 21 of the Constitution of the Republic of Lithuania (hereinafter – **Constitution**) (1992) establishes that the human person is inviolable. The content of the inviolability of the person as a protected value consists of physical and mental inviolability (Ruling of the Constitutional Court of the Republic of Lithuania of 4 June 2012). This right to the integrity of the person is not absolute, i.e., it may be limited. However, this may be done only on the grounds and in accordance with the procedure established by law (Ruling of the Constitutional Court of the Republic of Lithuania of 8 May 2000).

Paragraph 1 of Article 2.25 of the Civil Code of the Republic of Lithuania (2000) repeats the above-mentioned constitutional provision, *inter alia*, establishing that a natural person is inviolable. The inviolability of a natural person is his or her right to decide on the intervention of his or her body and the right not to have any intervention against his or her body without his or her consent (Mikelėnas et. al., 2002, pp. 75).

The European Court of Human Rights (hereinafter – **ECHR**), for its part, classifies the physical and psychological integrity of the individual as a concept of privacy within the meaning of Article 8 of Convention (ECHR, 2005). According to the ECHR (*Ibid*), even the slightest interference with a person's physical integrity against that person's will must be regarded as a restriction on the respect for private life guaranteed by Article 8 of the Convention.

The ECHR (2003, 2012) has also emphasized in its case law that the physical integrity of the individual covers the most intimate aspects of a person's private life. The slightest coercive medical intervention in the human body means the restriction/disregard of this right. The freedom to accept or refuse a particular medical procedure or to choose an alternative form of treatment is an indispensable part of the principles of free choice and personal autonomy (ECHR, 2010). The scope of free self-determination also includes the possibility of engaging in activities that may be perceived as physically or morally harmful or dangerous to that person (ECHR, 2012). Compulsory vaccination, as an involuntary medical procedure, is tantamount to restricting respect for private life, including the physical and psychological integrity of the person, guaranteed by 1st paragraph of Article 8 of the Convention (ECHR, 1999, 2002). But we also see the other side, on 8 April 2021 the ECHR has ruled that the Czech Republic's compulsory vaccination regime for children is without prejudice to the right to privacy enshrined in Article 8 of the Convention. It should be noted, that in each case it is necessary to assess individually and to answer the questions: was it „in accordance with the law"; pursued one or more of the legitimate aims set out therein; and was „necessary in a democratic society."

The constitutional principle of equality of persons for the law means the innate right of a person to be treated equally with others. Paragraph 1 of Article 29 of the Constitution (1992) enshrines the formal equality of all persons, Paragraph 2 enshrines the principle of non-discrimination of persons and non-granting of privileges (Ruling of the Constitutional Court of the Republic of Lithuania of 2 April 2001). The Constitutional Court has more than once stated in its rulings that this principle must be observed both when passing laws and applying them. That principle obliges the same facts to be treated in the same way in law and prohibits, in principle, the same facts from being treated differently arbitrarily. Thus, the Constitutional Court has more than once held that the constitutional principle of the law on equality of all persons would be violated if a certain group of persons to whom a legal norm is granted was treated differently from other addressees of the same norm, although there are no huge differences of magnitude that such unequal treatment is objectively justified.

In January 13, 2022 the Law on the Prevention and Control of Communicable Diseases of the People No. I-1553 Draft law amending Articles 11 and 18 was registered. That Draft law sought to introduce compulsory COVID-19 vaccination in Lithuania for workers in certain areas, e.g., 1) personal health care services and activ-

ities; 2) social services and activities. The registration and submission of such a draft law already show that vaccination has been considered by the responsible institutions and to be made compulsory in Lithuania for certain, distinct groups of persons.

Apart from the mandatory nature of vaccines (as there is currently no such imperative regulation in Lithuania), we are faced with a situation where such actions are carried out as a result of universal immunization, not only for personal benefit but also for the protection of society, we are talking about moral benefits (Largent and Miller, 2021). It is often the case that a person performs such actions for the „general good", the state strongly encourages such actions and we are under some pressure.

Interesting to note that under the Law on the Rights of Patients and Compensation for the Damage to Their Health (1996) a newly adopted clause with regard to consent form and content with regard to vaccination against COVID-19 applies (Article 16[1]). By this, it introduces specific requirements that apply for the consent of a patient to be vaccinated by, *inter alia* COVID-19 vaccines. Meaning that each time a person arrives for a COVID-19 vaccine it is presumed that the person expresses its consent if certain information about the vaccine is provided by the healthcare specialist or it is available in the premises of vaccination.

2. Mechanism of compensation for damages to person's health in Lithuania

The new wording of the Law on the Rights of Patients and Compensation of the Damage to their Health (1996), which entered into force on 1 January 2020, introduced significant changes in the process of compensation for damage to patients' health. A no-fault compensation model was introduced by the latter amendments, where patients' health damage is compensated without the need to prove illegal actions and the fault (guilt) of the person who committed it (the healthcare professional).

The following conditions for compensation for damages to the patient's health were established (Article 24(6)): 1) the damage caused to the patient's health and; 2) it is not unavoidable damage. The notion of unavoidable damage[1] is a new concept in the legislation and it requires to assess whether harm to the patient's health could have been avoided by providing healthcare in accordance with the quality requirements imposed on it. Patient can commence proceedings for damage compensation by submitting a form to the Commission on the Determination of Injury to Patients

[1] Unavoidable harm - harm to the patient's health that is not related to the provision of personal health care services or is related to personal health care services, but has arisen due to circumstances which the personal health care professional and/or personal health care institution could not foresee, control and/or prevent their way. The criteria for imminent damage shall be established by the Government of the Republic of Lithuania. Law of the Republic of Lithuania on Patients' Rights and Compensation for Damage to Health No. I - 1562 Law amending Articles 2, 7, 8, 13, 20 and Chapter V, supra note 49, Article 2 (91).

(hereinafter – the **Commission**) Patient is no longer required to prove illegal actions or guilt and a causal link between the damage to health and the provision of personal health care. It is only required to submit general information about how the damages occurred and prove damages (pecuniary and non-pecuniary) suffered by the patients. The rest is assessed by the Commission, with the assistance of experts as necessary.

It is agreeable that such model benefits patients as the compensation model is efficient and does not require costly and lengthy legal proceedings, making it easier for them to access a quick loss payment (Caplan and Reiss, 2020). It also contributes to greater legal certainty and predictability of the process.

However, Resolution of the Government of the Republic of Lithuania No. 3 of 8 January 2020 „On Approval of the Description of the Procedure for Compensation for Property and Non-Property Damage Caused by Damage to the Patient's Health" explicitly states that damages suffered due to side effects of medicinal products falls under the notion of unavoidable damage, therefore, it is not compensated. Namely, the provision states that: unavoidable damage among other things exists when it is a disease or a health disorder caused by the pharmacological properties of medicinal products when used in accordance with the conditions specified in the summary of product characteristics, diagnostic and treatment descriptions, diagnostic and treatment methods and/or diagnostic and treatment protocols.

Therefore, in light of such legal provisions side effects of a COVID-19 vaccine that are included in the summary of product characteristics are not covered by this model of compensation.

Lastly, who would respond if a person had a contraindication (hypersensitivity to the active substance or other excipient) and could not be vaccinated with any COVID-19 vaccine? In that case, in the absence of appropriate assessments from a doctor, would they be liable under the general no-fault harm model? The Supreme Court of Lithuania in civil case No. 3K-3-236/2010 clarified that the fact that the patient selected the treatment was purchased and had access to the data on the medicine in the package leaflet does not release the doctor from the obligation to provide the patient with all the necessary information. A doctor who fails to comply with the obligation to provide information may be liable for the damage caused to him or her as a result of the patient's failure to comply with that obligation and his or her lack of understanding of the effects of the treatment, even if the doctor acted diligently during the medical procedure. The patient may claim damages because, without full information, they may not be able to know and avoid the risks of treatment by giving up a particular treatment, as well as not being aware of the contraindications for that medicine.

3. How damages caused by COVID-19 vaccine can be reimbursed under current legislation?

The provisions of the law refer only to the provision of health care services. However, the damage caused by vaccines cannot only be the same as that caused by a person but is much more significant (Hickey and Ward, 2021).

Liability for poor quality vaccines, production, safety requirements may arise under Articles 6.292–6.300 of the Civil Code of the Republic of Lithuania under the terms of the manufacturer's civil liability (also known as product liability). The institute of damage caused by a product or service of poor quality is considered a special tort in the civil liability system – the principle of no-fault liability applies. Therefore, a consumer seeking adequate legal compensation would have to prove damages, poor quality of the product or service and the causal link between them (Ulonas and Novikovienė, 2002, pp. 602), and without proof of at least one such aspect, a person may not expect human redress of incurred damages/injuries.

From this, it implies that in case of circumstances of product liability (that is an absolutely different legal concept than the one of the compensation for damages caused by side effects (adverse reaction)), the manufacturer is responsible. It is acknowledged that there is no harm when the vaccine is used in accordance with the conditions set out in the Summary of Product Characteristics for this vaccine and the disease or disorder is due to their pharmacological properties. The person evaluates all possible side effects before deciding to be vaccinated, as well as before deciding to take any medication, and agrees to have the vaccine injected into the body during the invasive procedure. Thus, according to the general principles of healthcare provision, vaccines (which are not usually mandatory) are self-consent, and adverse reactions to vaccines can only be claimed if adverse reactions not listed in the summary of product characteristics have occurred.

In this light it is interesting to note certain provisions of the Advanced Purchase Agreements of certain vaccines, which define the conditions for the purchase of COVID-19 vaccines by the respective vaccine manufacturer and the European Commission (2021): „<…> *the use of Vaccines <...> will happen under epidemic conditions requiring such use, and the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States*". The Advanced Purchase Agreement of AstraZeneca (Vaxzevria) contains a provision stating: „*Each Participating Member State shall indemnify and hold harmless AstraZeneca, its Affiliates, subcontractors, licensors, and sub-licensees, and officers, directors, employees and other agents and representatives of each from and against any and all damages and liabilities <...>*".

Unfortunately, not all Advanced Purchase Agreement are publicly available, for example in case of Moderna vaccines, almost all clauses are marked as confidential

and there is no way to access it. Therefore, specific provisions with regard to product liability are unknown.

What does it mean, one may wonder? In general, it means that pharmaceutical companies remain responsible for product quality and safety requirements, they are subject to the manufacturer's civil liability, but they are not responsible for the (in) improper use of the vaccine and/or the side effects that could occur. Also, it is very likely that Governments, including Lithuania, will indemnify any product liability of the manufacturer following the provisions of Advanced Purchase Agreements.

Does that seem legally appropriate in the context of the peculiar vaccination regime that is applicable in Lithuania? The Government asks people to be vaccinated not only for their own safety but also for other members of society, therefore the no-fault model of compensation that can be called a „social contract" might be necessary – it assures those who have been vaccinated that the state will take care of them if there are serious side effects (Kod, 2021). It is reasonable to say that, if regulation were introduced requiring a person (such as a person working in a particular profession) to be vaccinated by state law, the possibility of a voluntary decision to be vaccinated would be substantially limited, in which case the state would have to compensate for any damage to their health (Ro, Ro and Kim, 2021). Compensation for damage to a patient's health caused by pandemic vaccines could not and should not be a sign of civil liability (an adverse reaction to a pandemic vaccine that has caused serious consequences is not related to illegal actions or omissions of others that would damage the health of the person vaccinated with the pandemic vaccine). Sometimes it can cause much greater harm/injuries and longlasting consequences than the careless or poor quality actions of a healthcare professional.

However, what are the damages caused by side effects (adverse reactions) of COVID-19 vaccines? If the mechanism of compensation for damages caused by side effects is introduced should it cover all damages of any side effect? What is known so far about the pharmacological properties of the vaccines in questions that might be helpful in deciding the scope of compensation mechanism?

4. Effects of vaccines and the damage – the pharmaceutical analysis

In very general terms, compensation of damages with regard to the medical preparations is a remedy in the form of a monetary award to be paid to a claimant as compensation for loss or injury. In most cases, the award is not warranted, because the side (or adverse) effects are in the pharmacology overview and description. When an individual is buying medical products, together with the products one will get a written information pack, which contains all side and adverse effects. It is the user of the product that is essentially taking the full risk.

According to the COVID-19 vaccines (which are considered as medical preparations), the current situation and predicament are different. It is a well-known fact, that the scientific evaluation procedure has not been finished. In other words, by standards, the vaccines are still in the research phase. For example, safety updates for the Comirnaty vaccine are still provided and updated monthly (EMA, 2021). During this phase, the process of gathering data about effectiveness is still undergoing. The same applies to the research of the side effects that vaccines could provoke.

The notion of public health emergency required urgent efforts to develop and test the efficacy and safety of vaccines to combat the COVID-19 pandemic. The emergency use approval has been granted to COVID-19 vaccines before the completion of conventional phases of clinical trials. However, there is no comprehensive review of safety data reported from the vaccine trials, which is critical information to inform the policies in order to improve uptake of COVID-19 vaccines and mitigate the risk aversion perceived due to the COVID-vaccine side effects.

At present, it is very crucial to establish the safety of the COVID-19 vaccines when emergency approval is being granted to these vaccines without completion of all phases of clinical trials. Since vaccines are still being tested in clinical trials, so far there are no official results that reported the comprehensive profile of COVID-19 vaccines.

4.1. Fully approved vaccines

On December 21, 2020 European Medicines Agency (EMA) authorized the first COVID-19 vaccine – Comirnaty. After about two weeks, on June 06, 2021 the EMA granted full approval to the Spikevax (previously Vaccine Moderna) COVID-19 vaccine.

Currently, there are five approved COVID-19 vaccines in Europe – the latest, Nuvaxovid, was approved just a few months ago – December 20, 2022.

Specifically, vaccines Janssen, Vaxzevria and Nuvaxovid are not currently recommended for people below 18 years of age. Comirnaty vaccine is fully approved for the prevention of COVID-19 in people 5 years of age and older, and Moderna is fully approved for people 6 years of age and older.

The COVID-19 vaccines create a so-called „grey-zone“ because the side-effects are: 1. still unknown and unidentified because of short time span; 2. known, but not yet registered officially and the process side-effect approval hasn‘t been finished. For example, one of the Comirnaty vaccine‘s adverse effects is Myocarditis/Pericarditis. The European Medicines Agency assessed this complication in May-July 2021, halfway through the vaccination process. It was recommended to supplement the package leaflet with a warning about myocarditis/pericarditis occurring in young men 14 days after the second dose of the vaccine, indicating that its frequency is not yet known (Aušrotas, 2021).

4.2. Information on the possible side effects of the vaccines

The information provided to the general public on the functioning of the medicinal product (in this case the vaccine) is significantly simplified. Comparing the package leaflets of all COVID-19 vaccines legally used in Lithuania, we can see that only the main possible side effects are presented.

Vaccine manufacturers in package leaflets that are available to the general public warn against general side effects, but there is little focus on more serious side effects. Generic side effects such as: injection site pain, swelling, general fatigue, headache, muscle pain, joint pain, fever, feeling unwell.

However, in the information provided to the health professionals (a summary of the characteristics of the medicinal product), which is publicly available, a slightly different picture is presented. In addition to all general data on the medicinal product, the proportion of clinical data, possible routes of administration, and general side effects, potentially serious and extremely serious side effects are also identified.

Adverse reactions observed during clinical studies are listed below according to the following frequency categories: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), Not known (cannot be estimated from the available data) (Summary of product characteristics).

Serious side effects include hypersensitivity and anaphylaxis, myocarditis and pericarditis, acute peripheral facial paralysis, paresthesia.

A number of anxiety-related reactions are described, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g., dizziness, heartbeat, increased heart rate, changes in blood pressure, paraesthesias, hyperaesthesia and sweating). Serious side effects – thrombocytopenia and clotting disorders – are reported.

Furthermore, in the general summary of characteristics of COVID-19 vaccines, clinical trials are taken into consideration. Conclusions are presented about collected data and results regarding the most common reactions in different groups of subjects and how these reactions are related to the number of doses.

Unfortunately, when studying it further, there are more unanswered questions like: why specific target audiences were selected for collecting data? There is a lack of focus groups within people with comorbidities, disabled people and elderly people. Also, it is missing information regarding the safety of vaccines for people with autoimmune or inflammatory disorders, and there is a question in theory if vaccine can affect their well-being as well as make their current diagnosis to get even worse. The document itself declares that there is a lack of information regarding these studies and that the risks and benefits should be considered.

Another big issue is when it comes to a question of whether it is safe to get the vaccine while having other vaccines or using specific (prescribed) long-term drugs, it is simply covered by the word „not recommended". Despite that, groups of people, that have weaker health are vaccinated in the first place and are not offered a proper compensation mechanism.

4.3. Analysis of Lithuania's medical situation in the context of the COVID-19 vaccines

From the start of vaccination on December 27, 2020 to December 31, 2021, a total of 4,131,021 vaccinations were performed in Lithuania (*Table No. 1*). For the second year running, the Commission has been receiving complaints about COVID-19 since the start of vaccination, i.e. From 27 December 2020 to 31 December 2021, a total of 6,808 initial reports were received (serious reactions to person's health – 407) on suspected adverse reactions (SAR) associated with the use of COVID-19 vaccines in Lithuania (VVKT, 2022) (*Table No. 2*).

Table No. 1

Vaccine	Vaccine doses	Number of suspected adverse reactions (SAR)	Percentage of SAR reports from the number of vaccinations	Number of SAR reports per 1000 vaccinations
Comirnaty	3 005 787	3 396	0,11	1,1
Spikevax	304 930	611	0,2	2,0
Vaxzevria	537 483	2 292	0,43	4,3
Jannsen	282 821	479	0,17	1,7
Total number of all vaccines	**4 131 021**	**6 808**	**0,16**	**1,6**

Table No. 2

Healthcare providers reports	Reports from patients	Reports submitted to EudraVigilance	Reports in total
816 (11,99 %)	5 574 (81,87 %)	418 (6,14 %)	6 808

Evaluating all the received reports of SAR in Lithuania in the period of 27/12/2020 – 31/12/2020, there was 0.16% of complaints from total number of vaccinations.

The majority of SAR complaints were regarding the Comirnaty vaccine. In this same period 47.3% of vaccinated people were male and 52.7% female. According to the official data, most of the SAR were received from vaccinated women – it is almost 72% of total SAR reports.

The severe side effects of each vaccine have similar symptoms, and the number is certainly not small, even considering the total number of people vaccinated (*Table No. 3*).

Table No. 3

Severe Symptoms	Events Reported
Syncope	82
Tachycardia	32
Stroke (cerebrovascular insult)	22
Myocarditis and pericarditis	18
Acute peripheral facial paralysis	17
Convulsion	14
Myocardial infarction/heart attack	9

Between 27 December 2020 and 31 December 2021, 29 deaths were reported (*Table No. 4*).

Table No. 4.

Vaccine	Number of deaths
Comirnaty	16
Vaxzevria	11
Spikevax	1
Covid-19 Vaccine Janssen	1
Total	**29**

In this case, it should be noted that in zero cases did the State Medicines Control Agency establish a direct causal link between vaccination with Covid-19 vaccines and the death of the patient.

Given that in Lithuania no mechanism of compensation for side effects caused by COVID-19 vaccines exist, such cases could not be reimbursed to the relatives of deceased people, as one of the essential features of the causal link could not been fulfilled.

Considering the non-exhaustive list of side effects that could be caused by the COVID-19 vaccine, it is reasonable to propose a certain nature of adverse reaction that shall be included in the compensation mechanism for patients. However, assessment of a particular side effect that could emerge newly shall be left open by the competent authority. Otherwise, patients could be deprived of effective remedies.

5. Damage compensation for COVID-19 vaccine – call for actions

During this period, when vaccination and revaccination of all individuals with booster doses are still being actively promoted, no changes in the legal framework have been adopted in Lithuania that would allow people to fully trust the COVID-19 vaccines and give the right to know that the side effects will be adequately compensated.

On January 13, 2022, draft amendments to the Law on the Rights of Patients and Compensation of the Damage to their Health No. I-1562 on Articles 24 and 25 were registered. This was supplemented by the draft Article 24 (1), registered by the Seimas on January 20, 2022 (hereinafter – both pieces of the draft legislation are called „Draft Law"). The purpose of this Draft Law is to enable adequate compensation for the damages (pecuniary and non-pecuniary) caused by vaccines to the patient's health. The draft law provides that:

1. *A patient or other person entitled to compensation in order to be compensated for the damage caused by an adverse reaction caused by vaccination during a state emergency and/or quarantine throughout the territory of the Republic of Lithuania in a Government Resolution on State Emergency and (or) quarantine the vaccine specified in the entire territory of the Republic of Lithuania, not later than within 3 years from the date on which it became aware or should have become aware of the damage caused by the vaccines, apply to the Commission in writing.*
   <...>
3. *Compensation shall be paid if the Commission finds that the damage to the patient's health is caused by vaccines and the provisions of Article 6.292 of the Civil Code do not apply to compensation for damage caused by vaccines.*
4. *Compensation in the amount specified in the decision of the Commission shall be paid by the Ministry of Health from the state budget funds allocated to it within 30 days after the date of the decision of the Commission".*

Indeed, one can agree that it is a good start needed for all patients suffered because of the side effects of COVID-19 vaccines. Of course, it is not yet adopted therefore, it is not a legal act in force. However, one could also raise a doubt whether such Draft Law is appropriate and enough?

It is foreseeable that the damage caused could be compensated only if it were caused by an adverse reaction that caused **serious consequences**. What would that

cover in particular? Compensation for damage, considering the definition of a **serious adverse reaction** in paragraph 44 of Article 2 of the Law on Pharmacy of Lithuania (2006), would cover damage in cases where a person has suffered **death, life-threatening, hospitalization or prolongation of the duration of his hospitalization, long-term/essential disability, incapacity for work or birth defect** as a result of the reaction to the vaccine. Other reactions would be considered as minor adverse reactions and their damage would be uncompensated (e.g., mild fever, flushing at the site of the puncture).

Hospitalization, disability, and other signs should not be considered the only evidence of injury. Hospitalization is not appropriate to address some of the officially approved adverse reactions to pandemic vaccines. For example, inflammation of the heart wall (pericarditis) (VVKT, 2021) can take many forms, one of which is chronic pericarditis, which can affect people throughout their lives, but in a milder form and sometimes gets worse when they need medical help, but not necessarily in a hospital (Hoit D., 2000). Pericardial effusion may also have consequences for cardiac function, although it may go unnoticed at first. Vaxzevria can also cause Guillain-Barré syndrome, which can cause significant damage to the human nervous system but does not require hospitalization (European Medicines Agency). Pandemic vaccines can also, in extremely rare cases, cause long-term side effects that have not been identified in the medical literature (British Institute of International and Comparative Law (BIICL), 2022). For example, the feeling of „burning" in the chest and digestive problems that interfere with sports or work does not necessarily mean going to the hospital or being called a disability, but it is still a significant injury that has a significant impact on a person's life (Van Tassel et. al., 2021).

In this light, it is reasonable to consider a separate commission, independent of the Ministry of Health, to be set up **to assess the damage caused by the possible side effects of vaccines.**

This should not be combined with the damages (i.e. loss of life or injury) caused by the existence of a „no-fault" model and the actions taken by health professionals. In this case, it would be proposed to require the commission to examine claims for compensation and determine the extent of the harm suffered by a person who has suffered damage from a pandemic vaccine, without establishing *a priori* criteria (such as hospitalization) as proposed by the Government. The commission should be eligible to assess the claim for compensation on the basis of the individual's medical history and the applicant's arguments about the damage suffered, rather than following „ticking the box" approach that is used in the current mechanism of the no-fault model, regardless of the specific cases and the consequences for the individual. It should be emphasized that such a commission should include particular experts such as: in vaccinology, immunology, neurology, pediatrics, public health ethics, health law, and public health policy (Keelan and Wilson, 2011).

Also, compensation from the funds of personal health care institutions, i.e. an account administered by an institution authorized by the Government, in which the contributions of personal health care institutions to compensation for damage are accumulated, would be unjustified and unfair. This fund is intended to compensate patients who have suffered adverse effects through the fault of healthcare professionals. The damage caused by vaccines is not the same as that done by healthcare professionals, so it would be wrong to use the funding for completely different purposes.

In the opinion of the authors, compensation for damages caused by pandemic vaccines should not be linked to a „no-fault" compensation mechanism, but to a separate cluster of compensation for injuries financed by the state budget.

With regard to causal link, following the current approach of the State Medicine Control Agency that no damages were linked to the use of vaccines, one shall consider the mechanism of proving the damages and their link to the vaccine. It could be difficult to prove the damages and causal link if more time has passed since the vaccination and the reaction does not appear immediately and the symptoms or damage do not appear until later.

Proof of causation can be linked to a closed list of recognized adverse reactions the ones that are provided in the US and in the EMA. However, an alternative option leaves the test open, as in the recent Canadian COVID-19-specific NFCS, or the COVAX scheme, where the possibility of compensation for adverse events later proved not to be linked to the vaccine is preferred to the risk of excluding worthy claims. In the context of novel pandemic vaccines, the latter seems more appropriate as knowledge about these products evolves and consolidates (Rizzi et al., 2021). With this in mind, the authors would suggest creating a certain formula that would calculate the amount of harm done to a person. Such a formula should take into account the injury factor with an amplitude ranging (e.g. from 1 to 200) and should include the nature of the damage and the level of the disorder. In this context, the formula must be adapted individually in each case. A similar scoring system, which the authors consider to be quite appropriate for determining the damage caused by vaccines, is provided in the Resolution of the Government of the Republic of Lithuania No. 3 of 8 January 2020 „On Approval of the Description of the Procedure for Compensation for Property and Non-Property Damage Caused by Damage to the Patient's Health".

Conclusions

1. The current legal framework in Lithuania stipulates that in the event of any possible side effects from the COVID-19 vaccine, a person may not benefit from a special simplified procedure for obtaining damages (the so-called „no-fault" procedure).

2. Pharmaceutical companies remain responsible for the product quality and safety requirements, they are subject to the manufacturer's civil liability, but they are not responsible for the (in) improper use of the vaccine and/or the side effects that could occur.
3. From 27 December 2020 to 31 December 2021, a total of official 6,808 initial reports were received on suspected adverse reactions (SAR) associated with the use of COVID-19 vaccines in Lithuania.
4. COVID-19 vaccination has been taking place on a very large scale in Lithuania for almost a year and a half, and we still do not have a legal mechanism for compensation for health damage. In this context, it is stated that compensation for the damage caused by the side effects of vaccines should be based on a no-fault damage model funded by a separate State Institute / Fund.
5. It is proposed to accelerate the adoption of the draft Law on the Rights of Patients and Compensation for Damage to Their Health and to address the following key aspects:
   5.1. To require the commission to examine claims for compensation and determine the extent of the harm suffered by a person who has suffered damage from a pandemic vaccine, without establishing a priori criteria (such as hospitalization) as proposed by the Government; an independent commission, independent of the Ministry of Health, should be set up to analyze and assess these situations.
   5.2. Compensation for damages caused by pandemic vaccines should not be linked to a „no-fault" compensation mechanism under the current legal framework, but to a separate cluster of compensation for injections financed by the state budget.
   5.3. It is proposed to establish a clear formula/mechanism according to which the harm caused to a patient by the side effects of COVID-19 vaccines should be determined with great precision in each case.

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THE DISTINCTIVE NATURE OF COVID-19 VACCINES: COMPENSATION FOR POTENTIAL DAMAGES UNDER THE LEGAL FRAMEWORK OF LITHUANIAN STATE IN THE CONTEXT OF GLOBAL EXAMPLES

Summary

This article evaluates the (non-)mandatory aspect of vaccination and the possibilities of compensation for possible damage in the context of COVID-19 vaccination in Lithuania, based on global examples and analyzes of other foreign countries. In order to fully assess the side effects of vaccines that could be a basis for claiming damages, a pharmaceutical analysis of the side effects of COVID-19 vaccines legally used in Lithuania and the European Union is presented. Given the nature of vaccines, the scale of vaccination, and the fact that vaccination has been taking place in Lithuania for about a year and a half, we still do not have a legal mechanism for compensation. According to that, the authors analyze the draft amendments to the Law on the Rights of Patients and Compensation of the Damage to their Health registered by the Parliament of the Republic of Lithuania in 2021 and indicate the options and essential suggestions on possible improvements.

COVID-19 VAKCINŲ IŠSKIRTINUMAS: KOMPENSACIJA UŽ GALIMAI PATIRTA ŽALĄ PAGAL LIETUVOS VALSTYBĖS TEISINĮ POBŪDĮ GLOBALIŲ PAVYZDŽIŲ KONTEKSTE

Santrauka

Šiame straipsnyje yra vertinamas vakcinavimo (ne)privalomumo aspektas bei kompensacijos galimybės už galimai patirtą žalą COVID-19 vakcinavimo kontekste Lietuvoje, remiantis globaliais pavydžiais bei kitų užsienio šalių analizėmis. Siekiant išsamiai įvertinti šalutinius poveikius, kurie galėtų būti pagrindas reikalauti žalos atlyginimo, pristatoma Lietuvoje ir Europos Sąjungoje teisėtai naudojamų COVID-19 vakcinų šalutinių poveikių farmacinė analizė. Atsižvelgiant į vakcinų pobūdį ir vakcinavimo mąstą bei tai, jog vakcinacija Lietuvoje vyksta jau beveik pusantrų metų, o žalos kompensavimo teisinio mechanizmo vis dar neturime, analizuojami Pacientų teisių ir žalos atlyginimo įstatymo pakeitimo pasiūlymai, įregistruoti Lietuvos Respublikos Seimo 2021 m. Teikiami praktiniai bei teoriniai argumentai dėl esminio poreikio tobulinti šiuos pasiūlymus toliau.