



# Does the Medical Treatment Risk Fund operate for the benefit of patients?

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## Summary

### Motivation

As medicine develops, available treatment methods also become more sophisticated. At the same time, the risks of harming the health or life of a patient during the medical treatment process are also increasing.

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare requires the Member States of the European Union to establish mechanisms enabling the patient to assert his or her rights and to receive compensation if the damage is caused to his or her health during the medical treatment process. Following the requirements of the Directive, according to the example of Sweden and Denmark, the Medical Treatment Risk Fund (hereinafter referred to as 'the Fund') was created and launched in Latvia on 23 Oct 2013. Prioritisation of the interests of the patients was among the crucial for making this choice.

When establishing the Fund, its ultimate goal was stipulated, that is, providing the patients with the opportunity to defend their rights and be reimbursed for the damage caused to their life or health by medical malpractice which would compensate for the loss of health or the spending on health improvement after the damage caused in an out-of-court procedure, by organising as fast, efficient and accessible to the patient as possible.

The Fund is under the responsibility of the government, and two authorities: Health Inspectorate (hereinafter referred to as 'the Inspectorate') and the National Health Service (hereinafter referred to as 'the Service') operate the Fund. The Fund follows the administrative procedure in reviewing patient claims that, according to the Ministry of Health of Latvia, increases the trust of patients in this model of receiving compensation and defending their rights.

Five years have passed since the establishment of the Fund, and over the years, the Fund has received more than 900 patient claims, has made more than 200 decisions recognising the existence of the damage caused and has paid compensation of 4.4 million euro to patients. In the opinion of the State Audit Office, this is a sufficient period and amount of claims to assess whether the newly established model of protection of patient rights has reached its primary goal.

The following criteria have been used in the audit to assess the performance of the Fund: is the Fund accessible to the patient, does the Fund review patient claims in due time, is the procedure for determining the amount of the compensation understandable to the patient, does the financial engineering process of the Fund comply with the requirements of the regulatory enactments, and is improvement of the Fund's operation ensured?

## Major conclusions

The State Audit Office concludes that the ultimate goal of the Fund to establish reasonable and efficient complaint procedures enabling the patient to receive compensation for the harm caused to his or her life or health according to the extrajudicial process is not reached. Therefore, there is no reason to believe that the Fund is operating in the interests of patients.

The process of administering patient claims for reimbursement established by the Fund cannot be described as accessible, timely, and understandable, so the auditors deduce that the Fund does not operate by the principles of good governance and does not respect the priority of the patients' interests.

*The attentive and respectful attitude of authority towards an individual characterises good governance, which includes not only the duty of the authority to act by regulatory enactments but also the continuous improvement of the quality of its services given that state administration serves the population.<sup>1</sup>*

The Ministry of Health presumes that the responsibility of the government over the Fund would increase the trust of patients in this model of receiving compensation and defending their rights. However, the problems identified in the organisation and management of the Fund during the audit do not improve the trust of patients.

*An authority is obliged to inform the public of its activities, especially a part of the public whose rights or legal interests are affected or may be affected by the actions of the given authority.<sup>2</sup>*

Unfortunately, the audit found that sufficient information on the Fund and its operational objectives is still lacking although the Fund was launched five years ago, which is a prerequisite for the Fund to be considered accessible and focused on the full protection of patient rights. Survey data shows that only 9% of respondents actually know what the Fund actually is.

*The authority must ensure that its operation provides fair procedures within a reasonable term.<sup>3</sup>*

The audit has established that the Fund infringes the deadlines for reviewing patient claims and taking decisions under the Law on the Rights of Patients. The Fund should review patient claims for compensation and make decisions no later than six months after receipt of the application, but the Fund has been able to deal with only 24% of the cases within this period. In cases where additional time is required to assess the circumstances, the Fund can decide within one year. There are 33% of the cases reviewed in such a term. However, the auditors have doubts about the justification for extending the deadlines, as there is no evidence of the need for additional circumstances to be assessed stated in the files under evaluation. By contrast, 33% of the decisions were taken within a time limit of more than one year, that is, late.

When making its decision, the Fund shall rely on the opinion provided by the Health Inspectorate on the existence or absence of the damage caused as well as on the amount of the damage determined. One must note that most of the time or approximately 90% of the claim administration time is devoted to expertise and preparation of the opinion. Moreover, the time of conducting expertise is increasing every year instead of decreasing. If these were 8 months on an average in

2014, then that was more than a year on an average in 2017. This means that if the Inspectorate prepares an opinion late, the decision of the Fund is taken late in any case.

The capacity and disorderly internal processes of the Health Inspectorate, which do not set deadlines for the execution of work or the responsible employees to control execution of the latter cause failures to meet the deadline. At the same time, one can mention the overly general regulatory framework for calculating the severity of damage caused to the health or life of patients among the main reasons for the delay. The Inspectorate has recognised the regulatory framework unclear and challenging to apply in practice. In the auditors' opinion, the fact that the Inspectorate itself critically evaluates the method for calculating the damage set forth by the regulatory framework of the Fund points to the risk that the rights of patients to impartial and fair procedures are not ensured. Even a sufficiently attentive and knowledgeable patient cannot trace and understand the way the damage is calculated. Therefore, the patient will not find it fair and impartial in any case when the maximum amount of compensation is not paid. This is also confirmed by the fact that 18% of the Fund's decisions are appealed to the Ministry of Health, and at least 48% of them are subsequently appealed to the Administrative Court.

*An authority must continuously check and improve the quality of the services provided by simplifying and improving procedures for the benefit of an individual.<sup>4</sup>*

When deciding on the establishment of the Fund and elaborating the framework regulating the activities of the Fund, the Ministry of Health was aware that the efficiency of the newly established Law Enforcement Institute should be assessed continuously after the Fund was launched. To evaluate and, if necessary, improve the process of providing services, it is essential to make sure that the Fund offers a set of patient-oriented activities, an appropriate culture of communication, reviewing of the claims and decision-making within the timeframe specified in the Law on the Rights of Patients. However, it has not carried out such an assessment. Also, changes to the regulatory framework have been purely technical and norm adjusting and have not resulted in improved efficiency of the Fund's performance, as the problems identified are still not eliminated.

One must note simultaneously that the Ministry of Health has sufficient information about the delays in reviewing process by the Health Inspectorate, the uncertain mechanism for determining the severity of the damage caused, and a considerable number of appeals.

*Public administration acts in the public interest.<sup>5</sup>*

The State Audit Office also wishes to draw attention to the financial engineering process of the Fund, which, according to the auditors, casts doubt on the Fund's compliance with the interests of patients and the principle that public administration acts in the public interest. According to the Cabinet Regulation, the annual amount of contributions of medical treatment institutions to the Fund should be determined to take into account the number of projected justified claims, the number of people employed in the medical treatment institution, and their specialities. However, the National Health Service actually does not make any projections but relies on the same assumptions defined in 2013 every year, namely, the assumption that one must count on ten justified claims in the amount of maximum compensation per year.

Although it has not had any impact so far, *id est*, the Fund's resources have been sufficient to pay compensations, the auditors believe that the financial resources of the Fund might be insufficient if the claims were reviewed in time and the number of requests increased.

At the same time, one must state that the Fund is not liable for the infringement of the deadlines to review patient claims specified in the Law on the Rights of Patients. Thus, by delaying the decision-making time, it is possible to provide that the compensations paid to patients do not exceed the amount of funding available in the annual budget, and the Fund generates surplus at the same time.

The term of payment of compensation provided for in the Cabinet Regulation, which is 90 business days, indicates priority concern for the state budget not for the interests of patients. Moreover, this period is not proportionate concerning the time taken to review the claim and to make the decision of six months and the procedural steps to be taken during that period. In particular, if the Service has made a decision on the satisfaction of the patient's claim by recognising that the health of the patient is harmed and obtaining the funds probably is critical, for example, to mitigate or prevent the consequences of the harm caused to the patient immediately.

A group of foreign experts has also evaluated the operation of the Fund. Although they provided a critical assessment of the past performance of the Fund in their report, the audit did not provide confidence on the interest of the Ministry of Health interest in introducing the recommendations that the experts have proposed.

The State Audit Office considers that, in order to achieve the goals of the Fund, improve, and develop its activities, the Ministry of Health and the institutions providing the operation of the Fund should take into account both the assessment of the problems identified in the report of the group of foreign experts, the opinions of the organisations involved in the healthcare process and the industry, and the performance analysis of the Fund and the recommendations given in this audit.

## Major recommendations

Following the findings of the audit, there are seven recommendations for improving the performance of the Fund provided to the Inspectorate and the Service in total.

To achieve the ultimate goal of the Fund, the State Audit Office calls on the Inspectorate, in cooperation with the Ministry of Health, to take measures to improve internal processes and internal control, as well as measures to provide that the procedure for reviewing claims of patients is comprehensible to patients, accessible, and timely:

- ❖ Carry out a detailed assessment of the Fund's processes, functions, and responsibilities and elaborate a performance improvement and optimisation plan;
- ❖ Evaluate the efficiency of the work of doctors-experts to determine the number of doctors-experts actually needed and, if necessary, to find a solution to the shortage of doctors-experts;
- ❖ Set detailed deadlines for actions to be taken during the administration of claims and appoint the employees responsible for carrying out and monitoring operations;
- ❖ Promote a constructive and open discussion during the debate of the draft methodology<sup>6</sup> for determining the severity of the damage by involving not only the subordinate institutions of the Ministry of Health, but also teaching staff from universities, experts of university hospitals, and the organisations protecting the patient rights to ensure the introduction of a precise mechanism for determining the severity of the damage;
- ❖ Take reasonable steps to inform the public about the rights of the population as patients in the event of harm caused to the patient due to medical malpractice.

In their turn, there are recommendations provided to the Service for improving the financial engineering process of the Fund and improving the debt collection process so that the Fund would be able to meet its liabilities, and the amount of the Fund's assets would be sufficient to cover the claims in the long run as the number of claims for reimbursement increases.

<sup>1</sup> Website of the Ombudsman's Office of the Republic of Latvia: <http://www.tiesibsargs.lv/lv/pages/cilvektiesibas/laba-parvaldiba>, viewed on 14 March 2019.

<sup>2</sup> Part 7, Article 10 of the Law on State Administration System.

<sup>3</sup> Part 5, Article 10 of the Law on State Administration System.

<sup>4</sup> Part 6, Article 10 of the Law on State Administration System.

<sup>5</sup> Part 3, Article 10 of the Law on State Administration System.

<sup>6</sup> Guidelines for the Application of Annex 2 "Recommendations for the Health Inspectorate to Determine the Amount of the Damage Caused to the Life and Health of a Patient in Per Cent" to Cabinet Regulation No 1268 "Regulations of the Operation of the Medical Treatment Risk Fund" of 5 Nov 2013.