



Delivery process of personal protective equipment (protective face masks and respirators) in the health sector

Interim report

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There are inspections performed and an interim report elaborated within the framework of the financial audit “On the accuracy of the drafting of the 2020 annual report of the Ministry of Health” (Audit schedule No 2.4.1-9/2020 of the Third Audit Department of the State Audit Office of 27 April 2020) following sub-clause c), Paragraph 3, Section 3 of the State Audit Office Law.

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Why have we drafted this Interim report?

Since International Standard on Auditing (ISA) 701, Communicating key audit matters in the independent auditor's report¹, the State Audit Office is required to assess the need to include key audit matters in the audit opinion on the financial statements.

For the purposes of those standards, key audit matters are matters that, in the auditor's professional judgment, are significant in the context of the audit of the financial statements of the reported period that one reports to the management of an audited entity and that have been the focus of the auditor's attention. There is no separate opinion on the key audit matters issued.

The information provided on key audit matters serves as additional information for potential users of the financial statements. It helps apprehend both matters that the auditor has identified as significant in the professional judgment and the audited entity and the areas where the management of the audited entity has made significant judgments while drafting the audited financial statements. This information may also serve as a basis for potential users to communicate further with the management of the audited entity about specific aspects of governance, audited financial statements, or audits performed.

The solidity and actual spending of the requests for additional funds allocated to address the consequences of COVID-19 are the key audit matter, which is crucial in all financial audits on the accuracy of the drafting of the annual statements for 2020 of the ministries and central governmental agencies.

In 2020, COVID-19 pandemic affected Latvia like the rest of the world. The Cabinet of Ministers adopted a decision on declaring a state of emergency on 12 March 2020, and the state of emergency continued until 9 June 2020². The extraordinary circumstances caused by COVID-19 affected the daily lives of the government, the public, and everyone both during and after the emergency. The new conditions required the ability to react and adapt quickly, as well as caused deviating from the usual order. Under the new conditions, the institutions should have been able to coordinate their activities more intensely and to co-operate with each other by avoiding legal formalism and the departmentalism to ensure the functioning of the state and the protection of each individual in emergency conditions³.

Overcoming the COVID-19 pandemic and dealing with its consequences have required significant funds from the state budget. Since the declaration of the state of emergency, the Cabinet of Ministers has made decisions in connection with overcoming the crisis caused by COVID-19 and eliminating its consequences on the allocation and reallocation of state budget funds for the implementation of basic functions for 806,907,224 EUR in total and has examined proposals for reallocation of funds for the implementation of projects and measures co-financed by European Union policy instruments and other foreign financial assistance for 496,000,000 EUR⁴. The State Audit Office pays special attention to assessing the spending of state budget funds allocated for overcoming the COVID-19 pandemic, preventing, and mitigating its consequences.

The Cabinet of Ministers has allocated additional funds of 38,252,838 EUR to the Ministry of Health in relation with the overcoming, mitigating, and eliminating the crisis caused by COVID-19 until 30 June 2020.

The COVID-19 pandemic is rapidly increasing the demand for personal protective equipment worldwide to protect the health and safety of healthcare personnel and the general public.

The Cabinet of Ministers allocated funds of 11.7 million euros from the state budget program “Contingency budget” to the Ministry of Health for the purchase of personal protective equipment between 3 March and 20 March 2020 pertaining to the elimination of the consequences of the crisis caused by COVID-19.

The State Audit Office initiated an audit on 27 April 2020 to assess the process of purchasing personal protective equipment (protective face masks and respirators) in emergency conditions by providing medical practitioners with personal protective equipment.

The State Audit Office draws attention to the fact that one has not done the following during the audit:

- ❖ Assessment of the functioning of the civil protection system during the emergency situation;
- ❖ Assessment of the authenticity of the certificates of delivered personal protective equipment (protective face masks and respirators) and the quality of the delivered goods;
- ❖ Recalculation of the demand for personal protective equipment required by the institutions by the methodology used and the assessment of the justification of the allocation.

The designated authorities of Latvia responded to the statements of international organisations (European Commission and World Health Organization) actively before declaring a state of emergency in January and early February 2020 by identifying the availability of personal protective equipment in medical institutions and instructing on the required amount of reserves. However, with the onset of an acute shortage of personal protective equipment throughout Europe, Latvia was also subject to a severe risk that the provision of personal protective equipment to medical practitioners would be insufficient. Even though nobody could predict the spread of the COVID-19 crisis in late February and early March, auditors must admit now (only three months later) that no one acted promptly to ensure transparency of preferential procurement procedures, which would reduce public debate significantly on the solidity of the purchases of personal protective equipment made during the state of emergency period, because no guidelines were drafted at the national level for procuring without the Public Procurement Law applied. Procurement in health institutions was also based on oral instructions, the full list of applicants was not published, and tracing the supplier evaluation process according to pre-defined criteria was impossible leading to the situation when the Director of the National Health Service made unilateral decisions on purchases of personal protective equipment from five suppliers at the end of March.

Summary

A functioning civil protection system must be in place for disaster forecasting and planning, implementing timely preventive measures, providing assistance, and reducing damage to people, the environment, and property in the country.

In Latvia, the civil protection system is decentralised. There is a designated ministry appointed for coordinating the management of each type of disaster. The Ministry of Health manages disaster management related to human infectious disease epidemics while the State Emergency Medical Service plans to manage, and coordinates the system of emergency and disaster medicine.

The Cabinet of Ministers approves the State Civil Protection Plan. Based on the risk assessment, the ministries must evaluate the provision of the sector with state material reserves annually according to their types. State material reserves are a set of material resources that can be requested and used by institutions involved in the management of disasters, military and other threats if the daily and reserve resources at its disposal cannot ensure the elimination of the consequences of an emergency.

How ready has been the government to provide personal protective equipment in an emergency?

Due to the long-term neglect of planning and financing of state material reserves, the health sector did not have an “airbag” to rely on when the emergency occurred if purchasing the personal protective equipment needed by the industry would have been impossible at all.

Since 2017, there is no valid State Civil Protection Plan based on disaster risk assessment in the country, which would specify the disaster management measures and their implementers in detail. There is no valid classification of state material reserves in the country either since 1 April 2020. In its turn, funding for the replenishment of the state material reserves of the health sector was granted last in 2018. Thus, when the crisis emerged, the amount of reserves did not correspond to the classification of state material reserves valid then. In such a situation, prompt and proportionate action by the designated authorities in the event of a real crisis is crucial.

The first case of COVID-19 in Latvia was diagnosed on 2 March 2020. Still, the Cabinet of Ministers allocated financial resources of 1.2 million euros to the Ministry of Health one day later to enable the Emergency Medical Service to purchase medical equipment, disposable personal protective equipment, medicines and disposables, and to cover other emergency expenses for epidemiological safety. Part of the funding allocated on 3 March 2020 (111,348 euros) was also earmarked for the replenishment of the state material reserves.

Aiming to limit the spread of COVID-19, Latvia announced the state of emergency on 12 March 2020. On 15 March 2020, the meeting of the designated authorities decided that the Emergency Medical Service and other healthcare institutions should purchase personal protective equipment in larger quantities so that one could also distribute them to other healthcare institutions if necessary.

On 20 March 2020, the Cabinet of Ministers allocated funding to the Ministry of Health for the purchase of personal protective equipment, which did not exceed 10 million euros, by stipulating at the same time that the Minister of Health should be authorised to decide on the use of funding under the actual need.

How ready was the health sector to provide personal protective equipment in an emergency?

Nobody had yet foreseen a pandemic of the magnitude as COVID-19 and related national emergencies in early 2020. However, the purchase of personal protective equipment was complicated throughout Europe already in the mid-February 2020, prices rose sharply, deliveries were delayed, and Latvian healthcare institutions could no longer purchase personal protective equipment within the framework of the concluded contracts. The termination of the first joint procurement of the European Commission announced on 28 February 2020 for the supply of personal protective equipment to all Member States without results and legislation adopted by the European Parliament and the EU Council on derogations from product safety requirements are evidence of emergency in the market of personal protective equipment and confirm the need for non-standard action of the designated authorities of Latvia.

However, there is a possibility that one would have procured the necessary personal protective equipment for at least one month if one had decided to pool the needs of all healthcare institutions and request public budget funding for one large joint procurement in late January and early February. Instead of that, the Emergency Medical Service chose to call on healthcare institutions to increase their reserves of personal protective equipment and make purchases independently.

The organisation of the process of purchasing personal protective equipment in the health sector

The National Health Service purchased personal protective equipment for two weeks by taking over this process from the Emergency Medical Service on 18 March 2020, and it already handed the purchasing process over to the National Defence Military Facilities and Procurement Centre on 2 April 2020. The health sector purchased personal protective equipment (protective face masks and respirators) from five companies for 5.7 million euros.

Although one allowed certain institutions not to apply the Public Procurement Law for the fast deliveries already from 3 March 2020, the Ministry of Finance and the Procurement Monitoring Bureau published guidelines for procurement during the emergency almost three months later, namely, on 29 April 2020.

Consequently, the Emergency Medical Service and the National Health Service had to make purchases of personal protective equipment in a situation where one had not defined the procuring requirements either at the national level or within the health sector. The way for preferential purchasing fell within the competence and responsibility of the official making the procurement.

The audit established that the procurement process in the health sector was based on verbal instructions. Moreover, the health sector had no previous experience in purchasing under comparable conditions, and the employees in charge of purchases acted in accordance with their understanding of the application of public procurement law to effective procurement due to the conditions caused by the state of emergency.

Although the National Health Service indicated that a working group dealing with the purchasing of personal protective equipment had been established by oral order of the Director of the Service, the auditors were unable to obtain any documentation on its activities. In addition, the audit revealed

that the four-eye principle was not applied in the decision-making process of contracting specific suppliers, whereas the Director of the National Health Service made decisions alone. One must emphasise that the Director of the National Health Service has also informed other institutions involved in crisis management, such as the State Operational Medical Commission, the Meeting of Designated Authorities about his decisions, thus obtaining indirect support for concluding transactions from senior officials (including Minister of Health, State Secretary of the Ministry of Health, Acting Head of the Secretariat of the Crisis Management Council, the Heads of the designated authorities of the health sector).

The auditors understand that the National Health Service had to procure in a situation of the most significant uncertainty about the future escalation of the COVID-19 crisis in the country, so the Service had to act quickly and decisively. However, one tolerated unilateral decisions in the health sector, thus creating a risk of corruption.

Although the National Health Service has defined the criteria for the selection of suppliers, it did not provide documentary evidence of the tender evaluation process following the set criteria to the auditors. Thus, the auditors were not convinced that the selected tenderers met the selection criteria set by the National Health Service.

The National Health Service used various information dissemination channels to invite tenderers, for example, by engaging the Latvian Employers' Confederation on 17 March 2020 and publishing press releases. According to the auditors, the fact that the National Health Service did not publish the list of all tenders caused significant discussions about the tenderer selection process. Please note that the Service has published information on offers from 65 suppliers (dated between 19 March 2020 and 9 April 2020) until 8 June 2020 by indicating that the Service would supplement the list. An unpublished list of tenders (between 17 March 2020 and 19 March 2020) has also been submitted to the auditors. One must stress that the unpublished list of tenders does not include information on any of the five companies, which supplied personal protective equipment, while the published list does not include information on the two companies mentioned before.

The State Audit Office considers that regular updating and publication of the list of tenderers would not require significant additional resources from the National Health Service. Still, it would facilitate the involvement of the health sector as a self-regulatory tool, thus assisting the state institution in evaluating tenderers fast.

Planning of personal protective equipment required in the health sector and other sectors

For all purchases of personal protective equipment made, the Emergency Medical Service relied on the calculations and needs of the health sector. When taking over the procurement, the National Health Service also focused on the needs of the sector. However, they purchased personal protective equipment with a reserve so that the ordered stocks would be sufficient for several months and one could channel them to social care centres if needed. The auditors find this action appropriate, taking into account the emergency.

At the same time, the National Health Service had acknowledged that when the Service took over the purchase of personal protective equipment on 18 March 2020, only the health sector was clear

about the planning of its quantities initially whereas specific data on the needs of other sectors were available only from 27 March 2020:

- ❖ One used the guidelines developed by the European Centre for Disease Prevention and Control on 7 February 2020 in the planning of personal protective equipment required in the health sector, which set out the minimum number of sets of personal protective equipment required in healthcare facilities for different morbidity scenarios to manage potential or confirmed cases of COVID-19;
- ❖ There was the Cross-sectoral Coordination Group headed by the State Fire and Rescue Service established on 16 March 2020, which elaborated a list of priority institutions and needs until 27 March 2020 and began inquiring all the sectors on personal protective equipment needs. The planning of personal protective equipment was performed using the guidelines “Rational use of personal protective equipment in case of coronavirus disease (COVID-19)” prepared by the Emergency Medical Service.

Conformity assessment of delivered goods

In response to the increased demand for personal protective equipment, the European Commission has published recommendations on conformity assessment and market surveillance procedures in the context of the COVID-19 threat on 13 March 2020 by also stating that the Member States might, on duly justified request, derogate from the conformity assessment procedures for personal protective equipment if their use was in the interest of health. However, one should verify that all personal protective equipment and medical devices placed on the market continue to protect the health and safety of users.

Only on 9 April 2020, the Cabinet of Ministers laid down the procedure for authorising the purchase of personal protective equipment and medical devices for which one had not initiated or completed the conformity assessment procedure and which had not been CE marked. The State Audit Office considers that the adoption of the national regulation almost a month after the issuance of the EC recommendations increased the degree of uncertainty significantly and entangled the chances of appropriate actions of the designated authorities. The State Audit Office also draws attention to the fact that LSEZ SIA *Lauma Fabrics* supplied 30,000 respirators without a CE certificate to the National Health Service on 2 April 2020. Although one purchased those respirators at a symbolic price (0.00001 euro per unit), they delivered them at a time when derogations from the conformity assessment procedures had not yet been regulated by law in Latvia. The auditors do not know why it took almost a month to elaborate on those procedures.

In the pre-crisis context, when purchasing personal protective equipment (protective face masks and respirators), the authorities did not check the authenticity of the documentation or the quality of the product in a situation when they did not doubt as to the good faith of a potential supplier. Suppliers were liable for the delivery of goods of substandard quality specified in the contracts.

In the auditors' view, one does not expect the designated authorities to impose additional control measures during the crisis when there is a shortage of protective face masks and respirators. Besides, in the event of a shortage of personal protective equipment, the purchasers such as the Emergency Medical Service and the National Health Service organised quality testing of the

supplied face mask and respirator samples to obtain confidence in the compliance of the delivered personal protective equipment with the key health and safety requirements when the news spread about counterfeit product certificates and conformity documents of manufacturers. The State Audit Office assesses the latter action definitely as a control measure meeting the principles of good governance and eligible.

As there is no laboratory in Latvia capable of quality and safety testing of personal protective equipment (protective face masks and respirators), the Institute of Occupational Safety and Environmental Health of Riga Stradins University, the Health Inspectorate, the Institute of Design Technology of Riga Technical University, the inpatient laboratory “Tuberculosis and Lung Diseases Centre” of Riga East Clinical University Hospital Ltd (hereinafter referred to as the East Hospital), and Consumer Rights Protection Centre carried out the testing.

However, the auditors point out that quality checks are inconsistent and not performed on all batches of goods delivered. For example, one has tested only one (the first) of five deliveries by GP Nord Ltd, one of two deliveries by Saules aptieka Ltd, while respirators received from Tavol Ltd did not undergo quality testing at all.

The contracts concluded by the National Health Service stipulate that the supplier shall be responsible for the quality and conformity of the delivered goods and shall cover all losses related to the non-conformity of the goods. If the National Health Service finds defects and non-conformities of the product, the supplier is obliged to replace the product with a high-quality product that complies with the terms of the contract without additional payment within a specified term or to indemnify for the poor quality of the product. The audit has found that when having discovered that the 540,000 respirators supplied by LSEZ SIA Lauma Fabrics differed obviously from both the terms and conditions of the contract and all the respirators supplied so far, the National Health Service did not accept the product by amending the contract and reducing the delivery.

The State Audit Office does not have information on documented complaints of healthcare institutions regarding the quality problems of the delivered personal protective equipment.

Transfer of the process of purchasing personal protective equipment to the State Defence Military Facilities and Procurement Centre

Following the order of the Cabinet of Ministers, the National Health Service handed over the organisation of centralised procurement of protective face masks and respirators to the National Defence Military Facilities and Procurement Centre, which took over it on 2 April 2020.

There were 45.7 million euros granted to the Ministry of Defence for the centralised purchase of personal protective equipment and disinfectants for 12 weeks on 21 April 2020.

Other significant information

Within this audit, the State Audit Office co-operates with the Economic Crime Combating Board of the State Police, which has initiated a sector examination on the procurement of personal protective equipment (protective face masks and respirators).

Recommendations and proposals by the State Audit Office

The State Audit Office has also started an audit in the defence sector on the centralised purchases of personal protective equipment and disinfectants organised by the State Defence Military Facilities and Procurement Centre by taking over and commencing the management of crisis-related reserves from 2 April 2020.

One also plans to audit the use of funding allocated to the National Defence Military Facilities and Procurement Centre for the procurement of personal protective equipment and disinfectant reserves according to the list of institutions and needs coordinated by the State Fire and Rescue Service.

After the completion of the previously mentioned audits, there will be proposals elaborated for the Cabinet of Ministers, taking into account the conclusions of this audit.

¹ The International Organisation of Supreme Audit Institutions (INTOSAI) also uses International Standards on Auditing for the financial audits, hence the latter are binding on the State Audit Office, which conducts audits in accordance with international standards on public sector auditing.

² Cabinet Order No 103 “On Declaring a State of Emergency” of 12 March 2020.

³ Communication of the President of Latvia No 8 “Basic Principles of Activities of State Constitutional Bodies in an Emergency Situation” of 23 March 2020.

⁴ Informative report of the Ministry of Finance on reallocation of the financing from the EU Structural Funds and the Cohesion Fund and solutions for mitigating the consequences of COVID-19, reviewed by the Cabinet Meeting on 19 May 2020.