Audit Report

No 20/32

Funds spent in connection with the epidemiological situation in the Czech Republic

The audit was included in the Audit Plan of the Supreme Audit Office (hereinafter also the 'SAO') for 2020 under number 20/32. The audit was headed and the Audit Report drawn up by the SAO Member Mr Josef Kubíček.

The aim of the audit was to verify whether selected organizational units of the state spent funds in accordance with legal regulations, especially in the purchase of personal protective equipment and other medical devices and services implemented for anti-epidemic measures in connection with the incidence of COVID-19 in the Czech Republic.

The audit was carried out at the entities listed below in the period from June 2020 to December 2020.

The audit covered the period from 2011 to 2020 and, where related, also the period preceding or following.

Audited entities:
Ministry of the Interior (hereinafter also the 'MoI'),
Ministry of Health (hereinafter also the 'MoH'),
Administration of State Material Reserves (hereinafter also the 'ASMR'),

At its V meeting held on 15 March 2021, the Board of the SAO adopted Resolution No 10/V/2021 approving the following wording of the Audit Report:

Facts related to the state's response to the epidemiological situation

from January to August 2020

7.5 billion. CZK

The total amount of funds paid for personal protective equipment and medical supplies, totalling **148 suppliers**.

5.6 billion. CZK

Financial amount paid to **14 suppliers** for supplied personal protective equipment and other medical devices.

0.987 billion. CZK

Funds directly spent on air and rail transport of material to the Czech Republic, including related services.

15,420 pcs

Approximate number of personal protective equipment and medical devices intended for respiratory protection in state material reserves and in faculty hospitals as at 31 December 2019.

34.3m pcs

Number of respirators[1] in the protective level of FFP3, FFP2, KN95, N95, GB19083-2010, GB2626-2006 acquired by central purchasing teams of MoI and MoH, whose total acquisition value was **CZK 2.8 billion.**

13.3m pcs

The number of respirators that failed to pass quality tests in the first testing, from a sample representing 28.3 million pieces, which the SAO examined during the audit.

For eight years, the MoH has not updated the Pandemic Plan of the Czech Republic and underestimated the preparedness of the health care system for mass contagion of people with new highly infectious diseases. The MoI, along with the MoH, also underestimated the crisis preparedness for this type of threat.

Note: For simplicity, the figures were rounded according to the standard rounding rules.

[1] A respirator is an inaccurate name of a protective semi-mask made of filtration material intended for personal protection of the respiratory system against hazardous particles. According to the Czech State Standard ČSN EN 149:2001 + A1:2009, it is correctly called the "Particle Filtering Half Face Mask". Particle protection is tested by means of a test device using aerosol formed by NaCl or paraffin oil particles according to ČSN EN 143. The filter is also tested with dolomite dust according to ČSN EN 143. In order to simplify this audit report, respirators of different protection classes according to standards other than ČSN are also referred to as FFP2, FFP3 or FFP1 respirators.

Summary and evaluation

The SAO carried out an audit of the funds spent by the state in the first eight months of 2020 when purchasing personal protective equipment and other medical devices[2] (hereinafter 'PPE' and 'MD') and services carried out in connection with the epidemiological situation caused by a pandemic of the new SARS-CoV-2 coronavirus causing COVID-19 infectious disease (hereinafter also 'COVID-19 pandemic' or 'COVID-19 epidemic').

The aim of the audit was to examine whether selected organizational units of the state, i.e. the Ministry of Health, the Ministry of the Interior and the Administration of State Material Reserves, spent funds in accordance with legal regulations, especially when purchasing personal protective equipment and other medical devices and services for the purposes of anti-epidemic measures in connection with the occurrence of COVID-19 disease in the Czech Republic.

The extent and nature of the COVID-19 pandemic are unprecedented in the history of the independent Czech Republic. The ongoing threat of this disease on the territory of our country is a major and long-term challenge for the entire population and leads to a heavy burden on health and social care and the basic components of the integrated rescue system. The cost of the response is extraordinary and all the long-term effects of this pandemic are not yet clear. The SAO is aware that in an effort to respond to an unprecedented health threat to citizens of the Czech Republic and workers of the so-called firing line, the audited entities had to reorganise their activities and services very quickly. This would not have been possible without the high workload of their employees and other collaborating forces.

MoH and MoI were not ready for a pandemic. The MoH significantly, and from the long-term perspective, underestimated the preparation of the health care system of the Czech Republic for epidemics associated with the occurrence of highly infectious diseases. The MoH had not updated the pandemic plan of the Czech Republic (hereinafter the "PP CR") since its last modification in 2011. The ministry's pandemic plans of the MoH and the MoI (hereinafter the "PP MoH" and "PP MoI") did not include the purchases of PPE and MD needed to manage an epidemic of extraordinary magnitude. The state of emergency stocks of PPE and MD, which the ASMR had in its warehouses, had not changed from 2011 until the occurrence of COVID-19 disease.

The SAO found that ministries, as public health care authorities and central government bodies for crisis management, had used only a small part of the pandemic preparedness plans. Inspections on pandemic preparedness had virtually not been carried out in recent

[2] A medical device, in accordance with Council Directive 93/42/EEC of 14 June 1993 on medical devices, a 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; Personal protective equipment is a device designed and manufactured to be worn or held by a person to protect against one or more risks to his health or safety.

years. The Central Epidemiological Commission (hereinafter also the "ÚEK") did not fulfil its role in the long term either.

The MoH responded to the shortage of PPE and MD in healthcare facilities with a delay and did not start their purchase at the time when they were still available on the market. The MoH and the MoI failed to purchase enough PPE and MD in an open procurement procedure shortly before the announcement of a state of emergency. After the announcement of a state of emergency on 12 March 2020, the Government of the Czech Republic authorised the MoH and the MoI to purchase of PPE and MD directly, using a legal exemption. [3]MoH and MoI in the period from 1 January 2020 to 31 August 2020 paid a total of CZK 8.5 billion for the purchase of PPE, MD and related services.

Unit prices of similar purchased goods differed significantly. The SAO recorded the most significant price fluctuations for individual types of PPE and MD both at the beginning of the state of emergency and at the interval of several more weeks, when the demanded goods were more available. In a number of cases, the MoH and the MoI accepted in concluded contracts prices of similar PPE and MD, which differed in the order of hundreds of Czech crowns per piece. Unit prices of FFP2 respirators often exceeded the prices of FFP3 respirators. A detailed overview of the funds spent on the purchase of PPE and MD is presented in Annex 1.

The Czech Republic has received donations to address the lack of PPE and MD through the MoH and the MoI. This included, among other things, reimbursement of the costs of using the customs warehouse of PPE and MD in the People's Republic of China (hereinafter the "PRC"), cash amounting to CZK 20 million for the purchase of medical supplies, but also over 8.5 million pcs of PPE (from face masks to special Smart Helmet KCN 901 helmets).

The SAO found that the organisation of purchases was chaotic with a number of shortcomings in the documentation. The SAO sees the risk of concluding business relations without verification of suppliers. The Ministries made mistakes that resulted in the agreement containing unfavourable contractual terms for the state, in a large price range for individual categories of goods and, among other things, in shortcomings in the quality of the delivered goods. The organisation of purchases of MoH and subsequently the MoI was not only affected by the time constraints and the lack of PPE and MD on the domestic and global markets, but also by the existence of two separate teams providing central purchases that did not cooperate. According to the SAO, this led to a weakening of the state's position in price negotiations and ultimately reduced transparency of purchases.

The MoI and the MoH spent a total of CZK 987 million for air and rail transport from the PRC and related services. The SAO found shortcomings in the contractual provision of payment for the transport of goods to the Czech Republic for non-state entities. These were costs in the amount of CZK 81 million, for which the SAO draws attention to the risk of non-payment, as the terms of payment were not contractually agreed in advance.

[3] Pursuant to the provisions of Section 29(1)(c) of Act No 134/2016 Coll., on Public Procurement, the contracting authority is not obliged to award a public contract in a procurement procedure if it concerns the award or performance of a public contract within the framework of specific security measures laid down by other laws and at the same time such a measure cannot be taken to enable the execution of the procurement procedure.

Pursuant to Commission Decision (EU) 2020/491,[4] these goods were exempted from customs duties and VAT provided that they were intended for distribution free of charge. The audited ministries did not ensure that non-state entities would maintain the conditions for the free distribution of transported goods.

During the audit of distribution within the Czech Republic, the SAO found a number of inaccuracies in the documentation of the receipt and dispensation of goods. Distribution models for PPE and MD did not exist for the event of a pandemic. Distribution of the PPE was provided by the MoI, the ASMR, regional Fire Rescue Services (hereinafter also 'FRS'), the Army of the Czech Republic, Česká pošta s.p. (Czech Post state enterprise), and private entities. Furthermore, the SAO found significant differences in the distribution of PPE and MD per capita between regions (details in Annex No 1 of this Audit Report). The SAO could not verify distribution to end users at the level of regions and municipalities due to its statutory audit scope.

The MoH and MoI ensured the verification of the quality of FFP3, FFP2, KN95, N95, GB19083, GB2626_2006 respirators, with regard to Commission Recommendation (EU) 2020/403[5] in a public research institution, on samples of delivered respirators which had not been certified by the[6] European Union (hereinafter also 'EU') at the time of delivery. In many cases, the samples failed to meet the monitored parameters for the PPE category. The SAO examined part of the test reports related to orders of 28.3 million pieces of PPE in the value of approximately CZK 1.8 billion. Out of this tested sample, 13.3 million respirators did not pass the tests in the first quality testing[7]. The SAO examined a selected sample of deliveries and found that in some cases the goods delivered within individual deliveries did not match the tested sample and the goods from some deliveries were not tested at all. The SAO assessed that the findings call into question the reliability of the entire process of verifying the quality of PPE set up by the MoI and the MoH.

As a rule, ministries did not provide information about the testing results to the entities designated for the distribution of the PPE. There is a risk that, in particular, health and social services providers received PPE that failed to comply with quality testing without knowing about this deficiency. The SAO could not verify within its legal audit scope the extent to which this risk might have been relevant.

The above assessment is based on the following main findings from the audit:

1. The MoH failed to fulfil the tasks arising from the PP ČR. The MoH has not updated the plan since 2011, although it was supposed to do so every two years. The plan also did not adjust the risk of SARS-type infectious diseases, even though it had been ordered by the government in 2010. The state of emergency supplies of PPE and MD, which the ASMR

[4] Commission Decision (EU) 2020/491 of 3 April 2020 on the exemption of goods necessary to combat the consequences of the spread of COVID-19 during 2020, from import duties and from import VAT.

[5] Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures in relation to the threat of infection with the new coronavirus.

[6] The term 'certification' in the text of this Audit Report means the demonstration of conformity of quality parameters of a product with the provisions of directives and standards.

[7] Part of samples of tested respirators (9.6 million pcs) in total value of CZK 635.1 million passed only in subsequent repeated tests.

had in its warehouses, had not changed since 2011. The ministries had to ensure the purchase of PPE and MD without using planned crisis procedures and outside the system of state material reserves.

The PP ČR is a basic document which sets out procedures and basic system of response to the pandemic situation[8].The PP ČR, or its last update, was approved by the Czech Government Resolution No 682 of 14 September 2011. This resolution also required the ministries and other central administrative offices (hereinafter also 'CAO') to update their pandemic plans. When updating the PP ČR, the MoH should have taken into account the fact that protection against new infectious diseases requires similar measures to be taken in the pandemic of influenza virus. This in the case of COVID-19 is confirmed by information from the National Institute of Public Health ('NIPH'), which summarizes the similarities and fundamental differences of the influenza virus and the SARS-CoV-2 virus[9].

One of the measures of the PP ČR was a periodic review of the pandemic plans by the crisis management authorities, at least once every 2 years or as needed. The audit revealed that the MoH had not updated the PP ČR since 2011 and had not even revised it, which, among other things, did not respect the recommendations of the World Health Organization (hereinafter also 'WHO '). From 2012 until the end of the audit, the MoH failed to update its PP. The MoI also did not follow the measures set out in the PP ČR when it made a single update for the MoI's PP in 2016.

The PP ČR envisages that a sufficient amount of PPE will be provided by health care providers in accordance with recommendations of public health protection authorities. The level of protection and conditions for the use of PPE for the protection of employees are set out in the annex to the PP ČR. For example, the MoH recommends in its PP the use of respiratory masks of the highest level of protection (FFP3) for all health care staff at the time of the influenza pandemic. However, the PP MoH neither informed how the health care providers should ensure a sufficient amount of PPE during a period of pandemic alert or announced pandemics, nor mentioned it in the annexes.

The total volume of PPE and MD stocks was completely negligible compared to their real need due to the high contagion of COVID-19 and could not resolve the critical shortage of PPE in the first weeks after the announcement of a state of emergency in the Czech Republic. The actual volume of PPE stocks in the health sector was limited to the creation of emergency stocks in the state material reserves and inviolable minimum volume of PPE in strategic stocks of faculty hospitals. The MoH set this in 2010 for the event of an emergency. For example, the supply of FFP3-class respirators within an inviolable minimum was sufficient for only 20 % of

[8] The obligation to process and coordinate the processing of the PP of the Czech Republic and the pandemic health plan arises from the provisions of Section 80 paragraph 1 letter x) of Act No 258/2000 Coll., on the Protection of Public Health and on Amendments to Some Related Acts. The first *pandemic plan of the Czech Republic* was adopted in 2006.

[9] Information from the State Closing Account published on 18 March 2020 under the link http://www.szu.cz/tema/prevence/chripka-versus-koronavirus-podobnosti-a-zasadni-rozdily-k-18.

the professional staff (doctors, nurses and other professions as rescuers, etc.) for a limited period of time (in a matter of hours) given by the applicability of these respirators.

In the state material reserves, a small amount of PPE standby stocks corresponding to the requirements of the MoH was available in the long term. Given that the situation of the pandemic falls within the MoH´s responsibility, the MoI did not include requirements regarding PPE and other MD kept in the state material reserves among its priorities.
Thus, at the time of the declaration of a state of emergency, the ASMR did not have any PPE in its stock for the staff of the integrated rescue system that was the competence of the MoI, and even no PPE was available for citizens. Only in connection with the development of the epidemiological situation in the world, in February 2020 the MoH asked the ASMR to replenish emergency supplies of the MoH — 1,000,000 pcs of protective face masks, 100,000 pcs of FFP3 masks without exhalation valve and 100,000 pcs of FFP3 respirators with exhalation valve.

In 2016, on the instructions of the Government, the MoI completed *the Threat Analysis for the Czech Republic* in cooperation with other CAOs [10] (hereinafter also 'Threat Analysis'). Among the 22 types of dangers with unacceptable risk, an *epidemic of a mass infection of persons* was newly identified and the MoH was established as a sole administrator responsible for this threat. Together with the approval of the Threat Analysis, the Government instructed, among other things, the Minister of Health, the Minister of the Interior and the Chairman of the ASMR to prepare a model plan for the *Epidemic – Mass Diseases (*hereinafter also 'model epidemic plan')[11] by 31 December 2017. However, the model epidemic plan did not contain specific procedures for central acquisition and distribution of PPE and MD[12].

The tasks of the MoI as a crisis management body result from the fulfilment of legal obligations pursuant to the provisions of Section 10 Paragraph 1 of Act No 240/2000 Coll. on Crisis Management and on Amendments to Certain Acts (hereinafter also 'Crisis Act')[13] This includes the obligation to control the preparedness of other ministries and other CAOs to deal with crisis situations, to monitor regional crisis plans and the transmission of data to ministries and other CAOs at their request under the Crisis Act. However, these controls with a focus on pandemic preparedness by the MoI (General Directorate of the Fire and Rescue Service of the Czech Republic) and with the necessary participation of the MoH were not carried out in the long term. Similarly, the preparedness for crisis (epidemic) situations in the MoH itself was not checked.

[10] Approved by Resolution of the Government of the Czech Republic No 369 of 27 April 2016, *on the Analysis of Threats for the Czech Republic*. The analysis was ordered by the MoI in cooperation with other central administrative authorities on the basis of Resolution of the Government of the Czech Republic No 805 of 23 October 2013 on the *Conception for the Protection of the Population up to 2020 with a view to 2030*.

[11] Model Plan *Epidemic – Mass Diseases* of September 2017, made by the MoH.

[12] During the audit, MoH updated the model plan taking into account the knowledge of the COVID-19 epidemic needs.

[13] The tasks of the MoI pursuant to paragraph 4 of the same provision shall be carried out by DG FRS.

The SAO scrutinised the provision of the necessary supplies[14] (hereinafter also 'NS') according to the submitted requirements of the regions directed to the MoH in the years 2013, 2015, 2017 and 2019 to ensure the emergency stocks of PPE and other MD. For example, in 2013 and 2015, the regions required to provide ventilators to support breathing in a total volume of up to 306 pieces. With reference to threat analysis in regions' crisis plans, the MoH stated that the requirements could not be ensured in the form of emergency stocks. In 2017, only 35 ventilators were requested by the Regions and the MoH stated that in this case the requirement is partially met and that any need will be dealt with in cooperation with healthcare providers in neighbouring regions.

2. The MoH and MoI in a relatively short time bridged the significant shortage of PPE and MD, namely through purchases worth almost CZK 7.5 billion. Each audited ministry created its own central purchasing team. Unfavourable contract terms concluded with suppliers or carriers, problems with transport, distribution of goods or their lack of quality were due, among other things, to the lacking cooperation between the two teams.

Before the announcement of the COVID-19 pandemic, both the MoI and the MoH sought to acquire PPE and MD through the award of public contracts, which, however, were cancelled due to the lack of bids and the MoI and the MoH used the exemptions under the Public Procurement Act referring to special security measures[15]. In addition, during the state of emergency, the MoI announced an open procurement procedure for the acquisition of PPE, through which it concluded several framework contracts, e.g. for the supply of FFP2, FFP3 respirators and face-masks.

The MoI and MoH created their own separate teams for central purchases that did not cooperate with each other and did not share information about individual prices or potential suppliers in the PPE and MD markets. The MoI created a purchasing team from its employees and cooperated primarily with the Joint Czech-Chinese Chamber of Mutual Cooperation (hereinafter also "the Chamber")[16]. The MoH´s purchasing team involved mainly representatives from individual hospitals, who had experience with PPE and MD purchases. The MoH also used the services of external experts in the purchasing team.

The system of purchases of PPE and MD was similarly managed in Latvia, where a two-track system involving the MoI and the MoH was created, but which later passed into the responsibility of the Ministry of Defence. Audit reports of Latvia's Supreme Audit Institution focused on purchases of the MoI, the MoH and the Ministry of Defence, totalling

[14] The necessary deliveries pursuant to Act No 241/2000 Coll., on Economic Measures for Crisis and on Amendments to Some Related Acts, are products, works or services without which it is not possible to ensure overcoming the crisis situation.

[15] Provision of § 29 letter c) of Act No 134/2016 Coll., on Public Procurement.

[16] It is a voluntary association of natural persons and legal entities interested in doing business in the Czech Republic and in the People's Republic of China. The main activities include e.g. establishing and expanding contacts between these persons and entities of both countries, providing information service to entrepreneurs and other stakeholders, or providing professional assistance in concluding business contracts.

approximately CZK 546 million, are available on its website[17]. The system of purchases was also dealt with by the Supreme Audit Institution of the United Kingdom (hereinafter also 'UK NAO')[18], which states that 86 % of all 8 600 contracts in question amounted to a total value of approximately CZK 539 billion were awarded by the British Ministry of Health and Social Welfare. Most of these contracts were PPE contracts and a total of 1,301 contracts worth almost CZK 10 billion were awarded directly without competition. **For the purposes of purchasing PPE, unlike in the Czech Republic, one inter-ministerial team of experts specialized in purchasing PPE was established.**

When purchasing PPE and MD, the MoH did not provide market research and did not set rules for assessing bids at a time of emergency. The MoH and the MoI did not adequately ensure audit trails for key phases of purchasing processes that preceded the expenditure of state budget funds. Documentation of key purchasing phases at both ministries was minimal. The organisation of purchases was chaotic with a number of shortcomings in the documentation, when business relations with suppliers were concluded without their verification. The ministries also made errors that resulted in negotiating unfavourable contractual terms for the state.

The MoI and MoH spent on purchases of PPE and MD and related services in the period from 1 January 2020 to 31 August 2020 a total of CZK 8.5 billion. Specifically, these were the following commodities and services:

Table No 1 – General overview of PPE and MD purchases made by the MoI and the MoH

Categories	Number of orders	Number of suppliers	Quantity acquired in pcs	Total paid in CZK including VAT
PPE and MD	420	148	302,040,138	7,473,127,239
Transportation	59	23	—	987,414,961
Other	141	58	328,645	64,390,390

Source: MoH and MoI documentation submitted, **Annex No 1**.

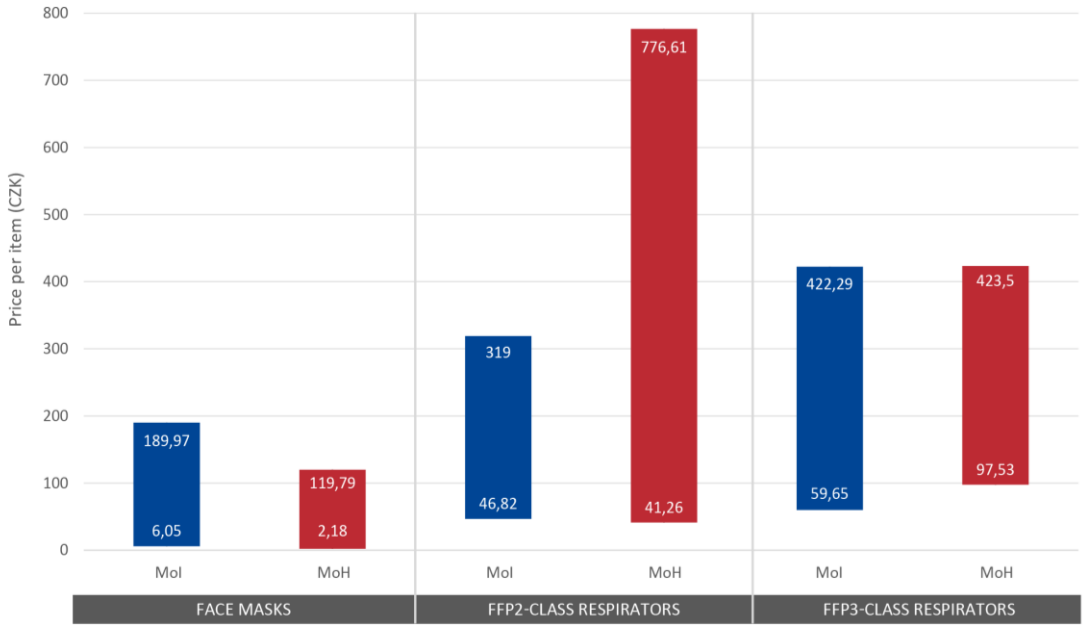
Note: in the Other category, e.g. services related to testing of samples were purchased, ensuring the operation of the information line.

During the same period, both ministries purchased PPE of the same level of respiratory protection. From the documentation submitted on the purchases of PPE and MD (see **Annex 1**), the SAO found different prices, precisely speaking, different price ranges. This was a period when the state prohibited the sale of FFP3 respirators to persons other than the state by means of emergency measures.

[17] SAI Latvia:
1) *The use of additional funding allocated to the Ministry of the Interior for the purchase of personal protective equipment and disinfectants, available on 15 February 2021 here;*
2) Health *Delivery process of personal protective equipment (protective face masks and respirators) in the health sector, available on 15 February 2021 here;*
3) *The procurement system established by the Ministry of Defence and the procurements made during the emergency to limit the spread of COVID-19, available on 15 February 2021 here;*

[18] UK SAI : *Investment into government procurement during the COVID-19 Pandemic, published on 15 February 2021 end available here.*

Chart No 1 — Range of unit prices of selected commodities purchased by MoI and MoH



Source: MoI and MoH documentation submitted, **Annex No. 1**
Note: These are purchases from January to August 2020.

The SAO found that the difference in prices was influenced by the technical specification of the product. This was particularly reflected in the category of face-masks, which, on the basis of the MoH and MoI procedures included both disposable face-masks and textile, reusable face-masks with printing. For example, the type and equipment of purchased pulmonary ventilators had a similar impact on the price.

On the other hand, the audit did not confirm the assumption that the biggest deviations for the unit prices of comparable goods occurred only in purchases in the first days of the state of emergency, when the market showed the greatest shortage of medical material.

The final prices for PPE and MD deliveries will still be affected by ongoing disputes over the reimbursement of their transportation costs, or a complaint procedure, where new goods are to be delivered for those which have failed to meet the qualitative parameters.

3. The state provided transport of PPE and MD mainly by air, including goods that were the property of non-state entities. The ministries did not contract the reimbursement of these costs and thus there is a risk of non-recovery.

The critical shortage of PPE and MD in EU countries forced the MoI and MoH to purchase these goods in many cases directly from foreign suppliers/producers, especially from the PRC. The ministries therefore had to provide transport of purchased commodities to the Czech Republic.

Most of the deliveries of goods from abroad were provided by the MoI within the air bridge, through which it transported material from the second half of March to the beginning of May

2020. The MoH provided part of the transport of goods from abroad itself, however, it also used transport organised by MoI.

As part of the air bridge, a total of 49 flights[19] took place, with the cost of using this air bridge amounted to CZK 688 million. The MoI paid a total of CZK 833.6 million for the transport of PPE and MD from the PRC and CZK 2.2 million for domestic transport in the PRC and other costs associated with the transport.

The MoH paid CZK 67.1 million for the transport and related services. Part of the air transport was also covered by advance invoices for these services, which amounted to CZK 83.9 million and were not finished until the end of the audit. The MoI also used the railway to transport PPE and MD. According to the SAO's findings, the rail transport costs of PPE and MD amounted to only CZK 13.98 million out of a total of CZK 987 million.

The SAO compared the transport costs for initial flights, which were provided by a special military aircraft and several large capacity aircraft AN-124 Ruslan (hereinafter also 'Ruslan'), for the subsequent air bridge and rail transport. The cost of transporting by Ruslan from Shenzen amounted to CZK 495/kg of transported cargo. This amount was affected by the short loading time at the airport, which made it impossible to use the entire capacity of the aircraft. The cost of transporting goods by air bridge from Shanghai amounted to CZK 436/kg. By using rail transport, transport costs were reduced to CZK 21/kg of transported cargo.

The audit found that the transport paid by the MoI was also used by non-state entities for the transport of goods that were in their possession. These goods were for the most part PPE and MD for the needs of the MoH, which ordered them from these entities. The costs of transporting these PPE and MD amounted to a total of CZK 81 million and on 5 November 2020 the MoI invoiced them to 15 entities. Both ministries began to address this issue two month after the transport had taken place. With the exception of one case, these re-invoices were not paid by the end of the audit. The majority of suppliers disagreed with the MoI and MoH procedures. They argued that they had already compensated the MoH for the transport through a discount on the purchase price and considered the further cost reimbursement as an unjustified claim.

The state transported PPE and MD for non-state entities without a contractual agreement on their final use. Pursuant to Commission Decision (EU) 2020/491, these goods were exempted from customs duties and VAT provided that they were intended for distribution free of charge. According to the SAO, there is a risk that such imported goods were not distributed in this way.

[19]The Shanghai Air Bridge included a total of 49 flights in the period from 24 March 2021 to 3 May 2021, the MoI built it due to logistical problems associated with flights from Shenzhen (one military special aircraft and 4 flights by Ruslan).

Although the Czech Government's Resolution No 286 of 23 March 2020[20] enabled the flexible distribution of PPE (face-masks, respirators) to citizens of the Czech Republic also through the Česká Pošta, s.p., local governments or any other appropriate way, the MoI did not set specific conditions for this distribution. The SAO found that the MoI had handed over 1.8 million pcs of PPE and MD to one business entity for its further distribution without contractually stipulating conditions for maintaining the public interest.

The MoI distributed the PPE to all subjects except those supplied by the MoH (e.g. faculty hospitals, testing centres and public health authorities). Based on a mutual agreement between the ASMR and the MoH, the ASMR received purchased PPE and MD and provided their storage and subsequent distribution. In the later period, the MoH distributed part of the material through the FRS to regions in their territorial competence, and e.g. to general practitioners, dentists and other distribution points. However, the SAO could not verify the PPE´s distribution to the target groups at the level of regions and municipalities with extended scope, with regard to its audit scope, which is limited to auditing the management of state property and the implementation of the state budget.

4. **The MoH started testing the quality of the PPE two weeks after the first orders had been delivered and even then, the quality control process of PPE and MD was reduced to a minimum compared to the normal range of testing. The same was the case with MoI. The testing process set by the ministries thus provided only a minimum guarantee of the quality of ordered uncertified goods.**

PPE and MD must normally undergo a demanding quality assessment process (hereinafter also 'certification') before being placed on the market in the Czech Republic or the EU. Before being placed on the market, they must comply with the requirements of directives and standards for the proper conformity assessment on the basis of which a declaration of conformity may be issued and the CE marking with the 'Notified Body' number may be obtained.[21]Medical devices must comply with the requirements of Council Directive[22]93/42/EEC and respirators must meet the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council.[23]Respirators for healthcare professionals must meet the requirements of both these regulations.

[20] Resolution of the Government ČR No 286 of 23 March 2020 *on the provision of the purchase and distribution of protective equipment needed to address and prevent the COVID-19 epidemic caused by the new coronavirus called SARS-CoV-2 by the Ministry of the Interior and the Ministry of Health.*

[21]The Notified Person – is an authorised person notified by the Office for Standardisation, Metrology and Testing, to the institutions of the European Union, or to the competent authorities of the EU Member States, that the person complies with the relevant requirements and is able to assess conformity under the relevant directives. The notified person shall be notified by the given Member State. On the basis of the documentation issued by the notified person, the marking of the products is possible with the European mark of conformity CE. Newly notified persons are referred to as notified bodies.

[22] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

[23] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Respirators, which have not yet undergone the whole conformity assessment process, may enter the market and distribution channels only on the basis of an exception of the Czech Trade Inspection Authority. In order to comply with this exception it is necessary to ensure compliance of the minimum technical condition of the product with the applicable regulations and to demonstrate its basic efficiency according to ČSN EN 149+A1[24]. In the context of the COVID-19 pandemic, such an exemption was granted by the EU Commission for importing scarce commodities from countries outside the EU based on Commission Recommendation (EU) 2020/403[25].Thus, imported commodities did not have to meet the EU's standard quality requirements at the time this recommendation was in force. However, the exception did not mean that any PPE could be delivered on the EU market without subsequent control. Minimum health and safety requirements had to be maintained.

One of the conditions for concluding business relations between the audited ministries and suppliers was that the supplier had to provide at least one of the following documents to the goods offered: CE Certificate, EU Declaration of Conformity, Manufacturer's request for notified workplace provided by required documents or test reports of products from Chinese accredited testing laboratories. In view of the fact that many European accredited testing laboratories suspended the issuance of their certificates at a time of emergency, the MoH and the MoI decided to test samples of respirators from the delivered orders in a public research institution. The aim was to verify compliance with the basic quality requirements (breathing resistance and initial aerosol penetrations). The MoH had not carried out these tests until 27 March 2020. From that date, the MoH had the possibility to delay deliveries in stock and provide samples of these deliveries for testing prior to their distribution.

As part of the purchases, MoH made a total of 120 orders for the supply of respirators, out of which 64 had valid CE certification for the EU market. The most common products that did not have documents in accordance with European regulations were respirators bearing the CN95, N95 and KN99 marks with 1, 2 and 3 grades, assessed according to the Chinese standards[26].The MoH provided the public research institution with samples of goods from 42 orders totalling 335 pieces of samples.

The MoI tested only samples of PPE produced outside the EU from individual deliveries. In all cases, these were PPE deliveries imported from the PRC. In the case of deliveries from domestic suppliers of goods, the MoI assumed that these were certified goods, although the deliveries were not supported by the relevant certification. These PPE deliveries were not tested. The SAO assesses this process of quality testing as non-transparent, as the ordered goods were usually transported to the Czech Republic in several deliveries, so only part of the delivery of the contract was tested. The SAO audited a selected sample of deliveries and found that in some cases the goods delivered in individual deliveries did not coincide with the tested

[24] Czech technical standard ČSN EN 149+A1 *Respiratory protective devices – Filter semi-masks to protect against particles – Requirements, testing and marking.*

[25] Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures for the threat of coronavirus COVID-19.

[26] GB 19083-2010 *Technical requirements for protective masks for medical use (health sector)* and B 2626-2006 *Respiratory protective devices – non*—powered air purifiers (in industry).

sample. Often, quality was guaranteed only for part deliveries (selected part deliveries) – details are in **Annex 2**.

Neither the MoI nor the MoH defined requirements for orders of respirators from the PRC which would take into account the different size needs of users on the European and Asian markets, nor did they distinguish their differences resulting from testing according to the relevant national standards.

With regard to the mentioned risks in the quality testing system of delivered respirators, the SAO examined in detail a selected sample of deliveries, which are listed in the following Table 2.

Table No 2 – Overview of orders from testing of the MoI and MoH in the SAO audited sample

Client	Respirators		Face masks		Number of orders
	million CZK	million pcs	million CZK	million pcs	
MoH	677.4	7.5	169.7	15.1	15
MoI	1,146	20.8	308.3	30.8	14
TOTAL	**1,823.4**	**28.3**	**478**	**45.9**	

Source: prepared by the SAO according to documents submitted by the MoI and MoH.

From the SAO audit carried out on a selected sample of orders, which included 28.3 million pcs of respirators for a total of CZK 1.8 billion [27], among other things, follows:

- respirators, which **passed quality testing**, accounted for almost 32 % of the total financial volume, i.e. CZK 576.7 million[28] (8,1 million pcs).
- Respirators, which **were not tested**, represented 20 % of the total financial volume of the sample, i.e. CZK 369.9 million (6.9 million pcs).
- Respirators that **failed in the first quality tests** amounted for almost 48 % of the total financial volume, which is CZK 876.6 million (13.3 million pcs). During **repeated testing, respirators** in the total value of CZK 635.1 million (9,6 million pcs) complied with the quality tests. Respirators with a total value of CZK 241.5 million (3,7 million pcs) **failed to pass the tests**.

By providing these goods to health and social care workers, the MoI and the MoH run the risk that workers received PPE that did not pass the above quality testing. To what extent this risk was met, the SAO could not verify due to its entrusted legal competence.

Details of the PPE sample examined are given in **Annex 2**.

[27] This is part of the sample of a total amount of CZK 2,3 billion.

[28] The basis for the calculation is CZK 1,823,216,769

SAO note: The above-mentioned part presents key points of our audit report´s summary. Further translation of the remaining part of this audit report is underway!