Discharge Hearing 8 November 2021

Questions to Commissioner Kyriakides by Monika Hohlmeier:

In 2020, 2.6bn EUR (40.5% of the MFF heading "security and citizenship") were paid from the Instrument for Emergency Support within the Union (ESI). In its Annual Report (box 7.3), ECA describes errors detected in ESI funded projects in the UK regarding the transportation of medical equipment: ECA was unable to verify whether a procurement procedure had been carried out and project costs were overstated.

- ***How did the Commission carry out controls on the procurement procedures regarding medical equipment etc. funded from the ESI?***

Commission reply:

The grant agreements for transporting medical equipment financed through the Emergency Support Instrument (ESI) required the beneficiaries to submit, together with the cost claim, an audit certificate by an independent certified auditor on the eligibility of the financial statements for all grants over EUR 750.000. The certificate includes the compliance with the public procurement procedure. Regrettably, in the specific case of the UK grant, the audit certificate on the eligibility of the financial statements, to which the Commission relied on, did not state that there were any detected irregularities. The irregularity was indeed detected ex-post by the European Court of Auditors (ECA).

In view of the ECA finding, the Commission is currently carrying out several ex-post audits on these grants. Verifying the compliance with the procurement procedures is included in the audit methodology of these financial audits. Out of the 13 grants for transporting medical equipment finalised in 2020, the Commission selected four for audit in 2021, including the full UK grant that was partly audited by the ECA. In financial terms, the audit coverage is 42 per cent covering around EUR 6.6 million.

	Total payments made
Total ESI grants for transporting medical equipment (EUR)	15.603.301,53
Ex-post audit sample	6.555.999,49
Audit coverage (%)	42,02%

- ***Where there other cases with overstated project costs? What is the total amount of these irregularities?***

Commission reply:

Out of 47 agreements signed in 2020 and seven signed in 2021 for transportation of medical equipment, the ex-ante controls detected, before payment, 13 grants (three of amounts under EUR 10) which claimed overstated costs of a total value around EUR 18 million.

- ***Did the Commission impose any financial correction or intends any recoveries? If yes, what is the total amount?***

> **Commission reply:**
> In the case of ESI grants, there was no pre-financing and consequently recovery orders are not needed. The overstated amounts detected during the ex-ante controls were deducted before the Commission performed the final payments.
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> In order to enhance the level of assurance, the Commission has launched four ex-post audits. The Commission has received the final report of one ex-post audit, which did not detect any irregularities that would lead to disallowances. The other three audits are still to be finalised. The Commission will ensure the financial follow-up once these audits have been concluded and will make these conclusions available.

In your reply to question 14, information on the amount of doses that have been disposed by Member States is missing.

- ***Could you please provide this information either now or in writing?***

> **Commission reply:**
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> The Commission does not have information on the disposal on vaccines by the Member States.

In your reply to questions 16 and 23, you mention that DG SANTE's new anti-fraud strategy is due for approval today, 8 November.

- ***Has it been approved? Could you please describe the main points of the new anti-fraud strategy?***

> **Commission reply:**
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> Yes, DG SANTE's anti-fraud strategy 2021-2024 was adopted by the Management Board in its meeting on 8 November 2021.
>
> It is important to highlight that SANTE's anti-fraud strategy was developed following the Commission's methodology, in close cooperation with the European Anti-Fraud Office (OLAF), and based on a solid fraud risk assessment. The strategy is complemented by a detailed action plan covering the years 2021 to 2024.
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> The main objectives of the strategy are to improve fraud prevention through increased staff fraud awareness and to enhance the fraud focus within the existing DG SANTE's practices and procedures, including in the relations with EU decentralised agencies and to ensure a good collaboration with OLAF and the European Public Prosecutor's Office. The anti-fraud strategy also aims at improving DG SANTE's IT control environment since, in the era of digitalisation and digital

transformation, cybersecurity became a top priority for different institutions across the globe, including the Commission.

- ***What were the main findings of the fraud risk assessment on new risks and fraud patterns emerging from DG SANTE's new activities and ways of working?***

Commission reply:

The fraud risk assessment revealed new risks of fraud in the following two areas:

(i) Public procurement: the COVID-19 crisis increased the amount of expenditure in the healthcare sector and this in turn increases the known risks of irregularities and fraud. Moreover, urgency and less competition in the market facilitate conflict of interest and corruption.

(ii) Fraud risks in the management of sensitive files and IT tools: the pandemic led to a rapid and important shift towards digitalisation, strengthening the importance of a secure IT environment and a new management approach towards sensitive files. Some of the most valuable information for the public interest resides in the form of digital assets maintained by the Commission. DG SANTE collects, creates, uses, stores, discloses, and discards information that has market value for the external stakeholders and a significant political impact. It is therefore essential that, in case of control breakdowns or weaknesses in the systems' development, the perpetrators are prevented from taking advantage of the new opportunities for fraud.

In 2020, DG SANTE carried out roughly half as many audits and controls as last year (111 compared to 209 in 2019). 16 out of 18 planned audits had to be carried out as remote audits instead of on-the-spot, and in total 70 of the 111 controls were carried out fully remote. ECA acknowledges that not carrying out on-the-spot checks may increase the detection risk (the risk that errors go undetected).

- ***Could you please comment on the detection risk for DG SANTE's remote audits?***

Commission reply:

DG SANTE carries out two different kinds of audits: (i) financial on-the-spot controls on DG SANTE's expenditure, and (ii) audits on the compliance with food safety rules.

Both remote and on-the-spot financial audits are typically carried out with Member State's Competent Authorities as the main beneficiaries. They are based mainly on interviews and documentary checks, for example, of invoices and extracts from databases. DG SANTE's remote financial audits allowed to use the same auditing techniques, cover the same audit scope, and follow the same auditing standards as on-the-spot audits. The risk that errors go undetected might increase if auditors are not present at the beneficiaries' sites, however in the type of financial audits DG SANTE is carrying out in the Member States it is unlikely that this has a significant effect on the detection risk.

As for the compliance audits, the decision to switch from on-the-spot to remote audits was taken as a response to the effects of the pandemic. DG SANTE's

experience in using remote assessment tools has overall been positive: the planning, organization and management of national controls can be reliably assessed by remote means. Remote assessments can be more advantageous than on-the-spot missions for this part of the audits since using modern video communications allowed to have all relevant parties present for key meetings. However, on-the-spot assessment is required to verify whether the planned arrangements work in practice. For this reason, DG SANTE's standard approach is to carry out audits that combine both remote and on-the-spot phases, which is expected to improve the overall effectiveness and coverage of the evaluations.

- ***How has this affected the level of assurance?***

Commission reply:

DG SANTE's error rate detected in financial audits amounted to 0.9% in 2020 compared to 0.5% in 2019 in the policy area "Food and Feed Safety". It has to be noted that the error rate in 2020 was based on a relatively low number of audits closed in 2020. However, the audit findings were in line with previous years' observations on the same kind of cost claims. These are indications that the level of assurance was not significantly affected by the lower number of finalised audits or by the use of remote audits.

<u>Vaccine Development/Advance Purchase Agreements/EFI funds for vaccine development</u>

- ***What is the current state of play regarding the failed and delayed deliveries by AstraZeneca?***

Commission reply:
Following the settlement agreement outlining clear and targeted delivery schedule commitments, the company has delivered up to date nearly 200 million doses, including more than 90 million doses for donations through COVAX. The company is delivering according to the agreed schedule.

- ***We fully acknowledge that the funding of research does not always result in a successful development. This is inherent in the nature of research. Could you please explain how the companies with Advance Purchase Agreements that failed to produce vaccines or that failed to receive approval by the EMA cooperated with the Commission along the process? How are they now cooperation with regard to production of vaccines that were developed by other companies?***

Commission reply:
The Commission and the Vaccines Steering Board are in regular contact with all companies who signed Advanced Purchase Agreements (APA), including regular updates on the clinical trials and progress of the authorisation processes. In October 2021, CureVac informed the Commission that it withdrew its vaccines from the European Medicines Agency's rolling review process, putting an end to its APA. CureVac informed that they were shifting focus to development of a second-generation vaccine.

- ***How did the Commission ensure that funds paid for the development of vaccines were exclusively used for this purpose - particularly regarding companies that failed to produce a vaccine that received EMA approval? Which controls were conducted for this purpose and how?***

Commission reply:
Following the termination of its contract by CureVac, the company and the Commission are in close exchange regarding the adequate termination procedure in line with the contract. It commits the company to provide the Commission with reports on the use of the down payment and conditions for any recovery.