

Press Release

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EU COVID-19 vaccine procurement: lessons to be learned, say EU auditors

The EU's tailor-made centralised system for vaccine procurement succeeded in creating an initially diversified portfolio of vaccine candidates and in procuring sufficient doses of COVID-19 vaccines. However, the EU started procurement later than the UK and the US, and when severe supply shortfalls occurred in the first half of 2021, it became clear that most contracts signed by the European Commission did not include specific provisions to address supply disruptions. The performance of the procurement process was not sufficiently assessed, a special report published today by the European Court of Auditors (ECA) concludes. The auditors also note that the Commission has not yet scrutinised or benchmarked that process to draw lessons for the future, nor does it currently plan to test its pandemic procurement system through stress-tests or simulations.

"Whether the Commission and Member States have procured COVID-19 vaccines effectively is a very pertinent question", said Joëlle Elvinger, the ECA member who led the audit. "We chose this topic given the central role that vaccines played in the response to the COVID-19 pandemic, the unprecedented nature of the EU's involvement in vaccine procurement and the expenditure involved. Our findings are intended to contribute to the ongoing development of the EU's pandemic preparedness and response capabilities."

When the EU's vaccine procurement process started in mid-2020, it was not known if or when a COVID-19 vaccine would reach the market. The EU had to act ahead of clear scientific data on vaccine candidates' safety and efficacy, and therefore chose to back a range of candidates to create an initial portfolio of different vaccine technologies and manufacturers. By November 2021, the Commission had signed €71 billion worth of contracts on behalf of the Member States to purchase up to 4.6 billion COVID-19 vaccine doses. Most of these contracts are advance purchase agreements in which the Commission shares the development risk of a vaccine with the vaccine manufacturers and supports the preparation of at-scale production capacity through upfront payments from the EU budget.

Negotiations followed a procurement process laid down in the EU's Financial Regulation, while the heart of the process was the preliminary negotiations that took place before a tender invitation was sent out. The EU had secured sufficient doses to vaccinate at least 70 % of the adult population by the end of the summer of 2021, after experiencing challenging supply shortfalls from two manufacturers in the first half of 2021. The Commission could, and in one case did, take

The purpose of this press release is to convey the main messages of the European Court of Auditors' special report. The full report is available at eca.europa.eu.

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manufacturers to court. According to the auditors, however, the EU's negotiators did not fully analyse the production and supply chain challenges of vaccine production until after signing most of the contracts. The terms of the contracts evolved over time, and those signed in 2021 have stronger provisions on key issues such as delivery schedules and production location than those signed in 2020. The terms negotiated are different for each contract, except for adherence to the principles of the Product Liability Directive. Member States agreed to reduce manufacturers' risks linked to liability for adverse effects (risk-sharing principle in the vaccine strategy). The provisions in the contracts concluded with COVID-19 vaccine manufacturers differ from pre-pandemic practice, as Member States have taken over some of the financial risks normally assumed by the vaccine manufacturers.

The Commission proposed to continue the procurement approach set up for COVID-19 for future health crises, but neither the Commission's nor the Council's "lessons learned" reports on the COVID-19 pandemic examined the performance of the vaccine procurement process, beyond its overall outcome. The auditors recommend to create pandemic procurement guidelines on the basis of lessons learnt, and to stress-test the EU's medical countermeasures procurement approach to be better equipped if needed in future.

Background information

Funding for vaccine procurement came partly from the Emergency Support Instrument (ESI) – a financing instrument directly managed by the Commission that allows it to provide support within the EU in case of disasters – and mainly from direct contributions from Member States' budgets.

Special report 19/2022, "EU COVID-19 vaccine procurement: Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed", is available on the <u>ECA</u> website. The audit expands on ECA's 2021 review on the <u>EU's initial contribution to the public health response to COVID-19</u>.

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