



Council of the
European Union

**Brussels, 21 October 2022
(OR. en)**

13889/22

LIMITE

**SAN 572
FIN 1129
PHARM 163
SOC 575
MI 770
FRONT 379
COVID-19 167
DEVGEN 192**

WORKING DOCUMENT

From: General Secretariat of the Council
To: Delegations

Subject: Draft Council conclusions on Special Report No 19/2022 by the European Court of Auditors: COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed

Delegations will find in the Annex a Presidency proposal for Council Conclusions on the abovementioned subject to be examined at the meeting of the Working Party on Public Health on 24 October 2022.

**Council conclusions on Special Report No 19/2022 by the European Court of Auditors:
COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but
performance of the process not sufficiently assessed**

(Draft)

THE COUNCIL OF THE EUROPEAN UNION:

- (1) WELCOMES the Special Report No 19/2022 by the European Court of Auditors (hereafter referred to as "the Court") and the replies of the Commission to the Report;
- (2) NOTES that the Court's audit assessed whether the Commission and Member States procured COVID-19 vaccines up to the end of 2021 effectively; in that endeavour, the Court reviewed whether:
 - the EU's preparations for the procurement of COVID-19 vaccines were effective;
 - the EU's negotiators were able to secure the EU's procurement objectives in the contracts it signed with vaccine manufacturers;
 - the Commission addressed any issues impacting the supply of vaccines.
- (3) RECALLS that the objectives of the EU Strategy for COVID-19 vaccines are to ensure the quality, safety and efficacy of vaccines, to secure timely access to vaccines for Member States and their population while leading the global solidarity effort and to ensure equitable access for all in the EU to an affordable vaccine as early as possible.
- (4) ACKNOWLEDGES that the EU Strategy for COVID-19 vaccines represents a significant achievement and highlights the added value of EU cooperation by ensuring that 80 % of the EU adult population was fully vaccinated by the end of 2021.

- (5) NOTES that the EU strategy for COVID-19 vaccines was centred around two bodies, particularly the Steering Board, responsible for overseeing negotiations and validating contracts before signature and the Joint negotiation team being in charge of negotiating the contracts.
- (6) NOTES that according to the Special Report, the President of the Commission conducted preliminary negotiations for a contract with Pfizer/BioNTech during March 2021, which was the only contract for which the Joint negotiation team was not involved. It is the biggest COVID-19 vaccine contract, which will dominate the EU's vaccine portfolio until the end of 2023
- (7) INVITES the Commission to continue the cooperation with Member States in order to fulfil the goals of the EU Vaccines Strategy.
- (8) TAKES NOTE of the findings of the Report, in particular that:
- The Commission produced its vaccine strategy in the early stages of the pandemic at a time when there were no COVID-19 vaccines available on the market;
 - The EU managed to procure COVID-19 vaccines by ensuring a diversified portfolio in order to spread the risk of failed vaccine development by signing contracts with several different manufacturers;
 - The EU's preparations for the procurement of COVID-19 vaccines were mostly effective, however the EU started the procurement process later than the UK and the US;
 - The terms of the contracts evolved over time and the EU's negotiators were better able to secure the EU's procurement objectives in the later contracts it signed with vaccine manufacturers;
 - The Commission and the majority of Member States who responded to the ECA survey wish to see a more standard liability regime when the standard marketing authorisation has been granted;

- The Commission has proposed the use of the procurement system for future health crises without first evaluating its performance or examining third country procurement system beforehand;
- The Commission did not fully analyse the production and supply chain challenges of vaccine production until after signing most of the contracts. The Commission only set up a task force to support manufacturing and supply chains eight months after the launch of the EU's vaccine COVID-19 procurement and while it did help resolve bottlenecks, its impact on the ramp-up of vaccine production was unclear.

(9) SHARES the observations of the Court to the findings and recommendations included in the Report, in particular that:

- The Commission achieved a diversified vaccine portfolio, but the EU is mainly dependent on one supplier for 2022-2023;
- The Commission supported contract implementation, in close cooperation with Member States, but these efforts had only a limited leverage to overcome supply challenges.

(10) WELCOMES the Commission's reply to the findings of the Court and the initiatives already taken to implement those recommendations, in particular the proposal for a Council Regulation on a framework of measures related to medical countermeasures in the event of a public health emergency at Union level.

(11) TAKES NOTE of the recommendations of the Court and thus INVITES the Commission to:

- Create pandemic procurement guidelines on the basis of lessons learnt to identify good practices for future negotiating teams;
- Carry out a risk assessment of the EU's procurement approach in order to propose appropriate measures;

- Run exercises to test all parts of its updated pandemic procurement framework to identify any weakness and areas for improvement.

(12) UNDERLINES the importance of drawing the lessons from COVID-19 vaccines procurement. Member States emphasise the need for more flexibility in future contracts when it comes to the delivery schedules, as well as for more precise definition of acceptable expiry periods. Member States, realizing role of the EU in vaccine donation, call for easing of donation conditions, so to allow fast delivered directly to third countries or donation of in-country doses.
