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From:	General Secretariat of the Council
To:	Delegations
Subject:	Special report 19/2022: EU COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed - <i>Council conclusions (8 December 2022)</i>

Delegations will find in Annex the Council conclusions on the above-mentioned subject adopted by the Council at its meeting held on 8 December 2022.

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**

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, published by the Commission, 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) RECALLS that the Member States and the Commission approved the Agreement which authorised the Commission to conclude agreements with vaccine manufacturers with the objective to procure Covid-19 vaccines on behalf of the Member States¹.
- (6) NOTES that according to the Special Report 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.
- (7) 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 in this stage of negotiations, contrary to the Commission decision on procuring COVID-19 vaccines. On 9 April 2021, the Commission presented to the steering board the conditions negotiated between the President of the Commission and Pfizer/BioNTech, and the steering board agreed to launch a call for tender. It is the biggest COVID-19 vaccine contract, which will dominate the EU's vaccine portfolio until the end of 2023.
- (8) INVITES the Commission to continue the cooperation with Member States in order to fulfil the goals of the EU Vaccines Strategy, while addressing the shortcomings, in particular in terms of transparency, governance and needs of Member States.
- (9) 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;

¹ Annex to Commission Decision C(2020) 4192 final of 18 June 2020

- 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 10 of the 14 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 in February 2021 and while it did help resolve bottlenecks, its impact on the ramp-up of vaccine production was unclear.

(10) 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 a limited leverage to overcome supply challenges;
- The EU's new regulations and activities in the field were not determined on the basis of an ex-ante impact assessment by the Commission.

- (11) WELCOMES the Commission's reply to the findings of the Court and the initiatives already taken to implement those recommendations, including 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 level².
- (12) TAKES NOTE of the recommendations of the Court and thus INVITES the Commission to:
- Create pandemic procurement guidelines within one year from the adoption of the Emergency Framework Regulation³ and the revised Financial Regulation⁴, on the basis of lessons learnt taking into account, when possible, existing evidence 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;
 - Carry out an independent evaluation of the adequacy of the procedures to assess effectiveness, prices, payment model, quantities of the COVID-19 vaccines procured by the EU from a public health perspective, elements of the contracts clauses as well as selection criteria of the Negotiating Team in order to feed into the guidelines developed;
 - Run exercises, in close cooperation with the Member States, in order to test all parts of its updated pandemic procurement framework to identify any weakness and areas for improvement.

² COM/2021/577 final
³ 2021/0294 (NLE)
⁴ 2022/0162 (COD)

- (13) UNDERLINES the importance of drawing the lessons from COVID-19 vaccines procurement. Taking into account the context of the Global Pandemic during which contracts were negotiated and without prejudice to the context, Member States emphasise the need for more flexibility for Member States in future contracts, especially when it comes to purchased quantities, delivery schedules and payment upon arrival depending on vaccines delivered, as well as for more precise definition of acceptable expiry periods. Realizing the role of the EU in actively contributing to a global response through vaccine donation, CALLS for easing of donation conditions, so to allow fast delivered directly to third countries or donation of in-country doses.
- (14) REGRETS the lack of reply from the Commission to the Court's information requests on the preliminary negotiations for the contract signed with Pfizer/BioNTech on 19 May 2021 and INVITES the Commission to provide the information necessary to allow Union institutions and bodies to carry out their tasks pursuant to the Treaties.
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