REPLIES OF THE EUROPEAN COMMISSION

TO THE EUROPEAN COURT OF AUDITORS' SPECIAL REPORT

EU COVID-19 vaccine procurement

Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed

Contents

This document presents the replies of the European Commission to observations of a Special Report of the European Court of Auditors, in line with Article 259 of the Financial Regulation and to be published together with the Special Report.

I. GENERAL INTRODUCTION TO THE COMMISSION REPLIES

The Commission welcomes this Special Report by the European Court of Auditors (ECA) on the EU COVID-19 vaccine procurement. Europeans have seen the benefits of what EU solidarity can achieve in health, especially with regard to the vaccines strategy to fight the COVID-19 pandemic.

The EU Vaccines Strategy presented by the Commission on 17 June 2020 aimed to accelerate the development, manufacturing and deployment of COVID-19 vaccines. For the first time, it established a system of procurement at central level and in close concertation with the Member States.

During the summer of 2020, only a few months after the beginning of the pandemic, the EU had in place, for the first time ever, a common vaccines strategy through the establishment of a system of emergency procurement at EU level for the benefit of all Member States. By working together with the Member States, the Commission was able to secure the broadest portfolio of vaccines in the world and ensure that all Member States – irrespective of their size - received them at the same time. Between December 2020 and March 2021, four COVID-19 vaccines had already received a conditional marketing authorisation for use in the EU. Although some countries were slightly faster at the beginning because they operated in a different legal context (see Section 2), the EU achieved this success while remaining open to the world by sharing vaccines.

By the end of August 2021, the Commission had already met its target of having 70% of the EU adult population fully vaccinated. By now, 83.3% of the EU adult population is fully vaccinated and 62.3% have received a booster dose. In a year, around 3 billion doses of vaccines have been produced in the EU[1]. In addition, the EU became the region in the world that had exported vaccines on the largest scale - about two-thirds of the vaccines produced in Europe were exported to 167 countries.

The Commission also continues to contribute to the work of the COVID-19 vaccine global access facility to ensure that vaccines are distributed equitably among participating countries according to the guidelines developed by the World Health Organization (WHO). As of May 2022, Team Europe has shared more than 470 million doses to third countries.

To procure the COVID-19 vaccines, the Commission followed the applicable legal framework, namely the Emergency Support Instrument[2] and the Financial Regulation[3]. After a few months into the process, the Commission adopted a communication on the lessons learned[4] from the COVID-19 pandemic. The COVID-19 pandemic gave insight into changes that could be made to strengthen the framework for health crisis preparedness and response at European level. This resulted in the adoption of the so-called Health Union proposals on 11 November 2020,[5] aimed at strengthening the legal framework for serious cross border threats to health as well as at reinforcing the crisis preparedness and response role of key Union agencies, including that of the European Centre for

[1] Figure deriving from APA deliveries and the export authorisation/monitoring mechanisms, from February 2021 to February 2022.

[2] Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.

[3] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018.

[4] COM(2021) 380 final of 15 June 2021.

[5] Communication from the Commission, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM(2020) 724 final.

Disease Prevention and Control (ECDC)[6]. In September 2021, the Commission's Health Emergency Preparedness and Response Authority (HERA) was created to contribute to ensuring the development, manufacturing, procurement, and equitable distribution of key medical supplies and equipment during both this and future health emergencies. The recognition of a public health emergency at Union level can trigger increased coordination and the development, stockpiling and procurement of crisis relevant products.

Moreover, based on lessons learned from COVID-19 outbreak, the Commission proposed modifications in the main legal framework applicable for procurement by Union Institutions. More precisely, the Commission adopted on 16 May 2022, an amending proposal to the Financial Regulation[7] including specific rules for crisis management (i.e. health crises), in order to ensure quicker response and ease the formalities for procurement procedures.

The Commission accepts the recommendations (see further Section III below).

II. COMMISSION REPLIES TO MAIN OBSERVATIONS OF THE ECA

1. The EU created a tailor-made procurement system for COVID-19 vaccines

The EU started the procurement process[8] in June 2020, only three months after the WHO declared the COVID-19 outbreak a global pandemic. This is an extraordinary achievement, given that it required activating and amending the Emergency Support Instrument (ESI) Regulation and the agreement of all 27 Member States (including the completion of their internal procedures) to form the necessary legal basis for the procurement. There was no precedent for procuring centrally vaccines at EU level**.**

Despite the complex procedures that were required in all Member States to set up the centralised procurement, the EU signed its first advance purchase agreement on 27 August 2020. In the EU, vaccination started on 26 December 2020, after the Commission had granted a conditional marketing authorisation for the first vaccine against COVID-19. By the end of August 2021, the Commission had already met its target of having 70% of the EU adult population fully vaccinated.

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6 Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, COM(2020) 727 final; and Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, COM(2020)726 final.

7 Proposal for a Regulation of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (recast), ref. COM(2022) 223 final.

8 See paragraphs 17-30 of the ECA report.

2. The EU's centralised procurement procedure followed the applicable legislation

The process of procuring vaccines followed the applicable legal framework[9], namely the Emergency Support Instrument and the Financial Regulation. The call for tender procedure was preceded by a distinct step, namely the preliminary market consultations. Those consultations were an important first step, given that no vaccine against COVID-19 existed at the time. The "term sheets"[10] were discussed with the manufacturers during the preliminary market consultations prior to the official start of the tender procedure and included only major elements (notably price, volume and third party liability). A number of very complex and important issues such as termination clauses and contractual liability were entirely new elements during the formal tendering process.

The first procurement procedure was launched after a prior agreement with the manufacturer had already been reached by the four Member States that had started the procedure as Inclusive Vaccine Alliance (IVA).

3. Contractual clauses and vaccine delivery

The Commission notes that the ECA benchmarks the EU's performance against that of the United Kingdom (UK) and the United States (US) (paragraph 13 of the ECA report). The Commission would like to make the following remarks in this context.

First, the ECA has not had access to the actual clauses of the US and UK contracts and has based its analysis on publicly available reports from the US and UK auditing bodies (boxes 2 and 3). Therefore, the examination of the contracts in the different jurisdictions was carried out without being able to analyse the text of the contracts.

Second, the Commission welcomes the ECA's recognition of the different legal and institutional context in which the contracts were concluded, applied and interpreted. As an example, in the US, the government could invoke the Defense Production Act (DPA) to conclude priority-rated contracts or place orders that take precedence over any others if a contractor is unable to make all of the contracted deliveries on time. This significantly alters the context in which government contracts for medical countermeasures in the US are concluded as compared to the EU (box 3). Moreover, a comparison based on contractual clauses alone does not take into account the rights and obligations that stem from the relevant applicable law to the contract that is different in each of the compared three jurisdictions. Belgian law, which is applicable to the EU contracts, provides for important mandatory contractual remedies that apply as between the parties even without specific remedial provisions in the contract.

Third, ECA's report argues that the priority clauses in the UK contracts are stronger than the contractual warranties in the EU contracts. However, the Commission considers that a priority clause is always in relation to certain deliveries as explained in the report (boxes 2 and 3), whereas a contractual warranty applies generally and provides for strong contractual protection, in particular when compared to a contract without any penalties for late delivery (as was the case for the UK contracts, box 2). This is exemplified through the court case the EU brought against one manufacturer (box 4). In that case, the Brussels court found that a priority clause in a UK contract could not be

[9] See paragraphs 35-39, and 48-49 of the ECA report.

[10] See paragraphs 33 and 35 of the ECA report.

invoked against the EU with the result that the clause was unenforceable against the EU due to a contractual warranty in the EU contract (paragraph 52 of the relevant court order).

Finally, the Commission emphasises that the EU's approach to third party liability and indemnification ensured that EU citizens' rights are protected and that legal liability stays with pharmaceutical companies in all cases. However, due to the pandemic conditions, Member States accepted to share some of the financial risks taken by the companies (paragraphs 9 to 11). The Commission notes that the ECA points to a different approach in the US and UK. For instance in the US the Public Readiness and Emergency Preparedness Act shields pharmaceutical companies from litigation (boxes 2 and 3).

4. Concerted efforts supported the ramp up of EU vaccine production capacity

In early 2021, the EU, and the world, faced an unprecedented need to scale up vaccine production[11]. When signing the first Advanced Purchase Agreements for COVID-19 vaccines in 2020, the Commission had limited information on production capacity and supply chains, especially in light of the uncertainty over which vaccines would be developed, authorised and administered.

The Commission's Task Force for Industrial Scale-up of COVID-19 vaccines (TFIS) was set up in February 2021, when the actual mass production had to start. It supported the resolution of critical bottlenecks related to the increased global demand on single use items (such as bioreactor bags, vials, tubes, filters) as well as lipids for mRNA vaccines. Five vaccine manufacturers and several of their key suppliers received support to prioritise the supply of critical inputs, with a direct effect on the ramp-up of production. The TFIS assessed vaccine manufacturers' supply chains and ability to deliver on commitments, as requested by the Commission decision-makers ahead of the signature of Advanced Purchase Agreements.[12] In addition, the TFIS monitored and mapped EU-based vaccine production, facilitated new industrial partnerships, and engaged in a dialogue with the US, to help mitigate shortages in the EU linked to the 'Defense Production Act'.

The competences of the Commission offer the possibility to directly intervene to affect production (State aid or Advanced Purchase Agreements), but also by working directly with industry and companies to address supply chain bottlenecks and fostering industrial partnerships, with a direct effect on production capacity. In the Commission's view, increase in production capacity results not only from commercial decisions taken by manufacturers, but also from the activation and expansion of production sites, sufficient supplies of critical ingredients and materials[13], strong international partnerships and close collaboration between the Commission and industry. The TFIS was able to play a facilitating and supporting role in this context. The establishment of a centralised procurement system for and by the 27 Member States, combined with the set-up of the TFIS and additional measures from Member States, impacted on and certainly facilitated the ramp up of the EU production capacity for COVID-19 vaccines, although it is difficult to quantify the impact.

The ECA stresses that the US and UK had anticipated manufacturing and supply chains problems earlier in the procurement process[14]. However, the pre-financing provided in accordance with the

[11] See paragraphs 61-68 of the ECA report.

[12] As such, the TFIS assessments were informing the Commission decision on the signature of the third contract with Pfizer-BioNTech, and first contracts with Novavax and Valneva.

[13] The TFIS helped resolve a substantial part of the around 150 supply chain bottlenecks it identified for various EU production sites, which facilitated the ramp-up of the companies' production capacity.

[14] See paragraph 64 of the ECA report.

Advanced Purchase Agreements also aimed at supporting the ramp up of the production, and by May 2021, the EU had surpassed the US in vaccine production.

As a result of several concerted efforts, the production capacity in the EU was significantly ramped up, from 20 million vaccine doses at the beginning of 2021 to a monthly capacity and actual production of around 300 million vaccine doses by the second half of 2021[15].

Lessons learnt from the TFIS experience were translated into the strong industrial dimension of HERA, to address supply chain and production issues: inventories of relevant production facilities in emergency times, continuous monitoring and mapping of relevant supply chains and production capacities in preparedness times, and the setting up of the EU FAB's ever-warm network of production capacities[16].

III. COMMISSION REPLIES TO THE RECOMMENDATIONS OF THE ECA

1. Recommendation 1 – Create pandemic procurement guidelines on the basis of lessons learned

(Target implementation date: one year from of the adoption of the two legal bases)

Once the Emergency Framework Regulation and the revised Financial Regulation have been adopted, after consulting Member State authorities and relevant stakeholders, and benchmarking with other procurement systems to identify good practices, the Commission should produce pandemic procurement guidelines and/or lessons learnt for future negotiating teams.

The Commission accepts the recommendation.

The Commission has put forward a legislative package of proposals for crisis management in the Financial Regulation recast proposal (adopted on 16 May 2022[17]) and a 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 ("Emergency Framework Regulation"[18]). Guidance will be produced for the interpretation of the new measures proposed within one year of the adoption of those acts by the legislator.

[15] Internal Commission monitoring, deriving from APA deliveries and the export authorisation/monitoring mechanisms.

[16] https://ec.europa.eu/commission/presscorner/detail/en/fs_22_2664

[17] https://ec.europa.eu/info/publications/financial-regulation_hu

[18] https://www.eumonitor.eu/9353000/1/j9vvik7m1c3gyxp/vlm9r29csjzc

2. Recommendation 2 – Stress-test the EU's medical countermeasures procurement approach

(Target implementation date: Q2 2024)

The Commission should, in order to be in line with best practices and contribute to the review of the Council Regulation on an emergency framework for medical countermeasures:

a) Carry out a risk assessment of the EU's procurement approach and propose appropriate measures.

b) Run exercises to test all parts of its updated pandemic procurement strategy/framework, including information and intelligence gathering, to identify any weaknesses and areas for improvement and publish the results.

The Commission accepts the recommendation.