

2021 Discharge to the Commission

**WRITTEN QUESTIONS TO COMMISSIONER STELLA
KYRIAKIDES**

Hearing on 8 November 2022

Questions concerning evaluation

1. Has the Commission carried out an evaluation of the performance of the Joint Procurement Agreement for medical countermeasures? Could you provide us updated information on the actions carried out under this instrument?

Commission's answer:

The performance of the Joint Procurement agreement (JPA) of 2014 is currently being assessed; an evaluation study is ongoing.

The assessment is looking into the effectiveness, efficiency, relevance, coherence and EU added value of both the legal framework and the implementation of the Agreement against the underlying policy objectives as defined in the legal framework in two different periods and contexts (i.e. until and since the COVID-19 pandemic). The study deliverables will also reflect on the future and provide several plausible scenarios aiming to understand the EU added value of the JPA and how/if it can work with the current regulatory framework and market situation; a monitoring and indicators framework; and a cost-benefit analysis tool.

In April 2022, Directorate-General for Health and Food Safety (DG SANTE) kicked-off an evaluation study, conducted by an external contractor, with the final report expected by the end of the year. An Inter-Service Steering Group with representatives from eight Directorate-Generals (the Commission's Health Emergency Preparedness and Response Authority (HERA), Legal Service (LS), Directorate-General for Budget (BUDG), Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (GROW), Directorate-General for European Civil Protection and Civil Aid Operations (ECHO), Directorate-General for Human Resources and Security (HR Medical Service), Joint Research Centre (JRC), and Directorate-General for Competition (COMP)) has been set-up to oversee the study deliverables from their respective policy angle.

As regards the actions carried out under this instrument, the Joint Procurement Agreement for medical countermeasures has been used for 13 procurement procedures: two procurements took place before the outbreak of the pandemic (with tender award dates in 2016 and 2019) and eleven during the pandemic (with tender award dates between February 2020 and April 2021). As of now, 37 countries¹ have signed the JPA.

Detailed information will be provided once the study is finalised.

¹ https://health.ec.europa.eu/other-pages/basic-page/joint-procurement-medical-countermeasures_en

Overall, the Commission has put in place 16 Joint Procurement Framework Agreements² since the start of the pandemic, with JPA countries signing more than 230 contracts under these framework agreements.

In 2020 Framework Agreements were put in place which covered Personal Protective Equipment, ventilators, laboratory equipment intensive care unit medicines, the therapeutic Remdesivir, and medical equipment for vaccination.

In 2021, Framework Agreements were concluded covering rapid antigen tests, the monoclonal antibodies Ronapreve, Sotrovimab and the combination medicinal product Bamlanivimab and Etesevimab

In 2022, Framework Agreements were signed for Remdesivir, Hipra Laboratories' (HIPRA) COVID-19 vaccine, and GlaxoSmithKline's (GSK) pandemic influenza vaccine. In addition, the Commission has launched a pilot project with the Dynamic Purchasing System which will make future joint procurements of Personal Protective Equipment swifter and more streamlined.

2. What role do you or your services have in the assessment of national Recovery and Resilience Plans, and what is the framework in place for assessing proposed investments and reforms of national health systems? Can you provide us with detailed information in this area?

Commission's answer:

According to a Commission Decision of 24 July 2020, Directorate-General Economic and Financial Affairs (DG ECFIN) and the Recovery and Resilience Task Force (SG-RECOVER) are jointly responsible for steering the design and implementation of the Recovery and Resilience Facility (RRF), including the assessments of the Recovery and Resilience Plans (RRPs). Within the Commission, Country teams from all relevant services provide their expertise for the discussions with Member States. While SG-RECOVER and DG ECFIN are leading the assessment of the RRFs and payment requests, experts in other Commission services are able to provide input and specifically consulted where relevant throughout the assessment work. DG SANTE plays an active part in this process. At political level, a Steering Board of Commissioners provides political guidance.

As regards the assessment process, the RRF Regulation provides a clear process and assessment criterion which the Commission has followed. An RRP is submitted by each Member State, and assessed – in its entirety – by the Commission. The assessment is based on 11 criteria included in Article 19 of the RRF Regulation and expanded on in Annex V of the RRF Regulation. They concern for instance the digital and green contributions of the RRP, the monitoring and control arrangements, and the cost estimate.

While established in the context of the COVID-19 pandemic, and the pandemic's social and economic effects, the RRF itself is not per se a programme dedicated to financing health measures. Rather, in line with the broad and wide impact of the crisis across all economic and

²https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/ensuring-availability-supplies-and-equipment_en#identifying-demands-and-matching-supplies-of-medical-equipment;

social sectors, the RRF can support reforms and investments across a wide breadth of policy areas. There is accordingly no dedicated criterion related to health. The only directly health-related assessment criterion is criterion 1, which requires the Commission to assess, whether “The recovery and resilience plan represents a comprehensive and adequately balanced response to the economic and social situation, thereby contributing appropriately to all six pillars referred to in Article 3, taking the specific challenges and the financial allocation of the Member State concerned into account.” Among the indicated six pillars, pillar 5 concerns “health, and economic, social and institutional resilience, with the aim of, inter alia, increasing crisis preparedness and crisis response capacity”.

DG SANTE participates in the country teams and focuses their input on key performance dimensions of health systems, such as effectiveness, accessibility and resilience. This support is informed by relevant policy initiatives such as the [State of Health in the EU](#) project. Similarly, this assessment builds on a long-standing series of health system assessments published under the [European Semester](#) cycle in various country reports. Also, results from additional initiatives supported by DG SANTE, such as the Member State expert group on Health System Performance Assessment inform SANTE’s work under the RRF. DG SANTE’s involvement had been broad as all Recovery and Resilience Plans adopted to date include measures with relevance to national health systems. This observation is in line with the fact that “Health resilience” features among the six pillars of the Recovery and Resilience Facility under Regulation 2021/241 establishing the Recovery and Resilience Facility. Moreover, when drafting their Recovery and Resilience Plans, Member States should look at the full set of country-specific recommendations addressed to them by the Council, in particular under the 2019 and 2020 Semester cycles (see Commission guidance SWD (2021)12³. In 2019, 16 Member States received a country-specific recommendation addressing healthcare and in 2020 all Member States received a country-specific recommendation addressing healthcare.

3. An ex post evaluation of the Third public Health programme has been launched in October 2020. What are so far the outcomes?

Commission’s answer:

The ex-post evaluation of the Third Health Programme 2014-2020 is still ongoing and results are therefore not available. It kicked off with the publication of its roadmap on the Commission’s portal in October 2020.

The study supporting the ex-post evaluation was launched in July 2021, following a call for tender enabling to select a contractor to assist the Commission. The service contract was awarded in June 2021.

Consultation activities, including an Online Public Consultation, were carried out from March to June 2022.

The evaluation study is now in its final stage. Results will be communicated by the contractor at the end October 2022 and will feed into the preparation of a Commission’s Staff Working Document.

³ https://ec.europa.eu/info/sites/default/files/document_travail_service_part2_v3_en.pdf

4. Can you describe the evolution of European Health data Space (EHDS)?

Commission's answer:

On 3 May 2022, the Commission adopted the proposal for a Regulation on a European Health Data Space (EHDS) and the accompanying communication⁴. The EHDS is one of the central building blocks of a strong European Health Union. The proposal aims to empower individuals to control and utilise their health data, to foster a genuine single market for digital health services and products and provide a consistent, trustworthy and efficient framework for re-use of health data for research, innovation, policy-making and regulatory activities, while ensuring full compliance with the EU's high standards of data protection.

The Council started examinations of the proposal immediately after its adoption by the Commission. Under the French Presidency of the Council a discussion on this topic was held at the EPSCO Council (Employment, Social Policy, Health and Consumer Affairs Council configuration) in June 2022 and the Member States largely supported the objectives of the proposal. Further progress in the examination of the proposal was made under the Czech Presidency of the Council.

In the meantime, the Commission in close collaboration with the Member States and other stakeholders promotes the acceleration of preparatory works for the implementation of the future European Health Data Space in the areas of data governance, interoperability, quality of data, and work progresses on two technical infrastructures: MyHealth@EU for cross-border exchanges of health data for primary use and HealthData@EU for secondary use of health data. Various activities (including direct grants, Joint Actions and other projects) are being supported from the EU4Health Programme and other Union funding instruments.

Questions concerning COVID-19

5. Which are the improvements which the Commission introduced in 2021 based on its experience from the COVID 19 crisis?

Commission's answer:

A key part of the Commission's response to the COVID-19 pandemic and future public health emergencies is the European Health Union legislative package adopted already in November 2020. The set of initiatives it includes aim to enhance EU capacity for preparedness, surveillance, risk assessment, early warning and response, to address cross-border health threats and better protect EU citizens:

- a new **Regulation on serious cross-border threats** to health to reinforce the EU health security framework;
- **revised mandates of the European Centre for Disease Control and Prevention (ECDC) and the European Medicines Agency (EMA)**, to strengthen the effectiveness of the agencies' operations and work;
- the setting up of the **European Health Emergency Preparedness and Response Authority (HERA)**, to ensure the availability of medical countermeasures in case of public health emergencies.

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022DC0196>

The Commission has launched a **Joint Action on Integrated Surveillance** under the 2021 Annual Workplan of the EU4Health programme. The Joint Action aims to support Member States in setting up and/or further develop their integrated Surveillance capacities for respiratory diseases according to the updated guidance of the ECDC.

The **Health Security Committee (HSC)** met (and still meets) on a weekly basis to coordinate the response to COVID-19 with Member States, as well as to pass on messages from ECDC regarding the epidemiological situation on a regular basis. Moreover, DG SANTE has run various surveys among the HSC, to take stock of the state of play in EU Member States regarding their COVID-19 preparedness and response measures.

DG SANTE was organising coordination **meetings with the ECDC Public Health Emergency Manager (PHE)** twice a week, to discuss possible measures to be taken by the Commission, the Member States and other Competent Authorities in the context of the COVID-19 pandemic.

Based on the development of the pandemic, experiences shared in the HSC as well as discussions with ECDC, DG SANTE, in close collaboration with numerous other DGs across the Commission, has **published various COVID-19 Commission Communications**, setting out the various lessons learnt, structures and processes established and funding made available in response to the COVID-19 pandemic.

The Regulation reinforcing the mandate of the EMA entered into force in March 2022 and allows the Agency to closely monitor and mitigate shortages of medicines and medical devices in preparation for and during crises, with engagement with industry.

The Regulation builds on existing structures and processes, ensuring that the EU regulatory network, in collaboration with pharmaceutical supply chain actors, can ensure better preparedness and coordinated response to supply of medicines during crises. The EMA has been key to our collective efforts to counter the impact of the COVID-19 pandemic on European patients.

Under the new legislation, the **European Medicines Agency** will be able to:

- monitor and mitigate the risk of shortages of medicines and medical devices, in particular for those on critical lists during major events and public health emergencies;
- set up, by February 2025, an interoperable IT platform at EU level to enable monitoring and reporting of shortages of medicinal products;
- provide scientific advice on medicines that may have the potential to treat, prevent or diagnose the diseases causing public health emergencies;
- coordinate studies to monitor the effectiveness and safety of vaccines;
- coordinate clinical trials for medicinal products intended to treat, prevent or diagnose diseases related to the public health emergencies; and finally,
- provide support for the expert panels of the Medical Device Regulation.

In 2021, the Commission established the Health Emergency and Preparedness Authority (HERA) providing a permanent integrated approach from the identification of threats to the development, manufacturing, procurement, and equitable distribution of key medical countermeasures needed to adequately prepare for and respond to the identified threats. Its action aim to strengthen the development, supply chains, manufacturing capacities and stockpiling of medical countermeasures.

6. Has the Commission already implemented recommendations by the Court of Auditors and the Ombudsman related to COVID responses? Which are the recommendations and how have they been implemented?

Commission's answer:**Court of Auditors**

The ECA recommended to:

- 1) Create pandemic procurement guidelines on the basis of lessons learnt;
- 2) Stress-test the EU's medical countermeasures procurement approach.

The Commission accepted the recommendations, and action be implemented according to the target dates agreed by the Commission and ECA, more precisely for Recommendation 1: one year from of the adoption of the two legal bases, namely the revised Financial Regulation and HERA Regulation; for Recommendation 2: by Q2 2024.

Ombudsman

DG SANTE responded to two Ombudsman cases in 2021/2022, both related to access to document requests. Throughout 2021, DG SANTE faced an exceptionally high workload with a series of access to documents requests related to its procurement and grant procedures. Special care was taken to safeguard confidential commercial information and prevent leaks, in accordance with Regulation (EU) 1049/2001.

In one case⁵, related to Advance Purchase Agreements for COVID-19 vaccines, the Ombudsman closed the case finding no maladministration, while providing guidance on how to release information (but not personal data) regarding the members of the team responsible for the negotiations with pharmaceutical companies. DG SANTE followed this guidance.

In another case⁶, the Ombudsman concluded that the Commission's refusal to give public access to documents constituted maladministration, mainly because of its refusal to grant access to the identity of manufacturers of medical masks distributed during the COVID-19 pandemic.

The Ombudsman recommended that the Commission reconsidered its position with a view to granting increased, if not full, access to the documents concerning the quality of the masks. Following additional information provided [full access was not granted] by the Commission, the Ombudsman closed the case in May 2022.

DG SANTE became aware of the quality issues with the medical masks it had purchased for direct delivery from the producer to the Member States. DG SANTE recalled the defective products and organised physical quality checks prior to further distribution to the Member States. Thanks to these rapid reactions, neither a health issue nor a financial loss was caused by the incident.

⁵ Case 175/2021/DL, opened on 29 January 2021: <https://www.ombudsman.europa.eu/en/case/en/58643>

⁶ Case 790/2021/MIG, opened on 30/04/2021:
<https://www.ombudsman.europa.eu/en/recommendation/en/148785>

7. Which are the improvements Commission introduced in 2021 based on its experience from the COVID 19 crisis? Has Commission already implemented recommendations by the Court of Auditors and the Ombudsman related to COVID responses?

Commission's answer:

Please also see replies to questions 5 and 6 above.

In addition, the Commission has proposed new provisions applicable to procurement processes for crisis situations to be included in the Recast Financial Regulation⁷.

The proposal reflects the measures used during COVID-19 Crisis based on the Emergency Support Regulation.⁸ More precisely, the provisions would allow an EU institution, EU body, an executive agency to procure on behalf or in the name of Member States or act as a central purchasing body in order to donate/resale goods/services to the Member States/partner organisations; it would also allow us to launch joint procurements without the EU Institutions being obliged to acquire the services/supplies.

Moreover, additional simplifications are proposed for extreme urgency situations following a crisis, in order to ensure quicker implementation and address the lessons learned from the Covid-19 crisis.

8. How did Commission coordinated with its DGs and Agencies for a better response to COVID 19 in 2021?

Commission's answer:

Since the beginning of the pandemic, DG SANTE has been closely working with other DGs; e.g. weekly COVID-19 coordination meetings are being held and on specific dossiers, particularly in the area of travel. Regarding the latter, more specific examples are the EU Digital COVID Certificate, in which DG SANTE is closely working together with DG JUST, DG HOME, DG CNECT and DG MOVE, as well as joint guidelines and recommendations published between the ECDC and the European Aviation Safety Agency (EASA).

During the COVID-19 pandemic, the Health Security Committee (HSC) has become a vital platform for acquiring data and information on Member States' approaches to the outbreak. While the scope of these discussions is on public health, these are often interconnected to other policy fields. Therefore, the HSC discussions (and agreed opinions) have not only informed SANTE policy making processes, but also other DGs (e.g. JUST, HOME, MOVE, CNECT, SG, HERA, ECHO). Representatives from other DGs have often presented at the HSC and have used the Committee as a vehicle to obtain further input to facilitate their policy work.

DG SANTE has been in regular meetings with the ECDC Public Health Emergency Manager (PHE) twice a week, to discuss possible measures to be taken by the Commission, the Member

⁷ https://ec.europa.eu/info/publications/financial-regulation_en

⁸ [Council Regulation \(EU\) 2020/521 of 14 April 2020, activating the emergency support under Regulation \(EU\) 2016/369, and amending its provision taking into account the COVID-19 outbreak.](#)

States and other Competent Authorities in response to upcoming changes of the pandemic, such as new variants, increases in vaccination etc. The DG SANTE and the ECDC have put in place a dedicated system for specific scientific requests coming from the Commission to the ECDC.

At the request by the Commission, the ECDC is producing specific regular outputs for monitoring the COVID-19 crisis, e.g. weekly COVID-19 policy briefs, daily communicable diseases reports, and COVID-19 vaccination reports. Furthermore, at the request by the Commission, the ECDC has published COVID-19 specific outputs, such as the weekly country review report (which lists all relevant indicators per country and as EU/EEA average), the COVID-19 vaccination tracker, the Non-pharmaceutical interventions (NPI) measures database, the COVID-19 variants dashboard and others. The ECDC has carried out about 19 Risk Assessments on COVID-19. The ECDC furthermore, did regularly present epidemiological data during the weekly Health Security Committee meetings. At the request by the Commission, the ECDC was also actively contributing the increase of COVID-19 vaccination uptake, by means of country visits and particular conferences to health care staff.

The European Medicines Agency has been key to our collective efforts to counter the impact that the COVID-19 pandemic has had on shortages of medicines. The Commission has cooperated with the Agency very well and very closely. The Commission is a member of The Executive Steering Group on Shortages and Safety of Medicinal Products (the 'Medicine Shortages Steering Group (MSSG)) and also attends and contributes to the Single Point of Contact Working Party meetings to support the work of the MSSG. More details have been presented in the European Health Union⁹ proposal¹⁰.

Please also see the reply to question 5 above.

Questions concerning HERA

9. We noted that CureVac notified the Commission of the termination of the Advance Purchase Agreement as it would not be in a position to obtain marketing authorisation for its vaccine before the end of 2021. We also noted that the Commission has received CureVac's report on spending of the advance payment and that the file has been transferred to the newly established European Health and Emergency Preparedness and Response Authority (HERA) in early 2022 for further analysis and handling. Could you nevertheless inform us about the amounts involved, what kind of activities haven been funded and whether there will be recoveries of the advance payment?

Commission's answer:

Following termination of the Advance Purchase Agreement (APA) between the Commission and CureVac and in line with its provisions, CureVac provided a Financial Statement detailing for which the upfront payments have been used. The contract defines what type of information relating to expenses should be specified in the Financial Statement. CureVac provided a detailed breakdown of costs; it shows that the upfront payment, received by CureVac in December 2020, was used in full to cover parts of CureVac's costs for clinical studies, for the

⁹ https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

¹⁰ https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041

creation of a European network of Contract Manufacturing Organisations (CMOs) and Suppliers, and for the purchase of raw materials to ensure the timely start of large-scale production.

Article II.14.5 (a) of the APA requires the contractor to send a list of any raw materials and primary components paid for with the up-front payments and not used (Refundable Items). Given that neither the Commission nor the Member States were in a position to physically take possession¹¹ of the raw materials and primary components that CureVac had purchased, it was agreed that CureVac would try to sell these materials, and reimburse the Commission with the funds received. On 8 June 2022, the Commission received an update from CureVac confirming that the company (with the Commission's prior agreement) has shipped part of the material to research organizations free of charge (in agreement with the Commission), sold part of the material mainly to other industrial partners (a share of which will be reimbursed to the Commission) and disposed of obsolete material, as necessary. CureVac are continuing their efforts and will continue to update the Commission at regular intervals.

It should be noted that the Vaccines Strategy Communication of June 2020 was explicit about the fact that these upfront payments were at risk, saying: *“The unprecedented circumstances in which the EU finds itself requires a bold response. Though steps will be taken to mitigate the risk – for example, by investing in a portfolio of companies covering different technologies - the failure rate of vaccine development is high. There is a very real risk that none of the supported candidates will be successful. However, the value of earlier access to a vaccine is enormous, in terms of lives saved and economic damage avoided. This makes the risk worth taking.*

This proposed framework is therefore an insurance policy, which transfers some of the risk from industry to the public authorities in return for assuring Member States equitable and affordable access to a vaccine, should one become available.”

10. - We note that the budget implementation of the Emergency Support Instrument (ESI) was handed over to the European Health and Emergency Preparedness and Response Authority (HERA) from 1 January 2022. The preparations for the handover were made in 2021. How did the handover take effect? Were risks assessed and mitigated? Were control procedures and staff transferred? Could you give us an impression of the activities you deployed in that regard?

Commission's answer:

HERA is responsible for budget implementation of the part of the Emergency Support Instrument (ESI) that concerns vaccines procurement. However, the ESI has expired on 31 January 2022. No ESI funds have been used for vaccines procurement since HERA took responsibility for the ESI budget. Budget implementation in this case therefore relates to funds already spent. Several staff members have been transferred from DG SANTE and other Commission services to HERA under the Memorandum of Understanding between HERA and DG SANTE, DG SANTE continues to support HERA closely on all questions of budget monitoring, while HERA is setting up its own internal control system (please see below).

¹¹ As regards the raw materials, neither the Commission nor the Member States were in a position to take ownership, store, and subsequently use them.

Questions concerning vaccines

11. In particular, how do you explain how many doses of Covid vaccines purchased in excess have expired and can no longer be used in the meantime, but are Member States obliged to continue paying them? Moreover, vaccine manufacturers are preparing to produce and bring to the internal market updated vaccines to the new variants of SARSCoV-2. On the basis of which analysis will the number of doses of vaccines to be purchased be decided? On the basis of which analysis will be set the price and efficiency of doses of new vaccines?

Commission's answer:

Vaccines are being supplied to Member States now on the basis of contracts signed in 2021, and under the terms and conditions (including price) that were agreed at that time. The volumes which were contracted for in 2021 were decided in the Vaccines Steering Board on the basis of Member States' collective assessment of the volumes they wished to ensure access to in the future.

Volumes ordered reflect Member States' wish to ensure sufficient access to these strategically vital products to deal with a highly uncertain epidemiological situation.

The current vaccines have a specific shelf life, which is set by the European Medicines Agency (EMA) in function of the particular characteristics of each vaccine. The maintenance of a certain level of strategic stockpiles in Member States is needed to ensure readiness for various epidemiological scenarios. This is akin to an insurance. This also means that some doses regrettably expire before they can be administered in Europe or globally. We are expending every effort to minimise the risk that stockpiles become unusable by working with manufacturers, global partners, and third countries. The management of stockpiles of expired doses is handled according to the norms applicable for medicinal products.

12. Considering that we have learned lessons from the past pandemic, are we prepared with stocks of medicines and treatment to intervene in patients who will have serious forms of Covid, but also for the possible side effects of the vaccine? What preventive measures do you see in order to ensure that new vaccines do not create adverse effects that would require additional budgetary expenditure and put life at risk? I would like for concrete answers from Commission as European citizens are waiting for more time.

Commission's answer:

With a few exceptions – notably COVID-19 vaccines and a limited number of therapeutics procured under the Joint Procurement Agreement - the purchase and deployment of medicines is a matter for Member States. The Commission can support Member States in purchasing medicinal products via additional Joint Procurement frameworks, if requested to do so by Member States.

The safety and efficacy of vaccines is ensured by the EU's robust and thorough regulatory system.

13. Vaccination remains important. What initiatives have been taken to encourage Europeans to be vaccinated excluding Covid vaccines?

Commission's answer:

Vaccination is a national competence, but the Commission supports EU Member States in reaching or maintaining high vaccination coverage rates in a life-course perspective. Our work on vaccination has since 2018 been guided by the Council Recommendation on vaccine-preventable diseases which calls for a large number of actions to be implemented by the Commission, EU Member States and stakeholders. The aim is to increase the uptake of vaccination across Europe, including by addressing vaccine hesitancy through the dissemination of reliable information and addressing false or misleading narratives. A roadmap was developed to support the implementation of those actions, and this roadmap is coming to an end by the end of this year. One key deliverable is the European Vaccination Information Portal, which provides objective and up-to-date evidence on vaccines and vaccinations, as well as the European Medicines Agency mechanisms in place to ensure that available vaccines conform to the highest standards of safety and effectiveness. A Joint Action on Vaccination, which officially ended in March this year, also contributed to the implementation of those actions.

Our next step is vaccination-related projects under EU4Health, including a project seeking to address physical obstacles to vaccination, and building on lessons learned during the COVID-19 pandemic. Several communication projects on the benefits of vaccination are also included, for example cartoons for young people, an e-course for teachers and promotion of material on social media. An influencer campaign on HPV is planned for January 2023. There are also vaccination-related projects under the Europe's Beating Cancer Plan. The Commission will, in particular, present a proposal for a Council Recommendation on vaccine-preventable cancers to help increase the uptake of vaccination against Human papillomaviruses and Hepatitis B virus across Europe.

14. Could the Commission explain how does it verify that COVID-19 vaccine manufacturers comply with the terms of advance purchase agreements, in particular as regards production cost estimates, the use of upfront financing and, where applicable, and no-profit clauses? Are there any corrective actions undertaken following such verifications? How were purchase prices set?

Commission's answer:

The Advance Purchase Agreements impose a reporting obligation on the vaccine manufacturers, in particular, but not limited to, on the use of the upfront payments. Progress reports were verified against the utilisation forecast of these payments, which were provided by the manufacturer and annexed to the agreement.

The Commission contributed to financing of the costs of COVID-19 vaccine development in the form of an up-front payment in order to de-risk the necessary investments and to increase the speed of vaccine research and clinical trials. The majority of the companies with whom the Advance Purchase Agreements were signed were able to successfully develop a vaccine and make doses available to deliver to the Member States. In cases where this did not occur, the contracts set out the corrective action to be taken – for an example, see the answer to question 9 above.

Moreover, without prejudice to the OLAF's competence to conduct inspections and investigations, the Advance Purchase Agreements and Purchase Agreements enable the Commission to request or perform audits on the implementation of these agreements until 5 years after the final payment. Should these audits reveal irregularities in the use of the down-payment, corrective action would be possible.

Purchase prices were only one of a number of elements of each contract that had to be negotiated with the manufacturer.

Additional questions

15. We have just learned from Curevac that the firm received 450 mln euros as the EU down payment in December 2020. Since Curevac abandoned development of its candidate vaccine, it provided to the Commission with a detailed breakdown on how the EU advance payment was used. Part of the payment was paid back to the Commission, and therefore to the European budget. Can DG SANTE provide to the committee the detailed breakdown of the amounts / advances paid by the Union to each of the seven pharmaceutical companies to pre-finance the supply of COVID vaccines for the EU under the APA contracts?

Commission's answer:

Due to its confidentiality obligations, the Commission is currently not in a position to publish this information. The Commission will make this information available to the European Parliament's Committee on Budgetary Control (CONT) in a secure way.

16. Did the contracted companies actually use the resources as expected and intended? What means of control or verification are at the COMM disposal and how they were used?

Commission's answer:

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Without prejudice to the OLAF's competence to conduct inspections and investigations, the Advance Purchase Agreements and Purchase Agreements enable the Commission to request or perform audits on the implementation of these agreements until 5 years after the final payment. Should these audits reveal irregularities in the use of the down-payment, corrective action would be possible. The Commission intends to carry out verifications on the implementation of the agreements, based on a risk assessment that will take into account whether the manufacturer obtained a conditional marketing authorisation for its COVID-19 vaccine and was able to deliver it to the Member States, and on whether Union budget was used for the upfront financing. The checks will take place in due course given the ongoing pandemic. First results can be expected by late 2024 and actual completion by December 2025.

17. Related to the point above, did the contracted companies actually use the resources to increase their production capacities? In the affirmative to which extent and how is it measurable (e.g. : new production sites, new recruitment, new machinery, outsourcing of production steps, etc);

Commission's answer:

The pre-financing provided in accordance with the Advanced Purchase Agreements aimed at – inter alia – supporting the ramp-up of the production. However, the increase in production capacity not only resulted from companies and EU's investments, but also from the activation and expansion of production sites, sufficient supplies of critical ingredients and materials, strong international partnerships and close collaboration between the Commission and industry.

As of its setup in February 2021, the European Commission's Task Force on industrial scale-up of COVID-19 vaccines had exchanges with manufacturers and suppliers in support of expanding the production of these vaccines in the EU and addressing bottlenecks in the supply chain (around 150 bottlenecks identified between February and June 2021). Since May 2021, in view of the conclusion of advanced purchase agreement between manufacturers and the Commission, the Task Force assessed the production capacities and supply chain of manufacturers, including with on-site visits, notably to ensure manufacturers were able to deliver on their commitments.

The Advance Purchase Agreements include provisions for the Commission to carry out on-the-spot checks and inspections until five years after the final payment. The Commission intends to carry out verifications based on a risk assessment that will take into account whether the manufacturer obtained a conditional marketing authorisation for its COVID-19 vaccine and was able to deliver it to the Member States as well as whether Union budget was used for the upfront financing. The checks will take place in due course given the ongoing pandemic. First results can be expected by late 2024 and actual completion by December 2025.

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reports were verified against the utilisation forecast of these payments, which were provided by the manufacturer and annexed to the agreement.

18. According the ECA special report 19/2022, all essential elements of the vaccine Advance Purchase Agreements were agreed upon during preliminary negotiations with the manufacturers (i.e. price, dose volumes, liability and indemnification, delivery schedule..). But, the EU negotiating team was not involved in the preliminary negotiations of the biggest contract that the EU has concluded so far (1.8 billion doses and 35 billion euros). According to ECA, the result of these negotiations (done by the president of the COMM) was indeed presented to the Steering Committee on 9 April 2021 and that the EU Member states have accepted it. Can the DG SANTE confirm to the committee that the dose price increase (from 15.5 to 19.5 euros) has been explained and justified to the Member States? Why the price per dose increased so much (by 26%) for such a big contract (1.8ml doses), instead of lowering it?"

Commission's answer:

There is a clear and transparent process in place that has applied in all negotiations. The EU Vaccine Strategy is a joint strategy: all contracts with vaccine developers have been negotiated jointly by the Commission and the Member States, considering vaccine needs of all EU countries. The negotiations were all done by a negotiation team consisting of representatives of the Commission and of several Member States. This team reported on a regular basis to a Steering Board, consisting of representatives of the Commission and all Member States. The role of the Steering Board was to set the mandate for the negotiators, identify the needs and steer the negotiations. Before each vaccine contract was concluded, it was submitted to the steering board. Member States were given the opportunity to opt out from the contract. So, all Member States are fully aware of and have negotiated all contractual terms and conditions, including on deliveries, with the companies.

Concerning the price, each contract must be seen in its entirety. It should be noted that the contract in question gave Member States considerable flexibility, including the possibility to order adapted vaccines along with priority access for those adapted vaccines.
