2020 Discharge to the Commission

WRITTEN QUESTIONS TO COMMISSIONER KYRIAKIDES

Hearing on 8 November 2021

Questions concerning general issues in the field of health

1. What is your first assessment of the pharmaceutical strategy for Europe launched in 2020?

Innovation, availability, access and affordability of medicinal products are topics that have been high on the political agenda for quite some years now. The Pharmaceutical Strategy, published in 2020, aims to ensure that citizens always have at their disposal safe and affordable medicines independently of where they live.

The Commission is tackling better availability of the right medicines through different initiatives:

- The Commission is finalising a study on the causes of shortages and potential solutions, and is also examining how to ensure the security of supply in the long term, via a structured dialogue.
- The strategy aims to support the development of new and innovative products to treat diseases for which there is still no treatment or no satisfactory treatment available.
- The planned revision of the European pharmaceutical legislation will examine ways to support innovation and products that target 'unmet medical needs'. The areas of antimicrobials is an example where there is a market failure but EU-level action can help.
- The Commission is working to ensure that children and patients suffering from rare diseases can get an appropriate treatment.
- The Commission is working with regulators and stakeholders, but also seeks the views of European citizens. Citizens are invited to respond to the open public consultation on the revision of the pharmaceutical legislation until 21 December 2021.

The first year of the strategy's implementation has already delivered on important flagships actions such as an agreement on the Health Technology Assessment Regulation and the establishment of the Health Emergency Preparedness and Response Authority (HERA).

The Pharmaceutical Strategy also aims to ensure a skilled workforce in the private and public sectors.

- NextGenerationEU and the Skills Agenda for Europe can help upskilling and reskilling in the EU.
- In preparation of the possible establishment of a skills partnership in health/pharmaceutical sectors under the Pact for Skills, a high-level roundtable with Commissioners Schmit and Breton was held on 18 February 2021.
- A pilot project on re/up skilling of the European Medicines Regulatory network is also under consideration.

Other deliverables are also advancing, including the structured dialogue on the vulnerabilities of the global supply chain which is close to completion.

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

The COVID-19 pandemic has challenged the continuity of routine vaccination programmes. In Europe, the impact is more limited, but even minor disruptions/delays will lead to an accumulation of susceptible individuals, and this can in turn lead to outbreaks of vaccine-preventable diseases.

The COVID-19 pandemic – and the new vaccines developed and rolled out in record time – has highlighted the importance of vaccination, not only against COVID-19, but in general. All the life-saving vaccines at our disposal are important, and we need to make use of the momentum created by the health crisis to pass on this message.

European countries are already doing a lot. Some send out reminder letters for childhood vaccines, some administer HPV vaccines in schools, many are organising large seasonal influenza vaccination campaigns.

The Council Recommendation on strengthened cooperation against vaccine-preventable diseases from 2018 is guiding the Commission's efforts in the field of vaccination. It calls for a large number of actions to be implemented by the Commission together with Member States, international organisations and other stakeholders.

Examples of actions are: the Global Vaccination Summit (2019), a feasibility study for an EU citizens' vaccination card, a Coalition for Vaccination bringing together European health professionals' and students' associations to advocate for vaccination.

As part of the EU4Health Programme, the Commission is currently setting up an EU Immunisation Initiative, building on the efforts on vaccination so far and taking the experience from the COVID-19 pandemic into account.

The Commission will focus on, for example, physical, practical and administrative obstacles to vaccination, stronger national decision-making on vaccination plans as well as myths, trends and misinformation on vaccination.

Both structural barriers to vaccination and mis- and disinformation can lead to vaccine hesitancy, and the COVID-19 pandemic has shown us how important it is to deal with this.

It is also important to have a comprehensive approach to vaccination as all the vaccines at our disposal are key public health tools.

3. The EU strategy included funding research on vaccine hesitancy as well as fighting disinformation, which could harm the success of mass immunisation campaigns. Could you give us some specific details concerning the results achieved in this area?

The Commission is aware that all the efforts in developing and deploying COVID-19 vaccines would remain vain if our citizens are not convinced of the benefits of vaccination. This is why the Commission is supporting research into vaccine-hesitant attitudes and the lack of trust in vaccines, which are driven by many factors, including misinformation. Three large consortia VAX-TRUST, JITSUVAX and RIVER-EU, supported by Horizon 2020[1] with a total EU contribution over EUR 9 million, are developing and testing interventions that should aid healthcare professionals and policy makers to improve vaccination uptake in the population.

One of the early outputs is the online COVID vaccines communication handbook and wiki[2]. This handbook, prepared by members of JITSUVAX[3] in collaboration with the World Health Organization (WHO) and other stakeholders and translated in 10 languages, tracks behavioural science evidence and provides advices about COVID-19 vaccine uptake, highlighting how the vaccines are overwhelmingly safe and effective. JITSUVAX has also produced a report on the analysis and classification of anti-vaccination arguments, mostly linked to the abundance of misinformation found online. This report will be used for the development of specific interventions to tackle misinformation.

In addition to these projects working on vaccine hesitancy, various projects funded under Horizon 2020 COVID-19 calls for expressions of interest and other calls for proposals include social and behavioural studies. These include the RECOVER project, which in December 2020 conducted a public survey to estimate self-reported COVID-19 vaccine acceptance in seven European countries, thereby identifying factors associated with vaccine acceptance and hesitancy. The PERISCOPE project has been working on understanding and promoting different communication strategies for promoting COVID-19 vaccine uptake. The COVINFORM project has been carrying out research to understand the impact of the COVID-responses on vulnerable and marginalised groups. Outputs include a series of bi-monthly reports on history and

1 Funded projects in the fight against disinformation | European Commission (europa.eu)
2 https://hackmd.io/@scibehC19vax/home
3 https://jitsuvax.notion.site/jitsuvax/JITSUVAX-97638f0709a249f18de1f3e036526600

facts of COVID-19 vaccines[4] ; infographics and best practices[5]; lessons learnt [6]; government responses[7] as well as a Whitepaper on "Inclusive Communication in times of crisis"[8].

On 15 October 2021, the European Centre for Disease Prevention and Control (ECDC) published the report "Facilitating COVID-19 vaccination acceptance and uptake in the EU/EEA" which aims to further support Member States in identifying barriers to the uptake of COVID-19 vaccination, and designing and implementing interventions aimed at increasing vaccination coverage[9].

The Commission has been monitoring vaccine confidence on a bi-annual basis since 2018, as a follow up to the Council Recommendation on strengthened cooperation against vaccine-preventable diseases. The 2020 report gives an insight into vaccine confidence at the start of the COVID-19 pandemic when reported confidence in vaccination was high, both among the public and healthcare professionals. The State of Vaccine Confidence in the EU report[10] also revealed that countries can undergo significant changes in vaccine confidence in short periods of time, highlighting the importance of continuous monitoring of vaccine confidence to allow rapid responses to address waning confidence and mitigate damaging effects on vaccination uptake. The 2022 edition of this project will offer further insights into how vaccine confidence has been affected by the pandemic and the impact of COVID-19 vaccination on broader confidence.

Eurobarometer surveys – along with external polls – have provided key insights into the motivations for vaccine hesitancy and these results have been taken into account in developing messaging.

In May 2021, a Flash Eurobarometer public opinion survey was conducted in the EU 27 Member States about attitudes on vaccination against COVID-19[11]. It showed that 69% were either already vaccinated, or eager to be vaccinated as soon as possible and 79% intended to get vaccinated sometime this year.

Those respondents reluctant to get vaccinated against COVID-19 soon mostly mentioned two reasons as either very or rather important: the belief that COVID-19 vaccines have not yet been sufficiently tested (85%) and worries about the side effects

4 https://www.covinform.eu/wp-content/uploads/sites/39/2021/01/COVINFORM-Bi-Monthly-Report-01-A4-1.0.pdf
5 https://www.covinform.eu/wp-content/uploads/sites/39/2021/03/COVINFORM-Brochure-A4-Bi-Monthly-Report-2.pdf
6 https://www.covinform.eu/wp-content/uploads/sites/39/2021/06/COVINFORM-Brochure-A4-Bi-Monthly-Report-3.pdf
7 https://www.covinform.eu/wp-content/uploads/sites/39/2021/07/COVINFORM-Brochure-A4-Bi-Monthly-Report-4-1.0.pdf
8 https://www.covinform.eu/wp-content/uploads/sites/39/2021/09/COVINFORM-Press-Release-3-Inclusive-communication-in-times-of-crisis.pdf
9 https://www.ecdc.europa.eu/en/news-events/covid-19-increase-vaccination-acceptance-and-uptake
10 State of Vaccine Confidence in the EU and the UK (2020) | Public Health (europa.eu)
11 Flash Eurobarometer 494 "Attitudes on vaccination against Covid-19". 26,106 interviews were conducted online between 21 and 26 May 2021.
Attitudes on vaccination against Covid-19 - June 2021 - Eurobarometer survey (europa.eu)

of the COVID-19 vaccines (82%). Other reasons listed in the survey for not getting vaccinated soon were much less frequently seen as important. Six in ten answered that an important reason was concerns about the effectiveness of the COVID-19 vaccines and the same percentage (60%) mention that the risks posed by COVID-19 in general were exaggerated. About half of the relevant respondents mentioned as an important reason that they thought their personal risk of being infected was very low or inexistent (52%) or they thought the COVID-19 pandemic would be over soon (49%). The reason respondents indicated least often as important was that they were against vaccines in general, with 40% of those who do not want to get vaccinated soon indicating this as a very or rather important reason.

Previously, questions about attitudes to vaccines and vaccination were also included in the Standard Eurobarometer survey 94 of winter 2020-2021[12] and in a desk research study including an online survey on "Public opinion about vaccination in the EU", conducted in December 2020[13]. In addition, our extensive media and social media monitoring and analysis – both day-to-day and linked to key political moments – has focused on identifying media reporting and opinion trends on vaccination issues, providing a complementary source of information on broad public opinion.

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

The Commission is currently working on the impact assessment of the European Health Data Space (EHDS), and the legislative proposal will be adopted in early 2022.

The study on the implementation of the General Data Protection Regulation (GDPR) rules in the context of health data was published early in 2021, and there are other studies ongoing that are supporting the impact assessment. The results of the open public consultation are expected to be published this autumn. The current assessment work includes evaluating the functioning of the eHealth Network, established under the Cross-Border Healthcare Directive (2011/24/EU).

The aim of the proposal on the European Health Data Space is to strengthen the exchange of health data for both primary and secondary uses of health data to harness data in direct care, support citizens' control over and access to their health data and to promote data-driven innovation in the EU's single market.

12 Eurobarometer 94 – winter 2020-2021 (europa.eu)

13 covid-19_vaccination_in_the_eu_desk_research_eurobarometer.pdf (europa.eu)

5. What are the initiatives which have been taken to facilitate and develop cross border healthcare?

In response to the COVID-19 pandemic the Commission produced guidelines on EU emergency assistance on cross-border cooperation in healthcare and adopted the EUR 3 billion Emergency Support Instrument (ESI) to support the cross-border transfer of medical equipment, medical teams and patients.

The Commission is carrying out an evaluation to assess how well Directive 2011/24/EU on patient rights in cross-border healthcare has performed, a decade after its adoption in 2011. The evaluation draws on a stakeholder consultation to assess remaining barriers for EU citizens to access cross-border healthcare. It also looks how effectively the European Reference Networks for rare and complex diseases are working to help improve the diagnosis and treatment of rare disease patients. The Commission's report on the operation of the Directive together with the evaluation will be published in April 2022.

Under the ESI, the Commission was entrusted with the implementation of the 'Mobility Package', which will soon close as the ESI activation for COVID-19 will end in January 2022. In total, more than 1000 flights and 500 operations on land or sea for transport of medical equipment and teams and the transfer of patients have been supported. Overall, cargo operations have been financed with more than EUR 164 million, and approximately EUR 3.2 million has also been awarded to Member States for the transport of medical teams and transfer of patients, supporting the transport of 293 medical workers and 35 patients. The above figures include the EUR 14.6 million that was recently granted to six Member States following the invitation launched on 5 May 2021 for EU Member States to apply for support for the transport of cargo of COVID-19 vaccination-related equipment and COVID-19 therapeutics. This invitation was launched in response to ongoing disruptions in the global transport market. This brings the number of Member States having benefitted from the ESI Mobility Package up to 20 plus the UK.

The application period for grants for the transfer of medical patients, and transport of medical personnel and teams as well as operational support for mobile medical response capacities was closed on 15 October 2021. Support to Member States was available for the cargo transport of COVID-19 vaccination-related equipment and COVID-19 therapeutics, and medical teams via the use of the Commission's transport broker until 1 November 2021.

After the end of the ESI Mobility Package, the Union Civil Protection Mechanism (UCPM) will continue to be the relevant framework to continue supporting Member States in their operational response to the COVID-19 pandemic.

Furthermore, the healthcare sector is supported by the European Regional Development Fund (ERDF) under the INTERREG programme. As a result, there is a better understanding of cross-border health services, their added value (for example,

by offering facilitated access to cross-border health services in the proximity of the patients) and the recurring problems they face (often linked to reimbursement of treatment costs).

For the 2021-2027 period, cooperation programmes will benefit of a total EU contribution of about EUR 8 billion (out of which EUR 5.8 billion for cross-border cooperation in border areas). Besides investments under Policy Objective for "More social Europe" (including cross-border healthcare), a specific INTERREG objective will support framework conditions to achieve better cooperation governance. In addition, the Commission's innovative scheme "B-solutions" provides legal support to public authorities in border regions to explore potential solutions to border obstacles. "B-solutions" has resolved 90 cases of border obstacles, including in the health sector, in 27 regions in 21 Member States.

The EU4Health work programme for 2021 has adopted several actions to facilitate and develop cross-border health care.

- An action for Member States authorities to support capacity building at national and Union level, using data analytics, artificial intelligence and electronic health data at Union level for real time surveillance. This action will support Union and national surveillance systems to ensure that they are integrated, which is essential to ensure a rapid response to cross-border health threats. (EUR 7 million).
- An action to contribute to the goals of the EU Action Plan on antimicrobial resistance and to support the coordination of measures to combat serious cross-border threats to health as well as to raise awareness on the citizens' use of antibiotics (EUR 1.5 million).
- Actions on intelligence gathering to develop a common methodology and protocol for intelligence gathering and analysis for serious cross-border threats to health and relevant medical countermeasures, which could ultimately be used by HERA. These actions will also support global surveillance by analysing the global nature of emerging serious cross-border threats to health (EUR 13 million).
- Actions to fund European Reference Networks in the field of rare or low prevalence complex diseases and specifically on rare urogenital conditions. This action will help in pooling knowledge, expertise and resources for the benefit of Union's patients suffering from rare urogenital diseases and their health professionals (EUR 0.2 million).
- Action for efficient cross-border reuse of data in the context of a digital infrastructure for the secondary use of health data (EUR 5 million).
- Action for a new service to increase the type of health data being exchanged across borders and add value to the continuity of care. It will facilitate cross-border healthcare and contribute to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare (EUR 11 million).

6. The access to innovative medicines and in general health care is still very different among Member States. What are the Commission's steps in order to reduce these differences, especially in the context of proposals for building a European Health Union?

The objective of the European Health Union is to better protect health of citizens, especially during crises. The current pandemic shows more than ever that this objective cannot be achieved without resilient health systems and this is why the European Health Union promotes stronger health systems. Accessibility is one of the key characteristics of a resilient health system.

Healthcare is part of the priorities of the EU social agenda translated into the European Pillar of Social Rights and more specifically into Principle 16 on access to healthcare. The commitment to improve social standards in Europe was renewed in the European Pillar of Social Rights Action Plan adopted on 3 March 2021. The Action Plan stresses the importance of the European Health Union in building more accessible health systems, while leaving no one behind. It commits to improve data and evidence on the problems experienced by groups who may be excluded from access to healthcare or face particular hurdles in accessing health services.

On 14 April 2021, the Expert Group on Health Systems Performance Assessment published a report on improving access to healthcare through more powerful measurement tools. The report explores tools which better capture the experience of patients in accessing certain health services and how to measure the underlying reasons of problems in accessing healthcare. To encourage Member States to develop better metrics and use it for designing more targeted policies, the Commission will provide further support via the EU4Health work programme.

The Commission promotes access to healthcare and universal health coverage via the European Semester. Past experience shows that Country Specific Recommendations in this area trigger positive policy feedback, resulting in reforms expanding the scope of healthcare coverage, reducing out-of-pocket payments and mobilising solutions to provide services in areas with less health services (medical deserts).

In 2020 all the Member States received Country Specific Recommendations in the health area and many of them called for improvements in accessibility. The Recovery and Resilience Facility also provides support to improve access to healthcare as part of resilient health systems. Many of the national Recovery and Resilience Plans include investments which aim to increase access via for example, expansion of healthcare services and infrastructure and alternative ways of accessing services, in particular through telemedicine.

Availability and access to medicines is key priority for the Commission. Everyone, independently of which country she or he lives in, should be able to have access to the

same treatments at the same time. To address inequalities,, the Commission will propose concrete actions to improve patients' access to medicines, for example by:

- Revising the pharmaceutical legislation to better link certain incentives for innovation with obligations for companies to market medicines faster and in more Member States;
- Engaging with companies that develop medicines for cancer and rare diseases to discuss with them proactively their plans to launch their products in different Member States; this with the aim to close the existing access gap between Member States.
- Improving access to generic and biosimilar medicines by reviewing the legislation to remove barriers that delay their timely entry to market and better promote competition with such products.

7. Same question for drugs of major therapeutic interest: Although they are widely consumed, they are not very profitable and are therefore very often out of stock due to the lack of interest shown by private laboratories, how Commission intends to raise the production in Europe?

The impact of shortages of medicines can be very severe on patients. Addressing shortages is one of the key objectives of the EU Pharmaceutical Strategy and the Commission is working to better understand the reasons behind them so that effective solutions can be proposed in the revision of the EU pharmaceutical legislation. The issue of security of supply will be also taken into account in the revision of the legislation. In this context, the Commission will assess to what extent the EU needs to build critical and strategic manufacturing capacities.

The Commission is looking also beyond current shortages, reflecting how to ensure the security of supply in the long term, through a structured dialogue.

This initiative brings together representatives of industry, patients, health professionals, Member States and academia to better understand the situation of the pharmaceutical supply chains and what are the main vulnerabilities and what causes them. Based on this understanding, the Commission will propose policy options to be considered to enhance the security of supply.

Last but not least, the Commission proposed to reinforce the role of the European Medicines Agency to enable better monitoring of critical medicines. The co-legislators reached the political agreement on the Commission's proposal on 28 October.

8. The Treaty on the Functioning of the European Union assigns relatively limited responsibilities to the EU for public health, which remains primarily a Member State competence. The legal framework gives the EU a supporting and coordinating role. The scale and speed of the required response to the pandemic was a challenge for all public

authorities. It was a challenge for the EU to rapidly complement the measures taken within its formal remit, by additional actions to support the public health response to the crisis. What lessons do these experiences provide for any future reform of the EU's competences in this field?

The Commission is coordinating a common European response to the pandemic, taking resolute action to reinforce our public health sector and mitigate the socio-economic impact in the European Union. Moreover, the Commission is mobilising all means at its disposal to help Member States coordinate their national responses and is providing information about the spread of the virus and effective efforts to contain it.

However, public health matters, which include the organisation of and the delivery of healthcare services, are the competence of EU Member States. Therefore, national governments decide on the specific measures to be implemented based on each country's national epidemiological and social situation.

Nevertheless, based on lessons learned from COVID-19, on 11 November 2020, the Commission put forward a set of proposals for building a European Health Union that looks to strengthen the EU's health security framework and reinforce the crisis preparedness and response role of key EU agencies: the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). The Commission has also established the Health Emergency Preparedness and Response Authority (HERA), to strengthen preparedness and crisis responsiveness at EU level.

The foundations of the European Health Union are within the boundaries of the current Treaty, and the proposed measures fully respect the responsibilities of the Member States for their public health policy and for the organisation and delivery of health services and medical care. By working with the European Parliament and the Council towards a stronger Health Union, the EU can be better equipped to prevent, prepare for and manage health crises, with all the societal and economic benefits that this would bring.

A reflection on further Treaty changes to provide the EU with a stronger competence in the area of health appears necessary and should take place in the context of the Conference on the Future of Europe.

9. What is the Commission's experience regarding the role, mandate and functioning of the Health Security Committee? Is the Committee adequately designed to support exchanges of information between Member States and the Commission, and coordinating national preparedness and response planning?

The Health Security Committee was established under Decision 1082/2013/EU on serious cross-border threats to health. It has been a key committee during the COVID-19 pandemic, with weekly discussion on the most relevant topics.

The Committee is mandated to reinforce the coordination and sharing of best practices and information on national preparedness activities.

Member States also consult each other within the Committee with a view to coordinating national responses to serious cross-border threats to health, including events declared a public health emergency of international concern by World Health Organisation in accordance with the International Health Regulations.

The Committee further deliberates on communication messages to healthcare professionals and the public in order to provide consistent and coherent information adapted to Member States' needs and circumstances.

The Committee used to meet every six months before the start of the pandemic. Since the initial phase of the COVID-19 crisis, weekly Health Security Committee meetings are taking place.

In the proposal for a new cross-border health threats Regulation, the Commission suggests strengthening the Health Security Committee. The text is in the negotiation process with the co-legislators. The Commission proposed to give the Health Security Committee a two-tier structure: one at a more high-level and one at technical/expert level. It also proposed that the Health Security Committee can issue opinions and guidelines.

10. The Commission’s clearing house for medical equipment (CCH) started operating on 1 April 2020 for a period of six months. It served as a platform for dialogue and information sharing with Member States’ representatives on the demand and supply of medical equipment at EU level and on the means to overcome shortages and build capacity. What were the most important achievements of the CCH?

The COVID-19 Clearing House for medical equipment was created by the Commission on 1 April 2020 for a period of six months. It aimed at facilitating the swift delivery of the medical supplies needed to fight the virus and overcome the public health crisis in the European Union.

Its missions and tasks ranged from gaining an overview of the demand for the most critically needed medical equipment in Member States to facilitating the matching of supply and demand of medical equipment at EU level. It also included supporting Member States, companies or other stakeholders in addressing technical/regulatory obstacles and bottlenecks in the supply chain; contributing to prioritisation under the Emergency Support Instrument; monitoring imports and export restrictions by third countries; and facilitation of best practice exchanges among Member States.

The House was organised in five product-related clusters based on the WHO COVID-19 disease commodity package: Personal Protective Equipment (PPE);

ventilators; other medical devices and hospital supplies; tests and testing materials (kits, reagents, hardware); and therapeutics and vaccines.

Main outputs included:

- Development of a set of tools (surveys, workshops etc.) to improve the knowledge of aggregated needs for crucial material at EU level, including a warning list regarding expected shortages in the short- and medium-term.
- Identification and – where possible – unblocking of bottle necks in the supply chain, such as spare parts for ventilators, supply of gloves and masks, disinfectants through dialogue with industry (globally) and Member States.
- Establishment of a database where Member States and industry could present their demand and supply for health-related material.
- Continuous dialogue with all stakeholders (governments, industry, health professionals etc.) to identify upcoming needs and possible bottlenecks, including in the relevant training of staff. Regulatory advice to Member States and companies.
- Preparatory work for actions under the Emergency Support Instrument (ESI).
- Preparatory work for the creation of the Health Emergency Preparedness and Response Authority (HERA), notably regarding demand analysis, supply assessment, gap identification and building of scenarios to help Member States anticipating demand.

Questions concerning COVID-19

11. What are the measures and the controls taken in the frame of the fight against fraud and misuses linked to the pandemic?

During the crisis, the Commission's Internal Control Framework remained fully applicable. Measures to prevent and detect fraud are part of this framework. It constitutes an important safeguard for the Commission's operations also in the context of the pandemic.

Early on, extensive guidance has been provided by the Commission's Central Financial Services to the Authorising Officers by Delegation on the effects of the pandemic on the implementation of the EU spending programmes. The use of flexibility introduced in March 2020, e.g. in terms of extension of deadlines for submission of tenders or proposals or simplified financial circuits, was discussed with central services at the level of Directors-General.

On-the-spot audits were replaced by remote audits, be it for ex-ante or ex-post financial control or for the implementation and enforcement of EU legislation on food and feed safety, animal health, animal welfare, plant health and in certain areas of human health protection. This included more risk-based audits and a review of the audit schedules.

During the summer 2020, a specific corporate risk exercise took place to assess the risks deriving from the COVID-19 crisis on the implementation of the EU budget. OLAF participated in this exercise and shared its insights into increased fraud risks, new fraud schemes and vulnerable areas.

The result of this risk assessment was shared with the European Court of Auditors and the discharge authority and led to the conclusion that the measures in place provided the necessary assurance in terms of legality and regularity of transactions.

Without qualifying the positive overall opinion of the Commission Internal Audit Service (IAS) for 2020, in an 'emphasis of matter' the internal auditor highlighted the challenges of implementing the EU budget in the context of the pandemic. In addition, he stressed the need for continuous monitoring and assessment of new risks and for the definition and implementation of corresponding mitigating measures. The challenges identified were, in particular, compliance with the applicable legal framework; the extent to which the necessary controls and verifications could be performed due to logistical constraints; and the potential impact on the Commission's corrective capacity. The IAS acknowledged that even before the summer of 2020, the Commission services assessed the risks deriving from the pandemic and related to the implementation of the EU budget, in terms both of compliance and performance, and adopted mitigating measures. The internal auditor stressed that the Commission services should continue to duly assess the financial management risks caused by the pandemic and define and implement adequate mitigating measures. The full text of the opinion can be found in Annex 8 of the Annual Management and Performance Report for the EU budget 2020[14].

12. The Covid-19 crisis has highlighted the shortcomings of the pharmaceutical production chain in Europe: today the continent is 80% dependent on China and India for the raw materials needed to develop medicines. Referring to the pharmaceutical strategy on 25 November 2020. Which incentives are envisaged to push manufacturers to produce vaccines in greater quantities?

One of the objectives of the revision of the pharmaceutical legislation is to make our framework future-proof, innovation friendly and adapted to progress and new possibilities. Bottlenecks and regulatory gaps hampering innovation and new breakthroughs should be avoided.

This means reducing administrative burden and adapting regulatory processes to take into account technological developments and streamlining procedures through digitalisation to reduce time and costs. This also implies having strong incentives where they are needed, most notably in areas with no treatment, for example for rare and paediatric cancers, neurodegenerative diseases, vaccines or antimicrobials.

[14] COM(2021) 301 final of 8.6.2021

The Commission will give incentives to industry, but will also expect accessibility to medicines to be improved, and for inequalities of access to disappear in the Union. The revision of the regulatory incentives (data and market protection) is a tool to make the EU pharmaceuticals system more attractive to innovation and balance the need for access but it cannot solve all problems.

International dependency may constitute a vulnerability, especially when there is no sufficient diversification of available supply sources. At the same time, the EU is one of the strongest regions in pharmaceutical manufacturing. There is need for a careful assessment of the situation in the supply chain, taking into account their globalised character and heterogeneity of the sector. The impact of any potential policy response must be carefully assessed.

As regards the high dependency on third countries on basic starting materials, solvents and reagents, there is a need to reflect how the EU could regain some technological capabilities through innovation, that would allow production in the EU in a sustainable way in order to diversify the supply chains, ensure greater global security of supply, and contribute to better crisis preparedness of the EU. The role of HERA is instrumental in this process.

13. Disinformation remains huge problem as well in the health sector, especially in relation to the Covid-19 crisis and now vaccination. Commission together with the High Representative already published a communication entitled "Tackling COVID-19 disinformation - Getting the facts right" in June 2020. What are the steps taken by DG SANTE in order to fight disinformation related to vaccines and vaccination, which still seems to be very prevalent especially in some Member States?

The Commission makes active efforts to address false and misleading information, both before and during the pandemic. This includes strong proactive messaging on the benefits of vaccination, monitoring and actively pre-bunking and debunking false or misleading narratives. The provision of reliable information is the reason for the development of European Vaccination Information Portal and the Coalition for Vaccination, comprised of healthcare professionals and student associations, following from the Council Recommendation on strengthened cooperation on vaccine preventable diseases.

The Commission has also focused on tackling misinformation and disinformation on COVID-19 related themes since the very first days of the crisis, in close collaboration with the European External Action Service and international organisations, such as WHO and NATO.

Specifically on COVID-19 vaccination, already in October 2020, the Commission's recommendation on the preparation of vaccination strategies drew attention to the need to enhance vaccine confidence through clear information campaigns.

The Commission has worked hand-in-hand with the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), as well as engaged with key stakeholders and influencers. This enabled the production and dissemination of video testimonials on the benefits of vaccination.

Since September 2021, the Commission has conducted mini communication campaigns in some Member States (Austria, Croatia, Czechia, Estonia, France, Germany, Poland and Slovakia), emphasising the role of the EU in the success of vaccination in the Union, i.e. the delivery of vaccines. The campaigns deliver positive messaging around vaccination, in particular emphasising the solidarity angle. In Romania and Bulgaria, the communication effort is focusing on ways to enhance the vaccination rate given the evolution of the pandemic in these countries. Campaigns have successfully run and concluded in Estonia, Slovakia and Croatia. The campaigns in Austria, Czechia, France and Germany have been launched recently.

Social media engagement:

Since January, the Commission has focused on an intensive social listening and engagement campaign. This includes proactive communication, monitoring of trends and false narratives, as well as replying to questions on all aspects of vaccines and vaccination, including external issues. It is clear that false or misleading information on social media can introduce doubt over the facts or play on existing doubt. Our policy is to engage constructively and empathetically. A

Community management:

The Commission puts in extra effort into engaging with users who comment about their own vaccination experience.

When monitoring performance and impact on the topic of vaccines, the Commission looked also at proactive communication, not only communication that aims at responding to disinformation.

The Commission's social media accounts regularly share information related to the EU's vaccination rates, the efforts towards global vaccination and fighting vaccine disinformation where it appears, as well as amplifying the "get vaccinated" message in countries where vaccination rates are still low.

In 2021, the Commission generated on social media more than 184 million impressions and more than 2 million interactions, 300 000 of which happened during these past three months.

In the week of 18-22 October 2021 alone, the Commission made 75 social media posts on vaccination topics (and 7 856 since the beginning of the year). Some recent highlights from the social media schedule include the "more than 75% of the EU adult population is now fully vaccinated against #COVID19" milestone, "one billion doses delivered worldwide", and a general reminder that vaccines work, as well as the potential challenges for a COVID-19/flu "twindemic".

Specific social media aspects:

The Commission has also produced extensive and varied social media products such as "Social media chats" and short Q&As. We have proactively communicated on vaccination numbers, with infographics and animations when milestones on numbers of delivered and administered vaccines have been reached.

Examples for social media chats:

- 23 Feb 2021, 5:30pm Instagram Chat LIVE on central account with Vice-President Vera Jourova on How do we fight against disinformation on vaccines.
- 24 March 2021 Instagram Chat LIVE with Dr. Peter Piot, virologist, on vaccines mutations
- 27 April 2021 Instagram Chat LIVE with vaccines advocate Silvia Romeo (Immunisation week)
- 28 April 2021 Instagram Chat LIVE with Commissioner Stella Kyriakides (Immunisation week)
- 29 April 2021 Twitter Chat with SANTE, EMA, ECDC
- Answers in 15 sec – Peter Piot
- 25 June 2021 Twitter Chat with EU doctors, nurses and pharmacists

The Commission's steering body for responding to disinformation, the 'internal Network against Disinformation' created a subgroup on vaccines and COVID-19 disinformation in December 2020. Since then it has engaged in continual monitoring of vaccine related narratives. The Network regularly convenes to discuss the reports from social media platforms within the context of the COVID-19 disinformation-monitoring programme and to work out strategies and lines to combat false or misleading narratives. This expertise is reflected in the weekly 'Fighting the Fallacies' internal report (launched in May 2021 at the request of President Von Der Leyen), which analyses thousands of articles by unverified sources and contributions from the Commission Representations and distils them into two or three trends for the week. The report also suggests counter narratives and strategies for community managers and communicators across the Commission.

Thanks to enhanced cooperation, the Commission has been able to better address misleading vaccine content. For example in October 2021, the services were able to combat a recent myth claiming that the Commission plans to phase out vaccinates in favour of therapeutics, by amending a misused press release and putting out positive communication messages on the necessity of vaccination. This was complimented by social media posts to clarify that developing COVID-19 treatments will not replace vaccines.

This new infrastructure has also allowed positive collaboration with agencies such as the European Medicines Agency and the European Centre for Disease Control and Prevention, in order to align messaging and to tackle key threats such as the misuse of the Eudravigilance platform that was picked up in the report monitoring.

14. There were differences related to the capacity of EU Member States to use Covid-19 vaccine doses assigned to them, resulting in disposal of unused vaccine doses. Does the Commission has the information how many doses were disposed in MS and if any actions were taken to avoid such waste, e.g. redistributing vaccines to other MS or third low-income countries? How many doses of vaccines did the EU make available globally through the COVAX platform? What was the average price?

The main action to avoid wasting vaccines is to ensure that Member States have the possibility to donate and resell the doses. To this end, specific clauses are included in both the Advance Purchase Agreements and the Purchase Agreements allowing for this process.

Team Europe is a lead contributor with over EUR 3 billion for the COVAX Facility to help secure access to fully donor-funded doses for 92 lower-income economies. To date (as of 15 October 2021), more than 365 million doses have been delivered by COVAX to 144 countries and territories.

Tri-partite agreements between manufacturers, COVAX-GAVI and one or several Member States are in place for the donation of doses to COVAX. This has allowed for more than 70 million doses of AstraZeneca vaccines to be donated to COVAX. More detailed and concrete information on the amount of doses that have been disposed by Member States.

To complement COVAX's efforts, the President of the Commission announced in the State of the Union address on 15 September 2021, that the Commission will add a donation of 200 million doses by mid-2022.

The EU Member States have also committed to share over 300 million doses, in particular through COVAX, as part of the EU sharing efforts. In total, we are working towards securing over 500 million doses for sharing by Team Europe by mid-2022.

The Commission continues to offer Member States a comprehensive support package – guidance, legal assistance, interface with COVAX, and policy coordination. The EU is also helping with transport and logistical support, including through the Union Civil Protection Mechanism to facilitate delivery of doses to our partners worldwide.

To date (as of 19 October) over 70 million vaccine doses have been donated (of which over 37 million were donated through COVAX).

15. There is an inherent conflict between speedy procurement and obtaining the lowest possible price when it comes to vaccine purchase agreements. How would you draw the balance regarding these two - sometimes conflicting - objectives?

The Commission's vaccine strategy has focused from the start on securing for EU citizens safe, effective and high quality vaccines, in a timely manner, at equitable conditions for all Member States.

When negotiating contracts with vaccines producers, the Commission takes into account a number of factors. The price per dose is one of them, together with several others, such as the technology used, the production capacity, the delivery schedule or the experience gained with previous deliveries.

The terms of the advance purchase agreements were negotiated in parallel with several vaccine manufacturers, with comparable prices in relation to the type of technology.

16. The COVID-19 pandemic led to a sudden and massive increase in demand for personal protective equipment – in particular face masks, hand sanitisers and testing kits. Demand came not only from the medical profession tasked with treating the virus but also from consumers wanting to keep themselves safe. Both were targeted by fraudsters, who saw major opportunities in what very quickly became a big business - as noted on page 66 of Volume II of the Commission's AMPR 2020. OLAF opened its investigation into this trade in fake and counterfeit goods on 19 March 2020 – right at the very start of the outbreak of the virus in Europe. OLAF also identified many opportunistic companies, trying to profit from the pandemic by moving into a new line of business, despite having no track record in the area and with little or no control over their supply chain. These companies are often easy targets for fraudsters, who create artificially long chains of intermediary shell companies that open and close quickly to hide their tracks – and which pass off fake and counterfeit products as the genuine article to unsuspecting clients. How is the Commission tackling these phenomena? Could you give us some details concerning cooperation with OLAF? The planned update of the current DG SANTE anti-fraud strategy and action plan (2017-2020) has been postponed to 2021 due to Covid-19 pandemic crisis. Could you elaborate at what stage DG SANTE currently is with its new anti-fraud strategy? When you expect it to be finalized?

European Commission's Anti-Fraud Office (OLAF) has been collecting intelligence and information on the trafficking of fake and substandard COVID-19 related products since the beginning of the pandemic. It provides customs authorities in the EU Member States and third countries with relevant information in real time. The products entered the EU by means of misdeclarations or fake certificates, black market sales, and smuggling.

So far, OLAF's investigation into counterfeit and substandard COVID-19-related material has led to the identification of some 1250 suspicious operators and to the seizure or detention of over 100 million items. These include, for example, units of hand sanitisers containing a high volume of methanol, substandard face masks, fake test kits.

In December 2020 and January 2021, OLAF organised jointly with the European Union Intellectual Property Office (EUIPO) and EUROPOL webinar discussions with representatives of pharmaceutical companies, right holders and law enforcement agencies and customs authorities from the EU and European Free Trade Association (EFTA) countries to raise awareness about possible fraud regarding vaccines.

OLAF has also warned governments and partners across the world against fake offers of COVID-19 vaccines.

During the Summer 2020, the Commission organised a specific corporate risk exercise to assess the risks deriving from the COVID-19 crisis on the implementation of the EU budget. OLAF participated in this exercise and shared its insights into increased fraud risks, new fraud schemes and vulnerable areas. New fraud risks were also discussed in the Fraud Prevention and Detection network and its subgroups in which Directorate General for Health and Food Safety (DG SANTE) participates actively.

In case of suspicions of fraud, DG SANTE and OLAF exchanged information on a day-to-day basis as fraud issues linked to the COVID-19 pandemic were a top priority.

An update of DG SANTE's anti-fraud strategy became necessary due to the significant changes in DG SANTE's control environment during the COVID-19 pandemic. Following the release of OLAF's methodology for services' anti-fraud strategies, in the second quarter 2021, DG SANTE carried out a fraud risk assessment to identify the new risks and fraud patterns that emerged in DG SANTE's new activities and new ways of working. In parallel, OLAF supported DG SANTE by organising a workshop on "Fraud prevention and detection", with special focus on procurement. Nearly 200 staff of DG SANTE participated.

Based on the fraud risk assessment, DG SANTE developed an anti-fraud action plan covering the years 2021 to 2024. It also reflects DG SANTE's responsibilities as spending DG under the action plan related to the Commission Anti-Fraud Strategy of 2019.

In October 2021, OLAF and a number of DGs peer reviewed DG SANTE's updated anti-fraud strategy and action plan. Having taken the results of the peer review into consideration, the anti-fraud strategy with its action plan (2021-2024) was submitted to DG SANTE's Management Board to be approved on 8 November 2021.

17. In January 2021, the ECA published a Review on 'The EU's initial response to COVID-19: learning lessons to improve European cooperation in public health'.
    - Did the Commission draw any lessons based on this review?
    - Were there any particular actions taken to address shortcomings identified by the review?

The review by the European Court of Auditors on the initial response to COVID-19 was very welcome. It gave a good snap shot of the situation in the first half of 2020

and highlighted some of the challenges faced by the EU in its support to Member States' public health response to the pandemic, i.e. the scale and speed of the required actions, the limited capacity of the Member States to absorb EU funds at the beginning of the pandemic, and the scarce market supply of Personal Protective Equipment.

The identified challenges were addressed largely by the set of proposals in November 2020 building the European Health Union. Key initiatives are to strengthen preparedness in the Member States, to build a more dynamic surveillance systems, to strengthen the European Centre for Disease Prevention and Control (ECDC), to improve data reporting of the Member States using health systems indicators, to strengthen the laboratory network, to establish a common approach to risk assessment in the different agencies, and to improve crisis response co-ordination.

Furthermore, the EU vaccine strategy of July 2020 led to the conclusion of Advance Purchase Agreements for vaccines that were negotiated jointly with the Member States. The Commission mitigated the inherent risk linked to vaccine development by investing in a range of vaccine technologies and companies.

The establishment of the Health Emergency Preparedness and Response Authority (HERA) is – inter alia – supporting a long-term vision for better pharmaceutical readiness for future health threats. The EU4Health Programme will provide financial support to many of these improvements.

Questions concerning cancer-related issues

18. What is your first assessment of the "Beating cancer plan" launched in 2020? In particular the prevention component which likely to be even more important given the number of people who following the Covid crisis have tended to postpone care or consultations?

Since the adoption of Europe's Beating Cancer Plan, the Commission has significantly advanced on the implementation of its flagships and supportive actions.

In particular, from a first assessment, the governance of the Plan will be ensured by (1) the sub-group on cancer under the Steering Group on Health Promotion and Disease Prevention, that will follow the implementation of the Cancer Plan and the Cancer Mission thereby engaging Member States from the health and research side (2) the Commission services in the Cancer Plan Implementation Group, with 26 Commission's services working jointly to ensure coherence of policy, actions and funding of the specific actions; and (3) the Stakeholder Contact Group set up under the EU Health Policy Platform to better guide the discussions and inputs from the stakeholder side in different sectors.

Support for a rapid and concrete implementation of actions will be provided under the Annual Work Programme 2021 of the EU4Health Programme, through 12 action grants, four Joint Actions, three open call for procurement, two direct grants to

international organisations, and administrative agreements with the Joint Research Centre for a total amount of EUR 81.5 million. The Commission is already preparing the next Annual Work Programme 2022, which will also include substantial support to ensure a concrete implementation of the Cancer Plan.

Prevention is a key pillar of the Cancer Plan as 40% of cancers can be avoided. The scope for action to prevent new cases is therefore immense. Specifically on prevention the EU4Health programme launched a Joint Action and a grant that will support Member States and civil society on HPV vaccination. Additional action grants will:

- Support targeted actions in the context of the 'HealthyLifestyle4All' initiative, for instance promoting healthy school environments, and health literacy in the area of cancer prevention;
- Support a better access to the recommendation of the European Code against Cancer, for instance with the development of a mobile app to improve the coverage of the Code, which will be also updated considering the recent scientific development.
- Help access to innovative personalised medicine approach to cancer prevention through the detection of individuals at higher risk to develop cancer in their life

In addition, a Knowledge Centre was launched at the Commission's Joint Research Centres, work on the revision the Council Recommendation on cancer screening has started, a healthy lifestyle campaign was launched with Commissioner Gabriel, the EU Health award on cancer prevention was announced.

The COVID-19 pandemic has highlighted the vital need for effective partnerships, support for vulnerable groups and contingency planning for continuity cancer care in future crises. The Cancer Plan responds to this demand.

The Cancer Plan continues to work in tandem with the Horizon Europe Mission on Cancer, ensuring coherence between ambitious research goals and realistic policy objectives.

Regular exchanges with the European Parliament's Beating Cancer Committee are ongoing and I spoke recently (on 27 September 2021) at the Committee.

An Implementation Roadmap for the Cancer Plan is currently being finalised - detailing the key milestones and timeline - and will be made public soon.

19. DG SANTE as specific Objectives in its AAR 2020 indicates diminishing the impact of cancer in Europe and patients' access to safe, innovative and affordable medicines and medical devices. Commission's investment in the use of mRNA technology in the Covid-19 vaccine definitely accelerated production, testing, approval and putting in the market this innovative vaccine. Is Commission planning to further invest to this technology in immunotherapy to treat cancer, which has been done by researchers for years but with much slower results? Could this contribute in achieving objectives related to cancer

impact and accessibility of innovative medicines? What are the biggest successes of the Europe's Beating Cancer Plan in terms of prevention, diagnosis, treatment, life as a cancer survivor and palliative care?

Although competence on investments in health, including in innovative treatments of cancer patients, lays under Member States' competence, the Commission helps countries to ensure access to diagnostics and treatments of cancer patients with innovative technologies, including immunotherapy.

Europe's Beating Cancer Plan intends to support actions through the Pharmaceutical Strategy for Europe, which proposes ways to improve access to medicinal products, and through the revision of the pharmaceutical legislation.

In addition, three calls for projects have been launched under the Annual Work Programme 2021 of the EU4Health Programme. These three projects will (1) improve access to innovative cancer diagnosis and treatments, including immunotherapies, through the use for instance of 'next generation sequencing' technology for quick and efficient genetic profiling of tumour cells, allowing Cancer Centres to share cancer profiles and applying the same or similar diagnostic and therapeutic approaches to patients with comparable cancer profiles; (2) give secure access to large amounts of genomic data for personalised medicine purposes, and (3) launch an EU platform to improve access to cancer medicines to support the repurposing of existing medicines.

Beside these actions, the new legal framework for clinical trials will apply by the end of 2021, and the Regulation on Health Technology Assessment will help ensure speedy access to innovative cancer diagnosis and treatments.

The success of Europe's Beating Cancer Plan in terms of prevention, diagnosis, treatment, life as a cancer survivor and palliative care cannot be assessed already now. But if success is measured on how it has been received by Member States, the Parliament, the stakeholders, including patients and civil society organisation, and on the resources pledged for its concrete implementation, the Commission has reached its first objective.

By 2024, the Commission will review the Cancer Plan and its progress and initial impact will be evaluated.

Questions concerning the control environment and risk management

20. DG SANTE in its AAR 2020 indicates that in order to ensure sound financial management during the COVID-19 crisis, on-the-spot controls were replaced by remote audits. Could you comment if such remote audits guarantee the same level of assurance as physical on-the-spot checks? How many on-spot audits and remote audits were performed in 2020 and what were the results?

Due to border and sanitary restrictions, on-the–spot audits in the frame of financial control on grants in the food and feed policy area had to be suspended in mid-March 2020. To a large extent, audit work continued and took place in the form of remote audits. In comparison to the 2020 audit work plan, out of 18 planned audits, two audits took place on-the-spot, while 16 were carried out as remote audits following the same audit work programme and applying the same auditing standards.

In reaction to the crisis, the audit schedule, however, had to be adapted by postponing two audits and anticipating two other audits from the same domain of animal diseases. As a result, the portfolio of six ex-ante audits on animal disease emergency measures and 12 ex-post audits on veterinary programmes and plant health surveys remained stable. Thus, the changes to the audit schedule were minor and did not affect the basis for the Director-General's declaration of assurance for 2020.

The audit findings, be it on the spot or at the desk, were in line with previous years' observations on the same kind of cost claims.

21. DG SANTE carries out over 200 audits and on the-spot visits per year to verify that EU rules on food and feed safety, animal health, animal welfare, plant health and some areas of human health are properly implemented and enforced in EU countries.
    - Question: How has the Covid-19 pandemic affected to the number of on the-spot visits?
    - Is there a need to increase on the- spot visits in the light of preventing possible new pandemics?

1. How has the Covid-19 pandemic affected the number of on the-spot visits?

Traditionally, DG SANTE has carried out audits and similar controls by travelling to the targeted countries. The pandemic has had an impact on DG SANTE's control programme, either because of the restrictions on travel or restrictions in place in the country being audited. DG SANTE adapted its approach and has performed most of its controls remotely, using the latest developments in video-conferencing.

In 2020, 111 audits and similar controls took place. 39 were carried out on-the-spot, two were partially remote, and 70 were carried out fully remotely. This compares to a total of 206 audits and other controls completed in 2019.

For 2021, by the end of October, 130 controls had already taken place. Of these, ten were carried out on-the-spot, six were partially remote and 114 were carried out fully remotely. In most cases, reports of the controls, whether on-the-spot or remote, have already been or will shortly be published on the Commission website[15].

2. Is there a need to increase on the- spot visits in the light of preventing possible new pandemics?

[15] https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

On the spot visits cannot prevent a pandemic. Their purpose is to evaluate and to improve compliance with EU law.

The control activities that DG SANTE undertakes in the health domain are not linked to the prevention of pandemics, but underpinned by specific legal obligations.

Within this context, the DG SANTE is always prepared to adapt its audit work programme to accommodate emerging priorities. With the experience gained since March 2020, the DG SANTE will routinely combine remote assessments with on-the-spot visits when carrying out future audits.

In its proposal for a new cross-border health threats regulation, the Commission suggests a strengthened system to assess EU Member States' preparedness plans, including country visits when necessary.

22. DG SANTE faced significant changes in its control environment and became aware of new risks and fraud patterns in its new activities. On page 55 of the 2020 annual activity report of DG SANTE we read the following: "In 2020, DG SANTE became aware of allegations of fraud in connection with the purchase of medical countermeasures, but without having an effect on DG SANTE's budget. DG SANTE was in close contact with OLAF to exchange information. Upon completing its selection activities, OLAF decided not to open a case as the suspicions of fraud were insufficient." Could you give us some details, please.

OLAF informed the Commission that the matter referred to by the Honourable Members was subject to a case selection procedure in 2020. Given that no EU budget had been involved in the relevant proceeding and that the Commission had never either concluded, or co-financed contracts with the company in question, OLAF decided to refrain from opening a case as the matter did not fall within its remit.

23. The AAR 2020 highlights that 'DG SANTE faced significant changes in its control environment and became aware of new risks and fraud patterns in its new activities'.
    - How did the Commission adapt its anti-fraud procedures to react to the new situation?
    - How will this experience be integrated into the planned update of the anti-fraud strategy, which has been postponed to 2021?

1. How did the Commission adapt its anti-fraud procedures to react to the new situation?

Measures to prevent and detect fraud are part of the Commission's Internal Control Framework which remained fully applicable during the pandemic. Early on, extensive guidance was provided by the Commission's Central Financial Services to the

Authorising Officers by Delegation on the effects of the pandemic on the implementation of the EU spending programmes. The use of flexibility introduced in March 2020, e.g. in terms of extension of deadlines for submission of tenders or proposals or simplified financial circuits, was discussed with central services at the level of Directors-General.

DG SANTE registered systematically each case of derogation from the Financial Regulation or Joint Procurement Agreement in so-called "exception reports". The decision to deviate from the rules was taken by the Director-General in consultation with the central services. With regard to joint procurement procedures, each derogation was brought to the attention of the participating Member States and met their approval. This ensured transparency, accountability and sound financial management despite derogations from rules and procedures.

In addition, DG SANTE organised quality checks of medical goods prior to their direct delivery from the producer to the Member States. This prevented not only financial losses but, first and foremost, health issues had defective medical supplies been placed on the market.

During the summer 2020, a specific corporate risk exercise took place to assess the risks deriving from the COVID-19 crisis on the implementation of the EU budget. OLAF participated in this exercise and shared its insights into increased fraud risks, new fraud schemes and vulnerable areas. New fraud risks were also discussed in the Fraud Prevention and Detection network in which DG SANTE participates actively.

In case of suspicions of fraud, DG SANTE and OLAF exchanged information on a day-to-day basis as fraud issues linked to the COVID-19 pandemic were a top priority.

2. How will this experience be integrated into the planned update of the anti-fraud strategy, which has been postponed to 2021?

Due to the significant changes in DG SANTE's control environment during the COVID-19 pandemic, an update of DG SANTE's anti-fraud strategy became necessary. Following OLAF's methodology for services' anti-fraud strategies, in the second quarter 2021, DG SANTE carried out a fraud risk assessment to identify the new risks and fraud patterns that emerged in DG SANTE's new activities and new ways of working. On this basis, DG SANTE's developed an action plan covering the years 2021 to 2024. It reflects the results of the fraud risk assessment as well as DG SANTE's responsibilities as spending DG under the action plan of the Commission Anti-Fraud Strategy of 2019.

DG SANTE submitted its draft anti-fraud strategy and action plan (2021-2024) to OLAF who organised a peer review with a number of DGs in October 2021. Having taken the results of the peer review into consideration, the anti-fraud strategy with its action plan (2021-2024) was submitted to DG SANTE's Management Board to be approved on 8 November 2021.

24. Despite numerous changes in procedures and deviations from rules to gain more flexibility in urgent procurement procedures DG SANTE did not consider it appropriate to make a reservation in the Director-General's declaration of assurance. Can you Commissioner give us the assurance that the identified weaknesses will not have a bearing on sound financial management and that the internal control system provides sufficient assurance in that regard?

During the crisis, the Commission's Internal Control Framework remained fully applicable. It constituted an important safeguard for its operations in the context of the pandemic. The annual assessment of the status of internal control led to a positive conclusion on the effectiveness of the internal control system, meaning that the components and principles were functioning, despite some need for improvement. These relate to ethics, staff allocation and professional development, functions that are only partially under DG SANTE's management.

Main steps taken to ensure sound financial management during the COVID-19 crisis have been discussed and decided at the highest hierarchical level and in close co-operation with central services. Discussions specifically focused on how to speed up, but still adequately control, (joint) public procurement procedures for medical countermeasures given the extreme urgency and pressure to act.

Each case of derogation from the Financial Regulation or Joint Procurement Agreement was registered systematically in so-called "exception reports". The decision to deviate from the rules was taken by the Director General in consultation with the central services. With regard to joint procurement procedures, each derogation was brought to the attention of the participating Member States and met their approval. This ensured transparency, accountability and sound financial management despite derogations from rules and procedures. These derogations and deviations did not result in weaknesses in DG SANTE's internal control system.

In addition, DG SANTE organised quality checks of medical goods prior to their direct delivery from the producer to the Member States. This prevented not only financial losses but, first and foremost, health issues had defective medical supplies been placed on the market.

In 2020, DG SANTE's was able to conduct remote audits when the COVID-19 pandemic prevented traveling. Audits could be finalised so that sufficient information was available for the declaration of assurance in 2020.

The detected error rate during ex-post controls on grants in the food safety policy area amounted to 0.9% in 2020. In 2020, DG SANTE's expenditure in the health domain increased sevenfold compared to previous years, principally in order to manage important parts of the Commission's health response to the COVID-19 pandemic: EUR 2.5 billion of the Emergency Support Instrument were paid mainly to purchase medical counter measures and vaccines. This expenditure is mainly based on procurement procedures, for which DG SANTE estimated the risk at payment at 2%,

similar to the level applied to procurements in the past. As this activity just started, there are no results of controls yet, and the future corrections were prudently estimated at 0%. As a result, the risk at closure is estimated at 2%. As this part of expenditure reached almost 85% of the DG's payments, whilst in 2019 it was only around 8%, the resulting estimated risk at closure for the whole DG increased significantly to 1.6%, but it does not exceed the materiality threshold of 2%.

The feedback received from the European Court of Auditors and the Commission Internal Audit Service (IAS) did not reveal any significant internal control issues. In addition, no OLAF investigation, Investigation and Disciplinary Office of the Commission report or Ombudsman case was addressed to DG SANTE that would point to serious control weaknesses.

Taking into account the conclusions of the review of all these elements supporting assurance, DG SANTE assessed that it had an effective, efficient, robust and reliable internal control system at its disposal in 2020. Against this background, DG SANTE did not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

25. In your mission letter you were tasked to work with the Member States to develop a strategy with concrete measures against food fraud, drawing on the work of OLAF in this area. What is the status quo of this strategy?

The Commission aims for zero-tolerance, increased prevention, deterrence and sanctions against agri-food fraud and recalls the need to enforce a level playing field for operators while preventing consumer deception. Engagement with stakeholders and a close collaboration with all Member States is essential in the fight against fraud. The doubling of exchanges within the EU Agri-Food Fraud Network over the past years (reaching almost 400 in 2020) demonstrates their interest on the matter.

In line with my mission letter, the Commission has focused its strategy against agri-food fraud on concrete actions in collaboration with the Member States, and in support of OLAF or EUROPOL investigations.

Actions coordinated at EU level covered COVID-19 related false claims on food supplements sold online, the assessment of the purity of certain spices, and the unauthorised use of bamboo additives in food contact material. Further actions will be initiated on authenticity, the illegal trade of cats and dogs and plant protection products.

The collaboration with OLAF is framed by an administrative arrangement easing exchange of information. The Commission also engaged with authorities in third countries to cooperate about potential fraudulent practices and in absence of appropriate reaction proposed special import conditions and/or heightened checks for

specific commodities (such as ethylene oxide in sesame seeds). We also developed electronic certification and encourage its use to make document forgery more difficult.

In addition, training and research programmes dedicated to agri-food fraud complement operational activities. They aim at mobilising as many actors as possible in line with our political commitments to the fight against agri-food fraud.

26. In your Strategic Plan for years 2020-2024 regarding fraud risk management you state that DG Sante has developed and implemented its own anti-fraud strategy and action plan on the basis of a specific fraud risk assessment and a methodology provided by OLAF. In the same strategic plan you also state that you will update the anti-fraud strategy and action plan for years 2021-2024.
    - Question: How has the cooperation with OLAF worked out and what is the current situation with the update of DG Sante anti-fraud strategy?

During the Summer 2020, a specific corporate risk exercise took place to assess the risks deriving from the COVID-19 crisis on the implementation of the EU budget. OLAF participated in this exercise and shared its insights into increased fraud risks, new fraud schemes and vulnerable areas. In 2020, new fraud risks were also discussed in the Fraud Prevention and Detection network and its sub-groups in which DG SANTE participates actively.

DG SANTE updated its anti-fraud strategy following OLAF's methodology for services' anti-fraud strategies. In the second quarter 2021, DG SANTE carried out a fraud risk assessment to identify the new risks and fraud patterns that emerged in DG SANTE's new activities and new ways of working. During the same time, OLAF supported DG SANTE by organising a remote workshop in DG SANTE on "Fraud prevention and detection", with special focus on procurement. Nearly 200 staff of DG SANTE participated.

Based on the fraud risk assessment, DG SANTE developed an anti-fraud action plan covering the years 2021 to 2024. It reflects also DG SANTE's main responsibilities as spending DG under the action plan of the Commission Anti-Fraud Strategy of 2019.

DG SANTE submitted its draft anti-fraud strategy and action plan (2021-2024) to OLAF, who organised a peer review with a number of DGs in October 2021. Having taken the results of the peer review into consideration, the anti-fraud strategy with its action plan (2021-2024) was submitted to DG SANTE's Management Board to be approved on 8 November 2021.

27. Since the publication of the DG SANTE's AAR 2020, which further measures have been taken to address the four IAS recommendations rated as 'very important'?

The implementation of the four open IAS recommendations rated "very important" has progressed in 2021 as follows:

1. IT system TRACES:
   The IAS carried out a follow-up audit on the on-going actions and concluded that the implementation of the recommendation is very well advanced. Thanks to the considerable progress made, the recommendation was downgraded from "very important" to "important". Full implementation is expected by late 2022.
2. Staffing of activities in the Health and Food Audits and Analysis Directorate of DG SANTE:
   DG SANTE has carefully reviewed the activities of all its Directorates during successive Unit Management Plan exercises in order to assess where DG priorities can best be dealt with. Several tasks to implement the recommendation had to be postponed mainly to address lessons learned due to the experience of doing remote audits during the on-going COVID-19 pandemic. Furthermore, an HR strategy for DG SANTE's audit Directorate will have to be coherent with the new HR strategy for the Commission which is not yet available.
3. Time reporting and performance monitoring Health and Food Audits and Analysis Directorate of DG SANTE:
   A pilot scheme for time-reporting and performance monitoring was about to be launched in mid-March 2020 but, due to the cancellation of audits and exceptional working arrangements during the pandemic, the action had to be postponed. The fact that audit work had to be performed remotely would not provide a relevant basis for developing a performance monitoring system for the Directorate's work. Therefore, the pilot scheme will be re-launched when the situation normalises.
4. Unit costs and lump sum methodology to be used in veterinary, plant health programmes and emergency measures:
   DG SANTE addressed the audit recommendation by an administrative arrangement with the Joint Research Centre (JRC). The whole project runs for three years until February 2023 and has already delivered positive results.
   Main elements of the recommendation are taken on board by the Health and Digital Executive Agency (HaDEA) since about 80% of the budget of the Food Chain strand was transferred to HaDEA on 1 September 2021.
   DG SANTE provided HaDEA with Standard Operating Procedures and guidelines in relation to the technical and financial management of veterinary and phyto-sanitary programmes.

28. The AAR 2020 of DG SANTE outlines several instances of non-compliance with the Financial Regulation and the Joint Procurement Agreement in the interest of providing a timely response to the Covid-19 pandemic.
    - Which additional control measures has the Commission taken to mitigate the non-compliance and prevent irregularities?

Main steps taken to ensure sound financial management during the COVID-19 crisis have been discussed and decided at the highest hierarchical level and in close co-operation with central services. Discussions specifically focused on how to speed up, but still adequately control, (joint) public procurement procedures for medical countermeasures given the extreme urgency and pressure to act.

Each case of derogation from the Financial Regulation or Joint Procurement Agreement was registered systematically in so-called "exception reports". Each report contained a description of the measures proposed to mitigate the risks and to avoid that the situation happens again. The decision to deviate from the rules was taken by the Director-General in consultation with the central services as regards the applicable rules. With regard to joint procurement procedures, each derogation was brought to the attention of the participating Member States and met their approval.

This ensured transparency, accountability and sound financial management despite derogations from rules and procedures.

In addition, DG SANTE organised quality checks of medical goods prior to their direct delivery from the producer to the Member States. This prevented not only financial losses but, first and foremost, health issues had defective medical supplies been placed on the market.

Questions concerning reporting and indicators

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

The ex-post evaluation of the Third Health Programme 2014-2020 was launched in October 2020, with the publication of a Roadmap to inform and consult EU citizens and with a call for tender for the study supporting the ex-post evaluation.

The tender procedure enabled the Commission to select a contractor and to sign a service contract at the end of the second quarter 2021. The study started in July and completed its initial phase in September 2021.

The contractor is currently conducting fieldwork, collecting data and other evidence to feed into the research and analytical phase of the study. This will include an Open Public Consultation of EU citizens and a targeted consultation/ /interviews of the stakeholders of the Health Programme.

The study is expected to be completed at the end of the second quarter 2022. Its final report and findings will serve as input to the Commission staff working document and to a report to the European Parliament and the Council, which is planned by the fourth quarter 2022.

Results and findings of the ex-post evaluation will help to implement the new EU4Health Programme 2021-2027.

30. In 2020, DG SANTE initiated work on the impact assessment for the revision of the EMA fees system. Is this impact assessment finalized and could you comment on the outcomes of it?

The impact assessment builds on the preceding evaluation and is ongoing. All relevant stakeholders have been consulted recently. The outcome is currently being analysed. The relevant technical study is expected by end of 2021.

31. Regarding the Food and Feed programme, the AMPR report indicates that two KPIs 'deserve attention'. Similarly, as for the Health Programme, the KPI related to the European accreditation scheme for breast cancer services is also evaluated as deserving attention.
    - Which actions has the Commission taken to improve the fulfilment of targets of the KPIs?
    - Which lessons has the Commission drawn for the performance framework of the new EU4Health programme?

1. Which actions has the Commission taken to improve the fulfilment of targets of the KPIs?

As regards the EU funded programmes on the eradication of bovine tuberculosis and brucellosis melitensis, progress has been made in most of the funded countries as the number of regions officially-free from the diseases has increased in several Member States.

In reaction to the lack of progress in two countries, financial penalties and budget reductions have been applied. Furthermore, the Commission created a Task Force as the main forum to exchange regularly information with the Member States on their animal disease eradication programmes.

With regard to the Key Performance Indicator on the European accreditation scheme for breast cancer services, a grant has been launched by DG SANTE to support accreditation and certification of quality assurance (QA) schemes for breast, colorectal and cervical cancer screening programmes. It will ensure an enhanced participation rate in the pilot run in real settings of the European QA scheme as well as a the

definition of a proposal for an enhanced uptake of the European QA scheme after the formal roll-out.

A modular approach has been adopted where individual components of the European QA scheme can be accredited to standards in compliance with national provisions. Moreover, flexibility is embedded for showing compliance by breast cancer services in order to foster inclusiveness of the scheme. This flexibility is fundamental considering the high heterogeneity and varying development levels of breast cancer services across Europe. This approach will thereby allow all those wishing to adhere to the European QA scheme, to come on board in stages, with evaluations performed in a teaching approach, while not putting additional burden on already advanced (e.g. accredited) services.

Provisions have been made for the recognition by the European QA scheme of existing (breast) cancer certification schemes operating in Europe covering different processes of breast cancer care. It is important that the services working to meet these requirements of other well-established schemes can be included in the European ones without additional administrative burden.

Furthermore, a feasibility study of the requirements is ongoing with the participation of 15 breast cancer services in ten Member States, to be followed by a pilot run in real settings to check the accredited certification process. Both aim at enhancing the implementation of the European QA scheme.

2. Which lessons has the Commission drawn for the performance framework of the new EU4Health programme?

The performance framework of the EU4Health programme (2021-2027) was developed in compliance with the Better Regulation principles and with standards developed under the EU Budget Performance Framework[16].

The Programme has established a sound performance framework, developed by the Commission and stemming from the list of performance indicators in Annex II of the EU4Health Regulation.

A system to measure progress towards the objectives requires performance indicators that monitor how the funded interventions are progressing, how the spending is delivering results, and how these results bring the programme closer to their stated objectives. In this sense, indicators in Annex II are complemented by a more comprehensive set of indicators as part of the monitoring and evaluation framework for the EU4HealthProgramme.

It is crucial to monitor the performance of interventions on the ground. At the same time, such monitoring and the related reporting obligations place administrative burdens on beneficiaries. Therefore, for each action, most meaningful indicators will

[16] Communication on the performance framework for the EU budget under the 2021-2027 MFF COM2021 (366)

be collected by the funding beneficiaries for monitoring progress of implementation and for highlighting the key results achieved.

The quality of data is a critical element of the performance framework, for effective monitoring and data strong evaluation. Data needs to be available on a regular basis and must be of sufficient quality and reliability.

As the implementation of the EU4Health Programme (2021-2027) just started with the launch of the first calls for proposals and contracts in the in the summer 2021, it is too early to draw lessons already from its performance framework.

Questions concerning Cross-border Health threats (African swine fever)

32. DG SANTE plays a leading role in managing cross border threats to health at EU level by coordinating and supporting action to prepare for and respond to such threats.
    a. How has the Commission helped on the ground to prevent the spread of the disease African Swine Fever?
    b. Where are the main difficulties in containing the disease?
    c. How does the Commission support the cross-border cooperation between member states?
    d. How does the Commission specifically support the member states?
    e. The state of Brandenburg has applied for a reduction in the duration of restricted zone III from twelve to three months in order to be able to process pigs from the region that are ready for slaughter as soon as possible otherwise the pigs will remain in their boxes which is a problem of animal welfare. How does the Commission support requests in emergency cases fast and reduces administrative hurdles?

1. How has the Commission helped on the ground to prevent the spread of the disease African swine fever?

The comprehensive EU effort includes:

- Daily technical exchanges between the Commission and Member States;
- Intervention of the EU Veterinary Emergency Team (EUVET). EUVET provides technical support and assistance on the spot. The team of highly qualified and experienced experts can be mobilised in 24h by the Commission,
- Scientific advice from the European Food Safety Authority (EFSA),
- Efficient diagnostic capabilities and technical expertise driven by the EU Reference Laboratory (EURL),
- Support to the national awareness campaigns and organisation of ad hoc trainings (via the Better Training for Safer Food instrument) for Member States and third countries,
- EU contribution to research projects directly related to African swine fever (including development of vaccine) amounts to EUR 30 million.
- Audits in the Member States and third countries,

- From 2014 to 2021, more than EUR 230 million have been granted to affected Member States in the framework of African swine fever Veterinary Programmes (e.g. co-financing of sampling and testing of domestic pigs and wild boar) and emergency measures (e.g. co-financing of culling of pigs, transport of carcasses for the disposal, cleaning and disinfection, etc.).
- Non-affected Member States have received co-financing, for example, for awareness programmes and passive surveillance in wild boar.
- Third countries have received co-financing, for example, for awareness programmes, testing and collection of dead wild boar, support for the purchase of equipment to control African swine fever.

2. Where are the main difficulties in containing the disease?

The main challenges are:

- Small-scale farms and backyards with low biosecurity. In some Member States, traditional small farms remain widespread.
- Long-term control, management and appropriate reduction of wild boar populations in both affected and disease-free areas.
- The 'human factor', which causes unpredictable long distance 'jumps' of the disease, mainly as a result of negligence.

3. How does the Commission support the cross-border cooperation between Member States?

The Commission kept the discussion on African swine fever high on the agenda, at both political and technical level (at the Agriculture and Fisheries Council, the working party of chief veterinary officers, the European Parliament, and the Regulatory Committees).

To enhance political awareness and cross-border cooperation on African swine fever at European and international level, the Commission has held a series of ministerial meetings to address the risks and map out possible ways to combat the disease. The last high-level conference, before the COVID crisis, dealing with 'the future of global pork production under the threat of African Swine Fever', was held on 17 January 2020, in the margins of International Green Week in Berlin.

The Commission intensively contributes to the Standing Group of Experts on African swine fever in the Baltic and Eastern Europe region that was set up under the Global Framework for the progressive control of Trans boundary Animal umbrella bringing together experts to build up a closer cooperation among countries affected by African swine fever and address the disease in a more collaborative and harmonised manner.

A recent example of contribution to cross-border cooperation is the high-level quadrilateral meeting to discuss cross-border cooperation held on 21 September 2021 between the Commission, Germany, Poland and the Czech Republic.

4. How does the Commission specifically support the member states?

In response to the epidemiological situation, the Commission has provided political, technical and financial support to both Member States and third countries. Through the veterinary programmes and emergency measures, the Commission has been financially supporting a number of measures aimed at African swine fever prevention, control and eradication:

- Direct costs relevant to emergency measures for eradication of outbreaks in pig farms (culling of pigs, transport of carcasses for the disposal, cleaning and disinfection, etc.);
- Sampling and testing of domestic pigs and wild boar;
- Awareness campaigns on African swine fever;
- Finding, collection and disposal of wild boar carcases;
- Other duly justified measures (such as strategic fencing)

In addition Member States can use additional tools to prevent, control and eradicate African swine fever under the Common Agricultural Policy (such as Rural Development, market support measures, etc.).

5. The state of Brandenburg has applied for a reduction in the duration of restricted zone III from twelve to three months in order to be able to process pigs from the region that are ready for slaughter as soon as possible otherwise the pigs will remain in their boxes which is a problem of animal welfare. How does the Commission support requests in emergency cases fast and reduces administrative hurdles?

The Commission Implementing Regulation (EU) 2021/605 laying down control measures for African swine fever provides for prohibition of movements of domestic pigs kept in restricted zones, to outside those zones.

Under specific conditions, the Regulation gives to the competent authority of the country concerned the possibility to derogate and authorise in case of animal welfare problems movements of domestic pigs kept in restricted zones III outside those zones to an establishment located in restricted zone II, in the territory of the same member country, or for immediate slaughter.

Questions concerning administration

33. Could you comment what savings and extra-costs incurred in 2020 related to staff, buildings maintenance, administration and travels?

As a consequence of the pandemic, the actual budget amounts spent on missions, conferences and meetings as well as training in 2020 were considerably lower than the amounts included in the 2020 budget. This led to savings of about EUR 67 million across all DGs, of which nearly half related to mission expenditure.

Part of these savings were redirected to other areas in need of reinforcement due to the COVID-19 crisis, such as expenditure for information and communication technology equipment and services and decentralised IT systems. This concerns in particular new structural needs related to the remote working pattern (upgrade of bandwidth, new collaboration processes, paperless environment, additional security features) as well as a decentralised IT systems (about EUR 31.5 million).

Further savings of about EUR 3 million occurred with respect to the budget for freelance interpreters (due to the reduced number of meetings).

Furthermore, appropriations from other areas of administrative expenditure have been redeployed to cover the following pandemic related needs:

- Expenditure of the medical service for the COVID-vaccination campaign, including sanitary measures in the childcare centres (EUR 4 million);
- Expenditure related to the provision of home office equipment to all staff (EUR 2 million).