2019 Discharge to the Commission

WRITTEN QUESTIONS TO COMMISSIONER KYRIAKIDES

Hearing on 7 January 2021; 9:00 – 10:30

Questions concerning general issues in the field of health and food safety policy

1. DG SANTE has continued its work on the two-year cycle 'State of Health in the EU'. In November 2019, DG SANTE published 30 Country Health Profiles, including for all EU Member States. In addition, DG SANTE issued a 'Companion Report' highlighting the key trends in the transformation of health systems across the EU. What other actions does the Commission plan in order to further promote the 'State of Health in the EU'? Which objectives of the strategy have changed with regard to the Covid-19 outbreak?

Commission's answer:

In November 2020, the publication of "Health at a Glance 2020: Europe" kicked off the third round (2020-2022) of the State of Health in the EU cycle. The first thematic chapter of this deliverable provided a first analysis of comparative data on how European countries have experienced and responded to the COVID-19 pandemic, including both outcomes and policies, with a view to present recommendations on how health systems can become more resilient to the ongoing pandemic as well as future health crises.

In the end of 2021, a new set of Country Health Profiles for the EU Member States, Norway and Iceland will be published. The structure of the profiles will remain largely consistent with the previous edition, but their content and analytical focus will be adjusted to accurately reflect the complex impact of the COVID-19 pandemic on national health systems. The 'resilience' section of the profiles will be significantly overhauled compared to previous editions to provide relevant, evidence-based analytical insights in support of policymakers' health system strengthening agenda in the aftermath of the COVID-19 crisis.

As per the strategy of the knowledge-brokering initiative itself, the experience of the pandemic has brought into sharp focus the need for robust and comparable information on health systems performance. Through the State of Health in the EU cycle, the European Commission intends to continue contributing to reducing this information gap, by regularly providing national-level health policymakers with a neutral, high-quality analysis base validated by international experts.

2. Training is a key component in strengthening the prevention and control of antimicrobial resistance across the human, veterinary and food sector. Training activities for EU Member States continued in 2019 within the 'Better Training for Safer Food' programme. This work should contribute to a decline in overall EU consumption of antibiotics. Based on the latest data available (2018), there has been a 6,5 % reduction since 2013. Has the consumption of antibiotics declined further? What would the Commission do to further advance a decline on the consumption of antibiotics?

Commission's answer:

The EU One Health action plan against AMR (antimicrobial resistance) adopted in 2017 includes over 70 actions covering human health, animal health, the environment as well as research and innovation aiming at reducing the use of antibiotics.

According to the most recent report from the European Centre for Disease Prevention and Control (ECDC) there was **a further 3.5% decline in antibiotic consumption in humans in the EU/EEA between 2018 and 2019. Antibiotic consumption in humans has declined by 9.8% since 2013 on average across the EU/EEA.** Many individual Member States have experienced declines in consumption but a small number of countries have had an increase over this period.

The challenge is to ensure that antibiotics are only used when they are genuinely needed because excessive and inappropriate use contributes to antimicrobial resistance. The Commission published guidelines on prudent use of antimicrobials in human health in 2017. We are supporting the implementation of this guidance and the development and implementation of national one health action plans on AMR, which include activities in both the human and animal health sectors to ensure appropriate antimicrobial use.

We will use the new EU4Health programme to reinforce our actions with Member States, with prescribers and with the public to further reduce inappropriate antibiotic use.

In the veterinary sector, significant progress has been made. Between 2011 and 2018, there has been a nearly 35% reduction in sales of veterinary antimicrobials across Europe, according to the latest report of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project. This is very encouraging, but more can be done. The EU Farm to Fork Strategy now sets an ambitious - yet realistic - objective of reducing overall EU sales of antimicrobials by 50% for farmed animals and in aquaculture by 2030, in line with the objective of the Green Deal to develop more sustainable food systems in the EU. The new EU Regulations on veterinary medicinal products and medicated feed, which will apply as of 2022, will be instrumental in the achievement of this objective as they provide for a wide range of concrete measures to fight

antimicrobials resistance and to promote a prudent use of antimicrobials in animals.

The Commission will continue Better Training for Safer Food activities on antimicrobial resistance for EU and non-EU countries that will restart through virtual courses in spring 2021.

Simultaneous action to reduce inappropriate antimicrobial use in humans and animals in line with the European One-Health action plan is of great importance. The Romanian Presidency in 2019 made AMR a priority and this led to a ministerial conference covering human health, animal health and the environment. The Commission provided major support to the discussions including co-funding the conference. Subsequently Council Conclusions were adopted on AMR which further reinforce Member States commitments to developing and implementing national one-health action plans on antimicrobial resistance. Through the EU health programme the Commission has funded actions by WHO to support EU Member States and by OECD to further develop understanding of the economic impact of AMR and the cost effectiveness of policies. We also put forward funding for stakeholder actions to support the implementation of the EU guidelines on prudent use of antimicrobials in human health; carried out 'One Health' visits to countries to provide advice on their activities and worked with the EU Health Security Committee to coordinate action on antimicrobial resistance with the support of guidance from the European Centre for disease prevention and control (ECDC).

With the aim to decline the consumption of the antibiotics, it is also crucial to raise awareness about threats to public health of antimicrobial resistance. Each year the Commission supports the European Antibiotics Awareness Day (EAAD), coordinated with the World Antimicrobial Awareness Week organised by WHO.

3. According to the European Health Consumer Index 2018, published in February 2019 by a Swedish company Health Consumer Powerhouse, the Netherlands, the Scandinavian countries, Luxembourg and Belgium are at the top of the ranking based on multiple indicators ranging from patient information to accessibility of care. These countries score more than 800 points out of a total of 1.000, followed closely by Austria, France and Germany. At the bottom of the rankings are Hungary and Poland, which have peaked below 600 points, and Romania, which has a score of only 549 points. What has the Commission done in order to reduce the still very large differences between the EU Member States?

Commission's answer:

The Commission stands ready to support Member States to improve the performance of their health systems within the confines of the competences

defined by the Treaty provisions. In this context, the Commission offers opportunities for knowledge exchange, technical assistance, investments and mechanisms for stronger collaboration and cooperation.

The Commission gathers knowledge and facilitates the sharing of best practices in health systems through for example the '*State of Health in the EU*' cycle (https://ec.europa.eu/health/state/summary_en) and projects funded by the Health Programme (. For example; JADECARE[1], SCIROCCO[2], VIGOUR[3]). Expert Group reports and opinions - for example, those produced by the *Expert Panel on Effective ways in Investing in Health* https://ec.europa.eu/health/exph/overview_en and *the Expert Group on Health Systems Performance Assessment* https://ec.europa.eu/health/systems_performance_assessment/policy/expert_group_en also provide non-binding, independent advice to Member States on how they can strengthen their health systems.

The Commission also supports health through the socio-economic coordination process of the European Semester. In 2020, all EU Member States received a country-specific recommendation on health[4], signaling the strong support from the Commission for countries to implement reforms in this area.

Lastly, the Commission supports the reduction of performance differences between health systems through several financing mechanisms at the disposal of Member States. Horizon Europe and Digital Europe can support research into improving Member States' health systems. The Cohesion Policy funds (ERDF, ESF+) and the InvestEU programmes can finance large investments in reforms, facilities and services. Some of these programmes also offer technical support to Member States if required.

Looking at the near future, the new Recovery and Resilience Facility and EU4Health instruments will provide a precious opportunity to accelerate health reforms and investments on a scale that has never been done before.

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1 Joint Action on Implementation of Digitally Enabled Integrated Person-Centred Care (JADECARE) aims to reinforce the capacity of health authorities to successfully address important aspects of health system transformation, in particular the transition to digitally enabled, integrated, person-centred care, and support the best practice transfer from the systems of the "early adopters" to the ones of the "next adopters".

2 Scaling Integrated Care in Context (SCIROCCO) aims to develop the Maturity Model into a validated and tested self-assessment tool that will facilitate the successful scaling up and transfer of good practices in integrated care across European region. https://www.scirocco-project.eu/

3 Evidence-based Guidance to Scale-up Integrated Care in Europe (VIGOUR) aims to effectively support care authorities in progressing the transformation of their health and care systems to provide sustainable models for integrated care which will facilitate identification of good practice and scaling-up. https://vigour-integratedcare.eu/

4 https://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?archtype=specific&newsletter_service_id=327&newsletter_issue_id=22416&page=1&fullDate=Wed%2020%20May%202020&lang=default

4. The Commission did not accept recommendation 2(a) of the European Court of Auditors' Special Report No 34/2016: 'Combating food waste'. The analysis of the Court showed that the Commission nevertheless implemented this recommendation as part of its CAP proposal in June 2018. Which recommendations in the area of health and food safety has the Commission further implemented, and which recommendations are not yet implemented?

Commission's answer:

Recommendations on Food Waste: In order to support the achievement of the United Nations Sustainable Development Goal (SDG) Target 12.3 on food loss and waste and to maximise the contribution of the European Union, the Commission has put in place a dedicated EU action plan. Food waste prevention was singled out as a priority area in the 2015 Circular Economy Action Plan[5], including both legislative and non-legislative initiatives, which have all been implemented.

Reducing food losses and food waste will be pursued as a key action strand in the European Commission's new Farm to Fork Strategy for a fair, healthy and environmentally friendly food system[6], adopted as part of the European Green Deal[7]. The strategy puts forward ambitious proposals to establish legally binding targets to reduce food waste across the EU by 2023 and to revise EU rules on date marking by 2022. The Commission will seek to scale up action across the EU, mobilising Member States, food businesses and civil society, notably through the work of the EU Platform on Food Losses and Food Waste and encouraging uptake of its recommendations for action[8] by all players. The Platform will be re-established for a second mandate, starting in 2022. The Commission will further integrate food loss and waste prevention in other EU policies. In addition to quantifying food waste levels, the Commission will investigate food losses at the production stage and explore ways of preventing them.

To investigate food losses and waste along the supply chain as well as explore ways of preventing them, the Commission has supported several research and innovation projects under the EU research and innovation framework programmes, 7th Framework Programme and Horizon 2020, for example FUSIONS, REFRESH, FOODRUS and LOWINFOOD that will take into account also the primary production level. In addition to projects that look explicitly at

5 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Closing the loop - An EU action plan for the Circular Economy, COM/2015/0614 final

6 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM/2020/381 final

7 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions European Green Deal, COM/2019/640 final

8 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_eu-actions_action_platform_key-recs_en.pdf?wtclear=laco

food losses and waste, numerous EU-funded projects indirectly tackle this issue by, for instance, improving the health of plants[9] and animals[10] thereby preventing on-farm losses. In Horizon Europe, the next research and innovation programme, the Commission will further support research and innovation to address food losses and waste at the production stage and long the supply chain.

Recommendations in the area of health and food safety: the Commission ensures that the audit recommendations proposed by the Court of Auditors (ECA) are addressed by proportionate action plans and monitors their implementation regularly.

Since 2016, the ECA issued 45 recommendations, for which DG SANTE is in the lead. According to the Commission's corporate monitoring system, 19 of these recommendations are fully implemented, four recommendations are partially implemented and are foreseen to be completed by end-2021 at the latest, and 22 recommendations issued in the last two years are currently on-going, with a target implementation date until end-2023.

Following the ECA audits, DG SANTE was associated DG for the implementation of another 23 recommendations, out of which 10 recommendations are fully or partially implemented, 11 recommendations are currently on-going and two were rejected as they were deemed already implemented.

5. DG SANTE reported that 22 Member States are part of the eHealth Digital Service Infrastructure, and three Member States have applied to a Connecting Europe Facility call to join later on. Have the applications of the three Member States under CEF been successful, and when is it expected that they will join the eHealth DSI? Which are the remaining two Member States, and does the Commission have information if they envisage to join the eHealth DSI in near future?

Commission's answer:

Currently, there are 25 Member States which have received the Connecting Europe Facility (CEF) Telecom Programme funds (from the CEF work Programmes of the years 2015, 2017 and 2019) to join the eHealth DSI – cross border exchanges of ePrescription and Patient Summaries. It is expected that those 25 Member States will start exchanging health data across the EU by 2025.

The two remaining Member States are Romania and Denmark. Romania confirmed their commitment to join the exchanges and is an active member of the

[9] https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/factsheet-agri-plant-health_en.pdf
[10] https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/factsheet-agri-animals-health_en.pdf

eHDSI communities. The Commission currently does not have any specific information on when Denmark plans to join the exchanges via the eHDSI. Both Romania and Denmark, are members of the eHealth Network and have their members in the eHealth DSI Member States Expert Group.

6. Regarding the transfer of the programmes and activities of CHAFEA to other executive agencies based in Brussels, what is the state of play of the social dialogue with the staff representatives concerning this transfer?

Commission's answer:

The transfer of programmes and activities of CHAFEA has been the subject of in-depth exchanges with staff representatives. This took place through direct contacts, information meetings with staff representatives of the Commission and of the agencies, written submissions and 'question and answer' documents available to all staff. Whilst the reprogramming decision itself is a budgetary and organisational matter which is not subject to a formal social dialogue process, the Commission services concerned (BUDG, SG and HR), together with the agencies' management and agencies' staff representatives, discussed the consequences for staff of the change and the mitigating measures that were offered in information meetings.

The changes for individual staff members are being discussed as the process is ongoing and staff representative were recently – on 14/12/2020 - updated through written answers sent by DG HR to the unions and the staff committees of the Commission and of the agencies. In addition, individual CHAFEA staff members were informed by the CHAFEA administration of the new agency they will transfer to. The respective DGs – in the exercise of their duty of care – continue the dialogue with staff on a joint or individual basis in the months to come, including in, if circumstances require, another social dialogue meeting.

7. Is there an updated DG SANTE Anti-fraud Strategy for 2020, to reflect the updated Commission Anti-fraud Strategy from 2019?

Commission's answer:

The main actions of DG SANTE's current Anti-fraud Strategy contribute to the objectives of the Commission Anti-Fraud Strategy from 2019. Once the Multi-annual Financial Framework 2021 to 2027 is adopted, DG SANTE will update its anti-fraud strategy and action plan to cover the years 2021-2024. The update will be based on a fraud risk assessment and lessons learned from the previous strategy and it will take the Commission Anti-Fraud Strategy and action plan of April 2019 into consideration.

Questions concerning the Health programme

8. Could the Commission please provide information about the current state of implementation of the Health Programme for the current programming period?

Commission's answer:

Regulation (EU) No 282/2014 established the third Programme for the Union's action in the field of health (2014-2020) as a financial instrument for policy coordination at EU level. The aim is to complement, support and add value to the policies of Member States in improving the health of EU citizens and reducing health inequalities, encouraging innovation in health and increasing the sustainability of health systems.

A major part of the Health Programme 2014-2020 (80% of the total programme budget) has been implemented by the Consumers Health Agriculture and Food Executive Agency (CHAFEA).

The mid-term evaluation of the 3rd Health Programme 2014-2020 was performed in 2017. Taken as a whole, the Programme was found to represent a major improvement compared to its predecessors, as the new structure increased the Health Programme's ability to target important health needs where it can add value, while allowing flexibility and ability to be responsive to changing circumstances and rapidly evolving needs.

The evaluation indicated that major achievements were:

- Establishing 24 European Reference Networks (ERNs);
- Supporting Member States to increase their capacity-building to respond to outbreaks (e.g. Ebola and Zika viruses);
- Contributing to the EU's migration policy by supporting Member States to respond to the health needs of high influx of migrants and refugees;
- Training health professionals and other front-line staff.

Other achievements of the Health Programme included exchanges of good practice in areas as diverse as alcohol reduction, cancer screening, HIV/AIDS and TB prevention, additional support for EU health legislation on medicinal products and medical devices, the eHealth Network activities and Health Technology Assessment.

A significant progress represented the joint work with the OECD and the European Observatory on Health Systems and Policies. This collaboration brought together internationally renowned expertise in the State of Health in the EU cycle to strengthen country-specific and EU-wide knowledge on health issues.

The Commission adopted the work programme for the last year 2020 of the 3rd Health Programme on 28 January 2020 (AWP 2020). It includes a number of actions (grants for projects and joint actions, operating grants, service contracts, etc.) and focuses on the following main topics: implementation of best practices in

the area of mental health; tobacco control; vaccination; health technology assessment cooperation; General Data Protection Regulation (GDPR) implementation in the health sector; innovation and e-health; health workforce reforms; healthcare procurement; international cooperation on pharmaceuticals; patient-reported measures and prioritisation for the implementation of best practices.

The expected results of the 2020 work programme include: (a) the exchange and adoption of best practices in various areas of health; (b) enhanced understanding of properties and regulatory implications of novel tobacco products and e-cigarettes; (c) increased vaccination uptake among disadvantaged groups and migrants; (d) enhanced knowledge base for the conception and implementation of reforms on retention policies, medical deserts and task-shifting related to the health workforce (e) a GDPR-compliant data governance model and code of conduct for health(care)-related data; (f) knowledge-sharing and discussion on public procurement in the healthcare sector; (g) an NGO contribution to achieving the objectives of the EU health programme.

Further to the Covid-19 outbreak, on-going actions and activities in preparation under the 2020 work programme and under previous annual work programmes have been reoriented to the largest extent possible towards combating the pandemic: examples are the *Joint Actions on Healthy Gateways* (switch from 'inter-epidemic' to 'emergency' mode); the *Strengthened International Health Regulations and Preparedness in the EU* Joint Action (SHARP Joint Action) and the *Joint Action on Bioterrorism*.

9. In its AAR 2019 DG SANTE identifies challenges for the implementation of the Health Programme in the current MFF period. Given the increased budget for the Programme for the next period and its importance in the context of the Covid-19 pandemic, what are the improvements introduced for the new period which are based on the lessons learnt from the current period, and which should ensure timely implementation of the programme?

Commission's answer:

The Commission continues to implement the 3rd Health Programme and started the ex-post evaluation only recently. It will provide a more detailed overview of the lessons learnt from the current period.

The mid-term evaluation of the 3rd Health Programme concluded that the programme had valid and appropriate objectives in place which led to actions which were focused and generated EU added value while accommodating existing needs and challenges. The evaluators found that the 3rd Health Programme contributed to significant progress in public health and that the allocation of resources was efficient overall. Programme management was mostly effective, and has improved since the predecessor Health Programme.

Further improvements should focus on three key areas: addressing cross-border health threats; improving economies of scale; and fostering the exchange and implementation of best practices. In the future, monitoring of implementation data and dissemination should be reinforced.

With EUR 5.1 billion, the new EU4Health Programme will be more than ten times larger than any predecessor Health Programme. EU4Health will help strengthen crisis preparedness and management of cross-border health threats as well as reinforcing the EU's healthcare systems overall. EU4Health opens up a new chapter for EU health policy, and sends a clear signal to people in Europe that public health is our priority and that we have listened to their concerns.

10. How is DG SANTE preparing itself and its executive agencies for the implementation of the increased budget and new tasks in the new programming period?

Commission's answer:

In addition to the resources already allocated to finalising the 3rd Health Programme, the Commission has established a specific Task Force that brings together the necessary expertise and experience to take forward the implementation of the EU4Health programme. The Task Force is responsible for the development of the new EU4Health work programmes, and will follow up the implementation and monitor progress of the EU4Health work programmes with the executive agency – the new Health and Digital Executive Agency, on which preparatory work is proceeding rapidly – and will provide policy feedback to the Commission.

Under the Commission proposal currently assessed by the Committee on Executive Agencies, the new Health and Digital Agency will have a team of up to 189 staff (in 2027) devoted to the implementation of the EU4Health programme and will also benefit from synergies deriving from the implementation of Health research under Horizon Europe. This represents a major strengthening compared to the current situation where the small executive agency CHAFEA implemented the current Health Programme with 35 staff.

11. At the end of 2019, as part of the Health programme, 12 procedures were launched and eight service contracts signed. Ten other offers have been published or are in the process of being published and are expected to be signed by June 2020. CHAFEA also signed three direct grants with international organisations, including the ‘State of Health in the EU’ grants with the OECD and the WHO. Does the Commission plan to continue these contracts even if they are no longer suited to the current health situation?

Commission's answer:

The direct grants signed with OECD and with WHO were implemented, while

taking account of and adapting to the new situation arising from the Covid-19 outbreak.

Activities carried out under the 2019 work programme which have been finalised concern thematic areas that are still key priorities on the Commission health Agenda. They concern areas directly related to Covid-19 pandemic (such as vaccination, preparedness, integrated cares), and others such as antimicrobial resistance; digital health, including European Reference Networks; determinants of health such as nutrition, tobacco and alcohol consumption.

Where the current Covid-19 crisis impacted on the planned tasks, CHAFEA, following guidance from the Commission, withdrew the related actions, for example, one tender on the feasibility study on physical stockpiling of vaccines was cancelled.

The EU and the Commission in particular, have put in place activities that are directly targeting the impact of the pandemic, without having to terminate running actions.

Questions related to crisis response measures

12. To support the Union's capacity to deal with crises, disease outbreaks require a collective cross-border response where EU actions offer a clear added-value. It is essential that the Member States respond quickly to outbreaks and contain them to protect human, animal and plant health. DG SANTE continued to support Member States to achieve this in 2019. What exact measures did DG SANTE carry out to achieve collective cross-border responses? Are there differences within the European countries - and if so, which kind?

Commission's answer:

a) In the field of overall preparedness and response planning, the following actions can be highlighted:

- The EU Health Programme provided funding and support for Member States through targeted Joint Actions. Here, capacities under the International Health Regulations, including for laboratories and points of entry, were strengthened and coordination across key sectors bolstered through the sharing of experiences and best practices, guidelines, trainings, exercises and the creation of networks and procedures.
- In particular, a Joint Action was launched in 2019 to strengthen preparedness against serious cross-border threats to health, including through laboratories in the EU (supported with EUR 7.9 million in the annual work programme 2018). A second Joint Action started preparatory work in 2019 on health preparedness and response to biological and chemical terror attacks involving the public health, civil protection and

law enforcement sectors, with a co-funding of EUR 5 million, which is scheduled to launch work in 2021.

- Mechanisms and procedures for the exchange of medical countermeasures was improved by joint work between the Health Security Committee (HSC) and the Commission, which produced systems and processes that support countries to enact this activity.
- The Early Warning and Response System (EWRS) provides the platform for the notification of alerts and response measures undertaken by Member States related to infectious disease outbreaks, and other threats of biological, chemical and unknown origin, including their intentional release. The re-engineering of the EWRS and the launch of the new, modern IT platform contributed to enhanced early warning, situational awareness and coordination with other relevant EU alert systems.
- The Commission with the Health Security Committee coordinated Member States' preparedness and response to major threats within the EU and beyond, such as measles, influenza, antimicrobial resistance, vector borne outbreaks and viral haemorrhagic fevers. In response to the Ebola outbreak in the Democratic Republic of Congo, the Health Security Committee exchanged information on preparedness and response to the outbreak, including on the availability of vaccines and other medical countermeasures, and on capacities to manage viral haemorrhagic cases. In addition, standard operating procedures have been put in place to enable the medical evacuation in humanitarian contexts for viral haemorrhagic fevers. The evacuation system is managed by the WHO, the European Commission provides support and facilitates the process to identify an EU/EEA Member State available and capable to receive and treat an international health or humanitarian aid worker.

b) In the field of vaccination, the following actions in the "collective cross-border responses" perspective were taken:

- Agreement for joint procurement of pandemic influenza vaccine. Regarding the successful conclusion of the joint procurement for the pandemic influenza, this procedure means that around half of the EU's total population would have access to vaccines in case of a pandemic.
- Set-up of a European Coalition for Vaccination bringing together European health professionals' and students' associations to commit to delivering accurate information to the public, combating myths and exchanging best practice
- Organisation of a Global Vaccination Summit to strengthen existing partnerships and collaboration with international actors and initiatives, such as the WHO.

13. How has the Commission adapted to the new Covid-19 situation in terms of new structures to prevent further pandemics and other disease with a large impact on the Union, and also globally?

Commission's answer:

In the 2020 State of the Union address, the President called on Europe to draw lessons from the current crisis and build a European Health Union, including a 'European BARDA – an agency for biomedical advanced research and development' to support capacity and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin. On 11 November 2020, the Commission put forward a set of proposals for a stronger EU Health Union, including the main elements of a novel Health Emergency and Response Authority, reinforced by the Commission's Pharmaceutical strategy adopted on 25 November 2020.

The main objective of the new EU Authority is to enable adequate EU preparedness by enabling an EU level countermeasure management system that would allow rapid access, availability and deployment of the most advanced medical and other measures in the event of a health emergency.

With the first ERAvsCorona Action Plan the Commission and Member States agreed to step up coordination and jointly increase support for research and innovation through 10 priority measures, in line with the objectives and tools of the European Research Area. Building on this experience, Member States and Commission are preparing a European Partnership under Horizon Europe for implementing a joint research and innovation programme on Pandemics Preparedness. These joint activities are also important prerequisites for stepping up global cooperation.

The Commission will continue to work with Member States, international stakeholders as well as partner countries. This includes, for example, close collaboration with the WHO, non-EU centres for disease control and prevention, Participating States in the Union Civil Protection Mechanism, as well as engagement in coordination platforms such as the Global Health Security Initiative and GloPiD-R, the network of preparedness research funders.

14. The role of the European Centre for Disease Prevention and Control (ECDC) might be less meaningful if a new authority is created. Is the plan for a new authority an official disavowal of the rather weak action of the ECDC, which on 17 January 2020 in its risk assessment specified that there was no risk of dissemination of the Covid-19 outside of China?

Commission's answer:

The role of the new EU Authority HERA will be complementary to the work of the ECDC.

The Covid-19 pandemic has demonstrated the need for and value of co-ordinated

EU level action and of building a European Health Union. The European Centre for Disease Prevention and Control's (ECDC) role in the EU's health security framework is crucial. However, there is a need to strengthen the Agency's capabilities to better protect citizens in line with the Commission's proposal. For example, its surveillance system has to be reinforced so as to deliver its full potential, as at present the ECDC has a limited mandate to provide analysed data that support evidence-based decision making. ECDC needs to be able to provide hands-on support to Member States, and the Agency's scientific recommendations for appropriate health measures need to address Member State specific elements.

15. Launching a new health authority and making the same mistakes again could be very damaging to the reputation of the Union with regard to its actions in favour of citizens, especially in the area of human health. How does the Commission plan to incorporate improved methods and performance criteria into its work in the field of health policy?

Commission's answer:

The future proposal for HERA will build on lessons learned from COVID-19 and also from the H1N1 outbreak in 2009. The Commission will address a gap which remains at the EU level regarding medical countermeasures. Specific methods and performance criteria will be developed in due course. An impact assessment will inform the Commission's proposal that will be adopted in 2021. The Commission will tap into knowledge and resources that exist at EU level (ECDC, European Medicines Agency, the European Union Agency for Cybersecurity etc) but also at national Member State level. Duplication will be avoided and the HERA will use and valorise what exists already at all levels. A properly mandated and resources dedicated structure will start operations in 2023. In this creation process, the Commission will also take into account the recommendations issued by the Court of Auditors in its recent report on decentralised agencies' performance. Moreover, the Commission will launch preparatory actions in 2021 that focus on emerging biological threats and anti-microbial resistance.

16. What will happen to the ECA and Ombudsman's recommendations made on the failures of the ECDC and the Medicines Agency and what are the Commissioner's opinions about these recommendations?

Commission's answer:

- European Court of Auditors recommendations

  The Commission notes that neither the European Court of Auditors' Special Report 22/2020 "Future of EU agencies – Potential for more flexibility and cooperation" nor the recent Ombudsman inquiries have thus far pointed to any specific failures of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

The Commission welcomes the European Court of Auditors' Special Report assessing the performance of all EU decentralised agencies in delivering EU policies, and accepts all recommendations addressed to the Commission. The Commission recalls that the Court's recommendation on more cooperation to, among other goals, achieve possible synergies is addressed to the agencies, which hold the main responsibility for their functioning. In line with the Common Approach, as agreed between the European Parliament, the Council and the Commission in 2012, the Commission remains committed to monitoring the performance of agencies, to ensure their continued relevance and achieve synergies and economies of scale. When carrying out evaluations and fitness checks of policy areas, the Commission attaches great importance to the coherence of agencies' tasks, to identify synergies and cut red tape, while considering potential mergers or closures of agencies. In addition, the Commission adopted in 2018 a new Framework Financial Regulation for EU bodies, setting out, *inter alia*, agencies' obligations to establish their strategy for achieving efficiency gains and synergies. Pursuant to these rules, the agencies' accountability and performance are also closely linked to their contribution to the achievement of the EU political priorities.

The Commission is now working on the follow-up to the Court's recommendations. The Commission recalls, however, that its influence on the governance of decentralised agencies is subject to the limits set by the legislator in their founding acts.

- **Ombudsman case on ECDC:**

  In the context of wider strategic work on the response of the EU administration during the COVID-19 crisis, the Ombudsman examined how the European Centre for Disease Prevention and Control (ECDC) gathered and communicated information during the COVID-19 crisis. It also addressed how the ECDC cooperates with the relevant authorities in EU Member States, as well as international organisations and authorities outside the EU, and the transparency of this cooperation https://www.ombudsman.europa.eu/en/correspondence/en/134848

  ECDC replied to the Ombudsman questions – inter alia – in a meeting in November and by letter in December (meeting minutes are published https://www.ombudsman.europa.eu/en/report/en/134847).

  ECDC explained that as soon as a cluster of pneumonia cases with unknown aetiology in Wuhan was identified by on-duty officers on 31 December 2019, ECDC took immediate actions and published a threat assessment on 9 January, on the day when China CDC first reported the identification of a novel coronavirus as the causative agent of the Wuhan outbreak.

On 17 January, a first assessment on the risk of transmission in the EU/EEA and the UK was published followed by three updates in the month of January, repeatedly highlighting that once community transmission would be detected in a EU Member State, the impact would be high. From January to December 2020, ECDC has updated its assessment of the risk nine times (13 updates) and produced 8 additional risk assessments on targeted issues (end of the year festive season, COVID-19 in minks, long-term care facilities, reinfection, resurgence of cases, new variants, children, and the situation in Italy).

ECDC assessed the risks based on the evidence known at the time of each of the assessments. The ECDC risk assessment methodology takes into account a combination of the probability that something might happen and the impact in case it happens. Using this methodology, the risks were assessed for different contexts (from risk of spread in the EU from China to risk to EU/EEA citizens in areas with community transmission and risk of severe disease etc). The risk moved from low at the beginning, to moderate and very high in line with the evolution of the outbreak and relevance for Europe.

ECDC identified and updated the needs for response to future progression, and already at the end of January, ECDC stressed that preparedness plans should be updated and that hospital preparedness needed to be increased. These recommendations were included in all ECDC risk assessments until beginning/mid-March, and supported with guidance documents.

- **Ombudsman case on EMA:**

  The Ombudsman examined the role of the European Medicines Agency and its pandemic task force during the COVID-19 crisis to ensure that the agency was going to apply the principles that had been agreed as part of the Ombudsman's enquiry into pre-submission activities. This was not a criticism or concern as such https://www.ombudsman.europa.eu/en/case/en/57427

  In its reply to the Ombudsman, EMA committed to upholding its long-standing commitment to the principles of openness, transparency and independence in how it assesses medicines for COVID-19 and to publish clinical data about them https://www.ombudsman.europa.eu/en/correspondence/en/133351

Questions concerning measures to promote human health

17. During the discharge procedure for financial year 2018, the Parliament regretted that the Commission does not provide the discharge authority with exact data

about burnout cases, but noted, however, that the Commission had launched a "fit at work" strategy including a health monitoring tool on absences and their causes, measures to achieve sound absence management, and a new medical control unit. Could the Commission now please provide exact data on burnout cases? What other measures did the Commission introduce and implement to fight burnouts in the Union?

Commission's answer:

The European Commission is facing the same challenges as other organisations/companies (e.g. need to deliver more with limited resources). The Commission developed a fully-fledged strategy in order to better address the needs of Commission staff as regards their health, promotion of physical activities, ergonomic workplace and better work/life balance Fit@work covering the period 2017-2020. It is complemented by an action plan covering the same period. The action plan includes regular training, for managers and staff, on stress management, psychosocial risks and detection of warning signs of burn out, as well as other awareness raising actions such as lunchtime debates, presentations and specific guides. The Commission offers annual medical visits to its staff members. During these consultations, the doctors can detect burn out symptoms. Staff members concerned may be invited, were appropriate, to contact the psychosocial sector of the Medical Service for support. Staff suffering from burn out or having difficulties in their professional life that could lead to a burn out can ask for professional advice and support from psychiatrists, psychologists and social assistant.

The Commission set up a new service for following medical absences and has drafted a revised decision on medical absences, which is currently being discussed with the staff representatives. A standard medical certificate where staff may ask their doctor to indicate diagnostic data on a voluntary basis, in order for the Commission to collect data in addition to the ones collected through medical controls. At this stage, it is difficult to have a precise figure on burn-out cases. As from 2021, the Commission will implement a new information system that will include where available the diagnostic associated with medical absences as well as the specialty of the prescribing doctor. This will allow, by the end of 2021, to have a more precise information about the causes of medical absences.

18. How does the Commission evaluate and rate its policy on endocrine disruptors?

Commission's answer:

In its Communication from November 2018 “Towards a comprehensive European Union framework on endocrine disruptors”, the Commission acknowledged the growing societal concerns about endocrine disruptors and announced the launch of a Fitness Check to assess whether relevant EU legislation delivers its overall objective to protect human health and the environment by minimising exposure to these substances. The intention was to take for the first time a cross-cutting look at

endocrine disruptors (building on scientific evidence and the significant amount of data already collected and analysed in the context of finalised and on-going evaluations), with a view to allow an analysis of how the different provisions/approaches on endocrine disruptors interact, identify any possible gaps, inconsistencies or synergies, and assess their collective impact in terms of costs and benefits for human health and the environment, the competitiveness of EU farmers and industry, and international trade.

The Fitness Check was published on 14 October 2020. It highlights the progress made in understanding endocrine disruptors and methodology developed in key research areas since the adoption of the 1999 Community Strategy, as well as legislation introduced to protect citizens from endocrine disruptors, notably for plant protection products and biocides. However, it identified a number of areas with potential for regulatory improvement, notably including the lack of a horizontal approach to identifying endocrine disruptors and the need to review and strengthen information requirements on endocrine disruptors to aid their identification, including their potential effects on vulnerable groups.

Building on the key findings of the Fitness Check, the Communication on a Chemicals Strategy for Sustainability (also published on 14 October 2020) announced that the Commission will:

- propose to establish legally binding hazard identification of endocrine disruptors, based on the definition of the World Health Organization, building on criteria already developed for pesticides and biocides, and apply it across all legislation;
- ensure that endocrine disruptors are banned in consumer products as soon as they are identified, allowing their use only where it is proven to be essential for society;
- strengthen workers' protection by introducing endocrine disruptors as a category of substances of very high concern under the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- ensure that sufficient and appropriate information is made available to authorities to allow the identification of endocrine disruptors by reviewing and strengthening information requirements across legislation;
- accelerate the development and uptake of methods to generate information on endocrine disruptors through screening and testing of substances.

The Commission is confident that the comprehensive range of actions outlined above will allow it to fill the gaps identified by the Fitness Check while at the same time delivering on its Green Deal objective to protect citizens and the environment better against hazardous chemicals.

19. Has the Commission supported any programme that fights disinformation on the risks of vaccination?

Commission's answer:

The Coalition for Vaccination, consisting of European health professionals' and students' associations, was supported with three service contacts (EUR 15 000 per contract from early 2020 budget; one contract per Coalition co-chair) to carry out three parallel advocacy campaigns for vaccination in 2020.

Via the Annual Work Programme 2019, the Joint Research Centre was tasked to carry out a study on behavioural determinants of vaccine hesitancy. The work is ongoing.

A direct contract was awarded to produce a State of Vaccine Confidence in the EU 2020 report (follow-up to a previous report on the same topic).

The work package 8 of the Joint Action on Vaccination (EU-JAV; an initiative complementing the Council Recommendation) conducted an analysis of the factors underlying vaccine hesitancy as perceived by people responsible for national vaccination programmes and collecting best practices to address it. The work is ongoing.

It can be noted that the Annual Work Programme 2020 of the Health Programme contains a call for proposals for stakeholder activities to support strengthened cooperation against vaccine-preventable diseases (EUR 1 million; call designed to further strengthen the Coalition for Vaccination) as well as two calls for proposals on addressing low vaccine uptake (EUR 9 million in total).

20. In 2019, DG SANTE prepared a guidance document on the application of new rules on the origin indication of the primary ingredient, and raised the commitment of the EU alcoholic beverage industry towards consumer information by facilitating the conclusion of two Memoranda of Understanding on the provision of energy value and of the list of ingredients, respectively by the EU spirit and beer sectors. How was the response of the EU spirit and beer sectors in this regard? What measures did the Commission impose to lower the consumption of alcohol? Did the consumption of alcohol decline as a result, by imposing measures to promote health?

Commission's answer:

Contrary to other pre-packaged foods, EU law does not require alcoholic beverages to bear a list of ingredients and a nutrition declaration on the label. In its 2017 report, the Commission concluded that such exemption is not justified and invited the industry to develop a uniform self-regulatory proposal aiming to provide the information in question on all alcoholic beverages.

In 2019, the Commission welcomed the signing of 2 Memoranda of Understanding, by the spirits sector committing to provide energy information on

label and the list of ingredients off label (25 % by 31 December 2020, 50 % by 31 December 2021 and 66 % by 31 December 2022), and in by the beer sector committing to label ingredients and energy values on all beer bottles and cans in the EU by 2022.

The Commission is committed to supporting Member States' efforts to reach the United Nations Sustainable Development Goals including Goal 3.5 on strengthening the prevention and treatment of harmful use of alcohol. The Steering Group on Health Promotion and Disease Prevention and the Best Practice Portal are the major tools to implement this approach by facilitating the implementation of evaluated best practices by Member States with Commission funding.

More specifically, to reduce alcohol-related harm in the EU the Commission launched between 2018 and 2020 the following four projects with a budget of more than EUR 3,5 million coming from the EU Health Programme (all four is still running):

(1) The DEEP SEAS project will develop and pilot a good practice in reducing alcohol consumption through primary care at regional level using Screening and Brief Interventions (SBIs).

(2) The FAR SEAS project (https://far-seas.eu/) aims to develop, pilot and evaluate an evidence-based good practice, at a regional level, to reduce the risk of Fetal Alcohol Spectrum Disorders (FASD) and alcohol-related harm in pregnant women and women of childbearing age.

These two projects will also organise a series of knowledge exchange and capacity building workshops among Member States on specific policy topics related to alcohol, including cancer.

(3) The third project is encompassing three studies:

- a study on the online advertising and marketing in new media, in order to have a better understanding of these practices and on the cross-border implications;
- a study mapping consumption patterns of low and zero alcohol beverages, and analysing their impact on reduction of alcohol related harm (either positive or negative) and;
- a study to evaluate the impact of warning messages of the existing textual and pictorial warnings and a proposal for warning messages based on a state-of-the-art knowledge on alcohol-related harm.

(4) The fourth project will provide a complete mapping (state-of-play) of the existing pricing policies and fiscal measures aiming to reduce the consumption of alcohol and of the products high in fat, sugar and salt (including non-alcoholic beverages) in the countries participating in the EU Health Programme and three other countries (Australia, Chile and the United

States). Best practices will be identified and discussed in nine case studies to support EU Member States considering the introduction of pricing policies and fiscal measures and to help them set up an effective approach.

Finally, as lifestyle patterns and behavioural health determinants such as alcohol consumption have an impact on premature mortality from non-communicable diseases in particular cancer, addressing the risk factors of cancer including alcohol consumption will be an important part of Europe's Beating Cancer Plan to be adopted in early 2021.

With regard to the development of alcohol consumption in general, the Health at a Glance : Europe 2020 is a first reference point (pages 144-145):

- Measured through sales data, overall alcohol consumption stood at 10 litres of pure alcohol per adult on average across EU countries in 2018, down from 11 litres in 2008 (Figure 4.7).
- Many European countries have implemented a range of policies to limit alcohol consumption, including taxation, restrictions on the availability of alcohol, bans on alcohol advertising, and public health campaigns (OECD, 2015).

Data on trends in alcohol consumption since 2019 is not yet available.

Questions on animal welfare and food safety

21. The Platform for Animal Welfare has promoted dialogue on animal welfare, EU rules and standards and better legislative implementation and enforcement. Two Platform meetings were organised in 2019. Moreover, the second EU Reference Centre for animal welfare was designated to work on the welfare of poultry and other small farmed animals. What has the Commission done to further ensure animal welfare within the EU?

Commission's answer:

In addition to the important work of the EU Platform for Animal Welfare and of the EU Reference Centres for Animal Welfare, the Commission has continued to perform its audits of the Member States to improve compliance with EU animal welfare rules. For example, some audits have been targeting the export of live animals.

Furthermore, the Commission has 1) published and disseminated extensive guidance documents, 2) supported Member States' enforcement by regular meetings of the network of National Contact Points for animal welfare during transport, and 3) continued to promote EU animal welfare standards internationally, in particular through a close cooperation with the World Organisation for Animal Health (OIE). Some of these activities have been performed in the context of the EU Animal Welfare Strategy (2012-2015).

In parallel, the Official Controls Regulation adopted in 2017 has provided new tools for better enforcement of the EU animal welfare legislation, including through its empowerments for the Commission to lay down additional rules. One example is Commission Implementing Regulation (EU) 2019/723 on a standard template for Member States' annual reports. This Regulation will bring data on animal welfare that are more comparable, something that will allow for more streamlined and efficient controls in the future.

In the context of the Farm to Fork Strategy, adopted in May 2020, the Commission plans to revise the EU animal welfare legislation by 2023, including on animal transport and the slaughter of animals. The content and scope of this revision will be defined on the basis of a fitness check and impact assessment. They will also identify the extent to which current legislation meets the sustainability objectives of the Farm to Fork Strategy. To ensure that the new legislation is aligned with the latest science, the Commission has already requested the European Food Safety Authority to provide new scientific opinions on animal welfare.

As a general comment, it should be underlined that the legislative proposals on the Common Agricultural Policy (CAP) beyond 2020 aim to make the CAP more responsive to current and future challenges such as climate change or generational renewal, while continuing to support European farmers for a sustainable and competitive agricultural sector. One of the objectives on the future CAP relates to improving the response of EU agriculture to societal demands on food, health and animal welfare. Further, the Green Deal of December 2019 and the Farm to Fork Strategy of May 2020 clearly confirm that CAP plans should lead to the use of more sustainable practices and better animal welfare.

The cross-compliance system already integrated the animal welfare policy into the CAP by including several EU legislation in its scope. In that sense, CAP beneficiaries not respecting these requirements on animal welfare will see their CAP payments reduced proportionally to the severity of their breach. Moreover, animal welfare is included under Farm advisory system which oblige Member States to make available advice for farmers on this issue and therefore increase farmers' awareness of animal welfare relevant EU legislation.

Under the European agricultural fund for rural development (EAFRD) it is possible to support targeted animal welfare measures, but also investments for better infrastructure and better preparedness via knowledge and training measures. The EAFRD supports the welfare of farm animals within the national and regional Rural Development Programmes, based on the respective SWOT analyses and needs assessments. In the programming period 2014-2020, 34 national or regional RDPs (in 18 Member States) have programmed measures on animal welfare supporting management contracts to improve the welfare of different farm animals including mainly cattle, pigs and poultry, but also sheep and goats. A total EAFRD amount of EUR 1.8 billion is programmed for the whole period. In

addition, and often in synergy to this, knowledge transfer and advisory services on the topic of enhanced animal welfare as well as investments in improving housing facilities are supported under rural development.

In addition, the Commission has launched a 'Study of the CAP measures promoting animal welfare and reduction of the antimicrobials use', results are expected by the end of 2021.

22. Following the 2018 judgment of the Court of Justice, DG SANTE launched in 2019 a study on the status of new genomic techniques under Union law. With regard to the implementation of the Directive on the Sustainable Use of Pesticides, in 2019 DG SANTE finalised the work on the establishment of two Harmonised Risk Indicators to estimate the trends in risk from pesticide use, and published the first results of said Indicators. Can the Commission give an update on the results of the Indicators?

Commission's answer:

On 27 August 2020, the Commission published updated EU Harmonised Risk Indicators for pesticides for the period 2011-2018 for the EU-28, including the United Kingdom.

Harmonised Risk Indicator 1 (HRI 1) measuring the use and risk of pesticides, shows a decrease of 17% since the baseline period in 2011-2013, but no change compared to 2017.

Harmonised Risk Indicator 2 (HRI 2), which is based on the number of emergency authorisations, shows an increase of 56% since the baseline period in 2011-2013, and an 8% increase compared to 2017.

These results show that there is no room for complacency if the European Union is to reduce the risks associated with pesticides.

The Commission is working on the development of further harmonised risk indicators, in conjunction with Member States, to better measure the evolution in the risks associated with, and dependency on, chemical pesticides.

Questions concerning the transparency of the APA contracts for vaccines

In the course of the Covid-19 pandemic the Commission has concluded Advanced Purchase Agreements (APAs) with pharmaceutical companies, including CureVac AstraZeneca, Sanofi-GSK, Janssen Pharmaceutica NV, Moderna and BioNtech-Pfizer, and is conducting exploratory talks with Novovax.

In these APAs, the Emergency Support Instrument (ESI) provides the necessary up-front financing to de-risk essential investments in order to increase the speed and scale of manufacturing of successful vaccines. In September 2020, the Parliament

approved, under the ESI, a total of EUR 2,61 billion up-front payments to the companies proposed by the Commission to be done in 2020.

Given that the vaccines are being developed with billions of euros of taxpayers' money from the Union and the Member States, it is important that the Commission makes the contracts transparent, and outlines how it will ensure access to these contracts by EU citizens' elected representatives. In its position on the EU budget for 2021, the Parliament requested that the Commission grants the budgetary authority access to the Covid-19 vaccine-related contracts before the end of the year 2020.

23. When will the Commission respond to the Parliament's demand of transparency on the vaccine-related documents, including the actual contracts? Can the Commission ensure that the documents will be accessible to all Members of the Parliament, who wish to have access to them?

Commission's answer:

An open and inclusive dialogue with the European Parliament and citizens on the European vaccine strategy and its implementation is essential. Commission representatives have attended Parliamentary Committee meetings and responded to numerous parliamentary questions.

Based on its experience with the intense, sensitive and multiple negotiations at the same time, the Commission considers that providing access to the Advanced Purchase Agreements (APAs) during these negotiations would be harmful to the ongoing negotiations process and to the entire procurement procedure. It would put at serious risk the goal of realising cost-efficiently the advance purchase of COVID-19 vaccines for all the Member States. Each APA contains commercially sensitive information. Its release can also undermine the Commission's negotiation position in trying to secure the best possible conditions in future agreements for the next generation of vaccines as well as negatively affect the ongoing procurement procedure for the purchase of COVID-19 vaccines. It can also potentially damage the competitive position of companies and erode their confidence in doing business in and with Europe

As outlined by Commissioner Kyriakides during the European Parliament's Plenary debate, the Commission will, once the entire negations process will be completed, make information from the contracts available to nominated Members of the European Parliament, with specific arrangements.

24. Who are the representatives of the Commission and the Member States in the joint negotiating team responsible for the negotiations on the contracts for the Covid-19 vaccines?

Commission's answer:

The joint negotiation team is a central body in ensuring that the negotiation process is effective and efficient and yields the result of purchasing a safe and

affordable COVID-19 vaccine. In line with the Decision C2020 (4192)[11], experts nominated by Member States work together with the Commission as one unit, the so-called "joint negotiation team". On the Commission side, the negotiations are led by Director-General of the Health and Food Safety Directorate-General. In line with the EU Courts case law, the Commission decided not to disclose the names of the members of the team in order to ensure that the joint negotiation team carries out its tasks independently and without being subject to undue external influence or pressure. Such pressure could indeed negatively influence or jeopardise the ongoing negotiation process and its objective of getting an access to a safe and affordable COVID-19 vaccine.

Each member of the joint negotiation team signed a declaration of the absence of conflict of interest, which among others requires the members to comply with provision of Article 61 of the Financial Regulation[12].

Questions concerning the Remdesivir treatment

On 7 October 2020, the Commission concluded a joint procurement framework deal with the drug manufacturer Gilead, after reports the day before of shortages of the antiviral Remdesivir in the UK, the Netherlands, Spain, and Poland. The Commission agreed to buy 500.000 treatment courses in six months for EUR 1 billion.

Although not all of these funds have been spent yet, 36 participating European countries (inside and outside the Union) have collectively already purchased more than 640.000 vials, amounting to EUR 220 million. The countries' volume of orders differs considerably, even though under the agreement all would have to pay EUR 345 per vial, or on average EUR 2.070 for a course of treatment.

Already in June 2020, the Gilead Sciences lab announced that government health care programmes would be charged 2.340 US dollars for each Remdesivir / Veklury treatment. In the agreement between Gilead and the Commission for the provision of 500.000 Remdesivir treatments, the price would be EUR 2.070, or about 2.440 US dollars per treatment.

25. Could the Commission please explain why, during the negotiations, it was led to pay a higher price than that initially announced by Gilead Sciences?

Commission's answer:

The price was discussed during the negotiations. It was concluded that the price per vial would be the same as Gilead had publicly announced. As the treatment courses vary between 5 – 10 vials per patient, the price is not fixed per treatment

[11] Commission Decision C(2020) 4192 final on the joint EU approach to COVID-19 vaccines procurement

[12] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union.

course but per vial.

Remdesivir is not a new treatment and, until recently, was provided free to US hospitals. The actual cost of producing Remdesivir is estimated to be less than one US dollar a day, or less than five euros for a five-day treatment.

26. Could the Commission please explain how, in the midst of a global pandemic, it justifies the abysmal difference between the estimated production cost and the acquisition cost?

Commission's answer:

Remdesivir is the only therapeutic that has a conditional marketing authorization for the EU. This places the manufacturer in a monopoly position. Gilead published the price and this is the price applied in the contracts.

27. As the contract has already been concluded, could the Commission please make this contract available to the discharge authority? If the Commission refuses to do so, even after the contract has been concluded, could the Commission please provide the CONT Committee information about the mechanism and criteria it has used to determine, before the negotiations, what price it is willing to pay for the drug on behalf of the EU Member States?

Commission's answer: SANTE (lead)

Information contained in the framework contract will be made available, respecting limitations that stem from the confidential nature of some elements.

The price is the same as the one publicly available.

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