Background paper - Workshop on EU Crisis Preparedness and Response

I - Agenda of the workshop session

The workshop will have a duration of two hours, including five ten to fifteen-minute interventions by high-level speakers from diverse horizons, representing EU and national authorities and medical, policy and legal academia. It is divided into two parts each followed by a Q&A session.

The Members of the European Parliament will be able to ask specific questions after each part, however more time will be dedicated for the second Q&A session, considering potential remaining questions linked to Part one.

Agenda of the workshop "EU Crisis Preparedness and Response"	
15:00 - 15:05	**Introductory remarks** *Vice-Chair of the COVI Committee* MEP Andreas GLÜCK (Renew)
15:05 - 15.20	**How can we better prepare for future health emergencies in the EU?** Dr. Andrea Ammon (European Centre for Disease Prevention and Control)
15.20 - 15.35	**PHIRI: harnessing health information to improve pandemic preparedness** Dr. Petronille Bogaert (Sciensano, Belgium)
15:35 – 15:50	**Q&A session with Members**
15:50 - 16:05	**Learning from an expert: the advisory role of researchers in public health policymaking** Prof. Marion Koopmans (Erasmus MC, Rotterdam)
16:05 -16:20	**Coordinative Europeanisation: The EU Institutional Architecture in the COVID-19 Response** Dr. Stella Ladi (Queen Mary University of London, UK)
16:20-16:35	**Governance of the European pandemic response mechanism: review and prospects** Pr. Claude Blumann (University Paris-Panthéon-Assas, France)
16:35 - 16:55	**Q&A session with Members**
16:55 - 17:00	**Closing remarks** *Vice-Chair of the COVI Committee* MEP Andreas GLÜCK (Renew)

II – Presentation of the expert-speakers and affiliations

This section presents the expert-speakers and their short biographies, along the thematic parts, including the respective affiliations relevant for the workshop.

Part 1

- **Dr. Andrea Ammon**, Director, European Centre for Disease Prevention and Control

Dr Andrea Ammon is Director of ECDC, elected for a period of five years extended until 15 June 2024. Andrea joined ECDC as the Head of the Surveillance Unit in 2005. The unit was responsible for developing The European Surveillance System (TESSy), implementing a long-term surveillance strategy for the European Union (EU), evaluating the Dedicated Surveillance Networks (DSN), performing step-by-step transfer of DSN activities to ECDC, revising the EU case definitions and producing an Annual Epidemiological Report on infectious diseases in the EU. From April 2011 to April 2015, Andrea Ammon was Deputy to the Director and Head of Unit for Resource Management and Coordination.

Prior to joining the ECDC, Dr Ammon served in several roles at the Robert Koch-Institute, most recently as Head of Department for Infectious Disease Epidemiology. In this capacity, she maintained and further developed the German national surveillance system; coordinated the national outbreak response team for current and emerging infections; coordinated emergency planning for influenza; directed the national Field Epidemiology Training Programme; coordinated epidemiological research programmes in infectious diseases and provided scientific advice for government Ministries, Members of Parliament, and the public.

The **European Centre for Disease Prevention and Control** (ECDC) is a public health agency of the European Union (EU), operational since 2005. ECDC's ambition is to protect over 500 million people from infectious diseases that are mainly caused by parasites and germs (such as viruses, bacteria and fungi). ECDC collects, analyses and shares data on more than 50 infectious disease topics such as COVID-19, influenza, HIV/AIDS, hepatitis, measles, tuberculosis, antimicrobial resistance and vaccination. ECDC experts assess risks to Europe and provide guidance to help countries prevent and respond to outbreaks and public health threats.

- **Dr. Petronille Bogaert**, Head of Unit EU Health Information System Unit, Sciensano.

Dr. Petronille Bogaert is project researcher and head of unit EU health information systems at Sciensano, Belgium. Her work primarily focuses on European research projects in the area of population health information. She is coordinating the Population Health Information Research Infrastructure (PHIRI) for COVID-19 which aims to strengthen the exchange of COVID-19 health information with 41 partners in 30 countries. The seven European projects she is involved in include the Joint Action Towards the European Health Data Space, EHDS2 Pilot, HERA-IT, BY-COVID and Healthy Cloud. She is a graduate from a double European Master of Public Health. She also holds a Bachelor's and Master's in Biomedical Sciences and has a PhD on the European perspective to support health information systems. She is president of the EUPHA Public health monitoring and reporting section, and she is a member of the ESCAIDE Scientific Committee.

Sciensano is a research institute and the national public health institute of Belgium, with more than 850 staff members who are committed to human and animal health every day. Sciensano's strength and uniqueness lie within the holistic and multidisciplinary approach to health. More particularly, Sciensano focuses on the close and indissoluble interconnection between human and animal health and their environment (the "One health" concept). By combining different research perspectives within this framework, Sciensano contributes in its unique way to everybody's health.

Part 2

➢ **Prof. Marion Koopmans**, Head of the Rotterdam Erasmus MC Department of Viroscience

Professor Marion Koopmans DVM PhD is director of the Department of Viroscience at Erasmus Medical Centre in The Netherlands, the WHO collaborating centre for Emerging Infectious Diseases (EID), director for EID of the Netherlands Centre for One Health NCOH and scientific director of the Pandemic and Disaster Preparedness Centre in Rotterdam/Delft The Netherlands. Her research focuses on emerging infections with special emphasis on unravelling pathways of disease emergence and spread at the human animal interface. Creating global networks to fight infectious diseases systematically and on a large scale is a common thread in Koopmans' work.

Koopmans coordinates the EU funded consortium VEO, which develops risk based innovative early warning surveillance in a One Health context and is deputy coordinator of a recently awarded HERA funded network of centres of excellence for EID research preparedness. In 2021, Koopmans founded the Pandemic and Disaster Preparedness Centre PDPC, a research centre with a focus on the occurrence and prevention of pandemics and climate-related disasters, combining expertise from technical, bio-medical, environmental and social sciences.

Koopmans has co-authored more than 700 articles that have been cited more than 40,000 times

➢ **Dr. Stella Ladi**, Professor, Queen Mary University of London, Panteion University Athens

Dr. Stella Ladi is a Reader at Queen Mary University of London and an Associate Professor at Panteion University in Athens. She is research fellow at the Hellenic Foundation for European and Foreign Policy (ELIAMEP) and Research Associate at the Hellenic Observatory, LSE.

She previously worked as a lecturer at University of Sheffield and University of Exeter. She has also been a Research Fellow at the Barcelona Institute of International Studies (IBEI). She has acted as a public policy expert at the Ministry of the Interior and the Ministry of the Aegean, Greece. In July 2002 she completed her PhD thesis at the University of York.

➢ **Prof. Claude Blumann**, Professor Emeritus, University Paris-Panthéon-Assas, Jean Monnet Chair of European Law.

Claude Blumann is a professor of public law since 2011 at the University Panthéon-Assas (Paris II), Paris, France. His research areas are EU institutional law, EU substantive law, EU litigation, and EU policies. He wrote central publications in France on EU Institutional Law and EU Internal Market Law. Most recently, he wrote “The adaptation of the functioning of the institutional system to the COVID crisis” in 2020.

He is a regular contributor to a variety of internationaly and europeanly recognised scientific journals such as the Quarerly Review of European Law, the Review of the Common Market and the European Union, European law Notebooks, or the Review of European Affairs. He is also responsabile for various sections in the Yearbook of European Law.

He has been involved in numerous international cooperation activities through teachings and conferences in many Member States such as Germany, Belgium, and Italy, and in non-EU member States, including Vietnam, Turkey, or in the United-States. From 1997 to 2001, he was the honorary president of the Commission for the Study of European Communities. Finally, he is also an expert consultant for the French Ministry of Research, the French High Council for the Evaluation of Research and Higher Education, the European Commission and the European Parliament, as well as for private organisations.

III - Context of the workshop

In order to ensure effective crisis preparedness and response/management at the European level, the European Union has adopted a wide range of actions, including improvements in its preparedness and response architecture and legal instruments, the establishment of the European Health Emergency Response and Preparedness Authority, and financial support to the Member States' public health systems. The EU is also active at the international level considering the global character of cross-border health threats and crises.

Improvements to the EU's preparedness and response

The Council adopted in October 2022 the final building blocks of the European Health Union including the Regulation on Serious cross-border health threats, the Regulation on the extended mandate of the European Centre for Disease Prevention and Control (ECDC), and the Emergency Framework Regulation to provide extra powers to the European Health Emergency Preparedness and Response Authority (HERA). These new rules build a strong legal framework to improve the EU's capacity in the vital areas of prevention, preparedness, surveillance, risk assessment, early warning, and response[1].

The European Commission published its first annual State of Health Preparedness Report on 30 November 2022, pointing out the progress made in the fields of preparedness and response since the beginning of the COVID-19 pandemic, focusing especially on medical counter-measures. The Report is based on the lessons learned during the pandemic and the work undertaken to strengthen preparedness and response. It also determines new challenges facing public health authorities and outlines the concrete actions that the Commission will take to directly address them[2]. This report is based on the three priority health threats identified by HERA in July 2022 (pathogens with high pandemic potential; chemical, biological, radiological and nuclear threats; antimicrobial resistance), and sets out key actions to further improve EU's preparedness in the next years. The next steps for better preparedness in medical countermeasures focus on four axes with concrete actions for 2023[3]:

- Establishing a financing system in order to encourage private investment in the development and production, where appropriate, of a wide range of medical countermeasures (HERA INVEST - €100 million, COVID-19 Vaccines 2.0 project - €80 million);
- Developing the Medical Countermeasures Intelligence (MCMI) Platform for threat assessment and intelligence gathering: This platform would be dedicated to deal with

[1] European Commission, Press release, European Health Union: building a stronger EU health response, 24 October 2022, https://ec.europa.eu/commission/presscorner/detail/en/IP_22_6363
[2] European Commission, Press release, European Health Union: first State of Health Preparedness Report shows EU's strong progress, 30 November 2022, https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7154
[3] Ibid n1.

"supply risk management and management systems for stockpiling"[4];

- Ensuring resilient supply chains and production capacity by, amongst others, strengthening EU FAB for the rapid production of medical countermeasures such as vaccines, and developing a dynamic purchasing system;
- Ensuring an international coordination and global collaboration. The Report should be read in conjunction with the new EU Global Health Strategy adopted in November 2022, which supports the global effort to strengthen preparedness for future health emergencies. For example, in December 2022, HERA and the WHO Hub have already agreed to strengthen cooperation on countermeasures for pandemics and epidemics.[5]

In order to foster research and innovation in developing prophylaxis for COVID-19 and long COVID, the European Commission announced in its Communication of 6 May 2021 an EU strategy on COVID-19 therapeutics complementing the EU Vaccines Strategy. The full lifecycle of medicines is covered by the Strategy: from research, development and manufacturing to procurement and deployment. This Strategy is part of the European Health Union, in which all the Member States jointly prepare and respond to health crises, but also ensure the availability of treatments needed to treat COVID-19[6].

To ensure that the health crisis can be monitored and managed at European level, the European Parliament has adopted resolutions and called for further actions beyond the COVID-19 pandemic:

- In its Resolution adopted on 15 May 2021, on accelerating progress and tackling inequalities towards ending AIDS as a public health threat by 2030, the European Parliament called on the Commission and Member States to explore the possibility of dissociating research and development expenditure from the price of medicines, for example through the use of patent pools, open access research and grants.
- In its Resolution adopted on 7 July 2021 on trade-related aspects and implications of COVID-19, the European Parliament emphasised the key role played by public-sector resources, allowing pharmaceutical companies to de-risk the whole vaccine value chain; it also considers that a multilateral intellectual property rights framework can provide protections and incentives that are critical for preparedness against future pandemics.

EU's financial support to Member States' public health systems

The European Union has also decided to increase the investments in the field of public health. The objective of the following EU programmes is to increase the support of the resilience of health systems:

- The Recovery and Resilience Facility (RFF) was established on 16 August 2020, making available grants and loans amounting to €723.8 billion for the Member States. It is composed of six pillars, including "Health, and economic, social and institutional

[4] Ibid n1.
[5] European Commission, News announcement, Global Health: HERA and WHO Hub strengthen cooperation on pandemic and epidemic countermeasures, 6 December 2022, https://health.ec.europa.eu/latest-updates/global-health-hera-and-who-hub-strengthen-cooperation-pandemic-and-epidemic-countermeasures-2022-12-06_en
[6] European Commission, press release, Coronavirus: Commission proposes EU Strategy for the development and availability of therapeutics, 6 May 2021.
https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2201

resilience".

- Recovery Assistance for Cohesion and the Territories of Europe (REACT-EU): This new instrument created under the NextGenerationEU aims at strengthening health and care systems in the Member States.
- Cohesion Funds: In order to support the Member States to face the pandemic crisis, the Commission has launched in April 2020 two packages of measures: the Coronavirus Response Investment Initiative (CRII) and the Coronavirus Response Investment Initiative Plus (CRII+) to the extent of giving the opportunity to the Member States to extend the cohesion funds to the pandemic crisis.
- InvestEU Programme: By supporting new investments, innovation and job creation in the EU for the period 2021-2027, this Programme constitutes plays a key role in the development of science and the clinical research;
- The Neighbourhood, Development and International Cooperation Instrument (outside the EU): For the period 2021-2027, this funding instrument has been granted of a general budget of €79.5 billion, including €3.18 billion which are dedicated to "rapid response actions".

Together, the total support to health emergency preparedness amounts to almost €30 billion under the current financing period, according to estimates of the European Commission.

Establishment of the Health Emergency Preparedness and Response Authority

In addition, modifications to the organisational structure of the EU's preparedness and response have been adopted. Besides in particular the extension of the ECDC's and EMA's mandate, the Health Emergency Preparedness and Response Authority (HERA) has been established in September 2021 to ensure a better organisation of European actions in case of health emergencies. The missions of HERA are **strengthening health security coordination** within the Union during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort; **addressing vulnerabilities and strategic dependencies** within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures; and contributing to **reinforce the global health emergency preparedness and response** architecture. It has been allocated of a budget of €6 billion for the period 2022-2027 funded by the current MFF (part of which will come from the Next Generation EU fund).

Considering the key role of HERA in the European Health Union, which aims at strengthening the EU's health emergency response and preparedness, by preventing, detecting and quickly responding to health emergencies, the European Parliament has decided to support the actions and missions of HERA:

- Regarding HERA's mandate, the European Parliament considered in its Resolution on the Pharmaceutical Strategy for Europe that HERA should identify health threats, initiate and support the development of innovation, establish a list of medicinal products of major therapeutic interest at EU level, facilitate their production within the EU, promote their joint purchase, and build up strategic stocks of these medicines.
- The European Parliament criticised the decision of the European Commission not to set up HERA as a fully-fledged independent authority and not to use the ordinary legislative procedure involving the European Parliament, limiting accountability and

transparency (Resolution on EU Transparency in the development, purchase and distribution of COVID-19 vaccines).

- In its October 2022 Resolution on the proposal for a Regulation on serious cross-border threats to health (adopted as Regulation (EU) 2022/2371), the European Parliament emphasised the need for coordination and cooperation of the different bodies established in the EU, including the Health Security Committee, the European Centre for Disease Prevention and Control, the European Medicines Agency and HERA to avoid any duplication of efforts, in particular with regard to the implementation of the emergency framework of measures for ensuring the supply of crisis-relevant medical counter-measures.

International support to investment in crisis preparedness and response

At an international level, and due to the urgent need to step up investments to strengthen the capacity of developing countries to prevent, prepare for, and respond to future global health threats, new funds have been established, with the support of the G20. Indeed, on 30 June 2022, a Financial Intermediary Fund (FIF) for Pandemic Prevention, Preparedness and Response (PPR) has been adopted by the World Bank board of Directors, in collaboration with the EU, which has helped to the establishment of this Fund following a hybrid donor meeting in Brussels on 19-20 July 2022. As a matter of fact, this meeting helped to adopt a coordinated approach regarding the FIF's scope and objectives, as well as its governance.

Indeed, due to the economic disparities between each State, not all of them are able to ensure effective crisis management of the pandemic. Thus, the FIF has been established in order to assist small and middle-income countries, in particular by filling the existing national capacity gaps in major areas as defined by the WHO's International Health Regulations adopted in 2005. Following its objectives, and the need to ensure an international cooperation, an agreement has been reached to further engage partner countries, as well as third parties (civil society organisations, potential implementing entities, and other stakeholders) on the FIF's design. Thus, the World Bank has officially established the FIF on 8-9 September 2022[7].

As a consequence of the latest massive outbreaks of the COVID-19 pandemic in the Popular Republic of China (PRC), Health Commissioner Stella Kyriakides proposed support from the EU by offering free vaccines, following a meeting of the EU Health Ministers. This action has been made possible in particular thanks to the large stocks of vaccines purchased by the Member States[8].

Simultaneously, some Member States decided to set up controls in order to avoid the development of new variants in their territories, although the Health Commissioner called for coordinated action at the European level, including pre-departure testing. During a meeting of the Health Security Committee in December 2022, Member States representatives decided to set up pre-departure testing for travellers coming from PRC[9]. The ECDC adopted an opinion on 3 January 2023, observing an important record of COVID-19 cases in the PRC, and the lack of relevant data on COVID-19 cases, as well as on hospital admissions, deaths and intensive care unit capacity in China. Nevertheless, the ECDC concludes that the EU/EEA

[7] World Bank, Kahkonen S., Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response - Engagement and Overview, https://projects.worldbank.org/en/projects-operations/products-and-services/brief/financial-intermediary-fund-for-pandemic-prevention-preparedness-and-response-engagement
[8] Financial Time, https://www.ft.com/content/1c46e139-4b98-4e3a-b66d-7a04c27893d2
[9] Reuters, 3 January 2023, https://www.reuters.com/world/europe/eu-discuss-coordinated-response-china-covid-situation-wed-2023-01-02/

should not be impacted by the increase of COVID-19 cases in China, notably thanks to high population immunity in Europe. The EU's Integrated Political Crisis Response Group (IPCR) and European Commission are currently preparing a set of preventive measures, including hygiene and health measures e.g. mask recommendations on flights from China; wastewater monitoring for aircrafts; genomic surveillance at airports; but also increasing the European vigilance on testing and vaccination[10].

[10] Swedish Presidency of the Council of the European Union, Presidency Statement on the Coordination of COVID-19 travel measures, 4 January 2023. Available at: https://swedish-presidency.consilium.europa.eu/en/news/presidency-statement-on-the-coordination-of-covid-19-travel-measures/.

IV – Background to interventions

How can we better prepare for future health emergencies in the EU?, Dr. Andrea Ammon (European Centre for Disease Prevention and Control)

ECDC Director, Andrea Ammon, will focus her presentation on the lessons learned from the COVID-19 pandemic, and in light of ECDC's recently strengthened mandate look into how we can better prepare for future health emergencies.

The COVID-19 pandemic has provided us with a unique opportunity to learn lessons on how international organisations and countries could be better prepared to deal with future health emergencies.

Following a brief overview of the mission and role of the European Centre for Disease Prevention and Control (ECDC), Dr Ammon will highlight some of the lessons learned from the pandemic, from conducting after-action reviews to building capacity and resilience in the public health systems and improving surveillance and preparedness.

Furthermore, Dr Ammon will emphasize that these lessons are transferable to other health threats such as the risk of the emergence of new pathogens and resistance to antimicrobials, and that future preparedness planning needs to be based on a multi-sectorial and multi-disciplinary approach.

In view of some of the gaps identified during the pandemic, EU Institutions and Member States called for a stronger role for ECDC in coordinating and standardising EU/EEA surveillance and in enhancing pandemic preparedness.

As part of the final building blocks of the European Health Union, the adoption of a reinforced ECDC mandate in November 2022, together with the new regulation of Serious cross-border health threats, allows the Agency to have an even stronger role in six main areas – epidemiological surveillance; foresight, modelling and analytics; better preparedness and response in Member States; EU Health Task Force; health system capacity; and an expanded international role.

Dr Ammon's final focus will be on how we all – policy makers, national, EU and International organisations – need to collaborate together across all sectors, and at all levels, to create resilience and to build trust, thus contributing to the EU and global health security architecture.

Population Health Information Research Infrastructure: harnessing health information to improve pandemic preparedness, Dr. Petronille Bogart (Sciensano, Belgium)

When the COVID-19 crisis hit, the resilience of health systems, defined as the ability to absorb, adapt, and transform to cope with shocks, was found to be different in European countries. The pandemic showed that a substantial number of European countries had health information systems that were not well equipped to accommodate data and information flows that were needed. Also, rapidly sharing data and information across European borders and ensuring comparability of data proved to be difficult. To support the efforts to strengthen health systems in Europe and their preparedness, important lessons can be learned, and best practices can

be put forward to help countries assess their own response to the COVID-19 pandemic. In times of crisis and beyond, the availability and trustworthiness of health information is of great importance. PHIRI is playing a key role in this.

PHIRI, the Population Health Information Research Infrastructure, facilitates the best available evidence for research on health and well-being of populations as impacted by COVID-19. PHIRI allows for better coordinated European efforts across national and European stakeholders to generate the best COVID-19 population health knowledge. It supports research across Europe through the identification, access, assessment and reuse of population health and non-health data to underpin public health policy decisions. PHIRI increases national and European pandemic preparedness through research and policy support. An integrated and sustainable EU-wide population health information system facilitates better harmonised response at EU level to the COVID-19 pandemic with far-reaching repercussions on citizens' health, wellbeing, mobility, and employment. PHIRI now covers 30 European countries, partnering with national public health institutes, ministries of health and/or research, research institutes and universities.

The Health Information Portal is a one-stop shop facilitating access to population health and health care data, information and expertise in Europe. The Portal includes a metadata catalogue on health data sources, its providers and managers; a metadata catalogue on trainings in all areas of population health information; overviews of EU health information projects; and a dedicated COVID-19 policy measures corner. The Health Information Portal works towards services and tools necessary for researchers to access and link different data sources and to use Pan-European data in a GDPR compliant, federated way.

PHIRI performs country visits, to map 12 national health information systems that monitor the effects of COVID-19 on population health. Strengths and weaknesses of the COVID-19 health information systems of Member States are identified and recommendations are formulated.

PHIRI provides a biweekly platform for rapid exchange of policy questions: quick exchange between experts and institutions supporting the national governments in the crisis response. Examples of key topics addressed are long-COVID, COVID-19 legislation for data exchange, digitalization and key COVID-19 statistics such as mortality. Through this unique platform, PHIRI has been able to respond to urgent questions put forward by policy makers for which European response was needed.

Public Health Foresight Studies are essential to gain insight in future health impacts of the SARS-CoV-2 pandemic, e.g. due to changes in regular healthcare delivery, lifestyle, and socio-economic developments. Foresight is a systematic, participatory, and vision-building process that explores the future to anticipate future trends and support present-day actions. PHIRI supports European countries in developing future scenarios to gain insights in possible future health impacts of the COVID-19 outbreak and beyond.

There is an increased need for more global health approaches requiring sophisticated and sustainable health information systems and the development of new digital health technologies. These digital health technologies require skilled professionals to manage the data and public health information in efficient ways. At the same time, new challenges in public health, such as pandemics, are demanding highly qualified experts to respond to them. Currently, large inequalities exist regarding the availability and training of qualified public health information professionals in Europe. PHIRI strengthens the public health information workforce in Europe with several capacity building activities on health information and

knowledge translation.

Learning from an expert: the advisory role of researchers in public health policymaking, Prof. Marion Koopmans (Erasmus MC, Rotterdam)

Preamble / perspective: Prof. Koopmans' perspective is that of a scientist with a history in public health (as head of a national virology laboratory), and of academic emerging disease preparedness research (director of newly established pandemic and disaster preparedness centre). When heading the national virology laboratory, Prof. Koopmans was engaged with ECDC as national microbiology focal point. Since then and continuing in my academic role, she has served as advisor in national outbreak management teams (for Ebola, Zika, influenza, avian influenza, monkeypox, COVID-19, COVID in mink), in the national health council (vaccine recommendations), the expert group on COVID for president von der Leyen, and in various WHO advisory functions (a.o. the IHR emergency committee, the technical advisory group on virus evolution).

What are the lessons learned in connection with the EU response and coordination mechanisms between Member States in the early stages of the COVID-19 pandemic? Since then, which opportunities have arisen and which shortcomings have become apparent, including for example in the areas of resources to public health systems, industry supply value chains, and access to medicines?

Critical observations:

1. European laboratories were the first to develop key diagnostic assays that were distributed globally through an informal international network of specialised laboratories that have collaborated through different grants. This network was convened by WHO. This is a critical pillar of EID response. Assays were deployed globally, by WHO, guided by risk targeting of regions at highest risk of importations.
2. Several EU scientists were part of the initial WHO technical advisory groups convened in February 2020 to identify key knowledge gaps. This set the agenda for rapid research funding calls, and a network of globally collaborating researchers convening biweekly to provide input to the WHO response effort.
3. The core networks and sharing systems in place in Europe (EVDlabnet, EVAg, ENA, PREPARE, COMPARE/VEO a.o.) were asked by the EC funders to pivot to COVID-19 response. This yielded key initial findings regarding disease characteristics and helped provide insight in modes of transmission.
4. EU funded clinical research networks were instrumental in doing decisive clinical trials, although the time to result was longer than needed due to fragmentation of research response in Europe and within Member States.
5. Once the pandemic hit Europe, every country seemed to respond on its own. What ensued was a rather uncoordinated international response with differences between Member States that were not supported by evidence (e.g. border closures).
6. Proper systems to assess the severity of the incoming pandemic were not in place, and there was a patch work of different surveillance methods within and between countries. As a consequence, Europe initially had to rely largely on information from Asia, which was difficult to assess.

7. Lack of collaboration also was visible in the choices made by countries with regards to shipments of critical supplies, leading to uneven access to essential resources (for instance test kits, reagents, face masks, respirators).

8. The uncertainties in underlying assumptions are well known in emerging infectious disease response, but were difficult to understand for citizens, experts from unrelated fields, and (some) policy makers. There was no mechanism to channel this debate, including the increasing amount of misinformation.

9. The prepositioned and trained preparedness plans were (are?) not well connected between public health, care and cure sector, and did not take critical resource limitations into account. They rapidly needed to be extended to include wider representation, including clinical experts, long term care professionals who were not necessarily familiar with pandemic response.

10. The potential involvement of animals had not been systematically included in preparedness and response plans.

11. ECDC risk assessments are valued and of high quality but work primarily with public health partners and have (and seek) limited input from specialised research networks.

12. The EU COVID-19 data portal was launched fast, but the technical infrastructure was funded from grants with many use cases competing for the limited resources.

13. Privacy issues that are interpreted differently in each Member State hampered proper outbreak research and surveillance, as well as international collaboration in clinical studies.

What other areas, key to strengthen the EU's strategic health preparedness and response system, should future State of Health Preparedness reports also focus on, especially with respect to the COVID-19 and potential future pandemics?

14. As a majority of new diseases result from spill over of animal pathogens, there is much to be gained with including a One Health lens in pandemic preparedness planning and (research) response. This is not mentioned in most future pandemic preparedness plans.

15. Basic research has led to the development of mRNA vaccines, novel diagnostic platforms, innovative trial methodologies, basic insight in viral evolution, etc. Investments in basic science continue to be critical.

What are the challenges related to the Commission's planned development of a Medical Countermeasures Intelligence (MCMI) Platform for threat assessment and intelligence gathering, for example in relation to methodology, IT tools, minimum common standards, and criteria?

16. An intelligence system that tracks development of medical countermeasures seems a good idea, although this may not be straightforward in view of intellectual property protection. As a large part of research into medical countermeasures occurs outside of Europe, the scope of this MCMI platform would need to be global. For threat assessment, from the written information, there is a risk of duplication of efforts with the work of ECDC. There may be opportunity for scientific input through the recently launched HERA laboratory research network and the above-mentioned networks, a.o. This platform ideally would also include countermeasures that can be implemented in

the veterinary field.

What should be taken into consideration in the process of improving European governance and cooperation between existing and newly established institutions and bodies such as HERA, in terms of, for example, joint procurement agreements, adapting regulations, data exchange, and research;

17. Europe had many elements in place that facilitated rapid research response and contributed to essential knowledge gathering directly inputting into policy advise. However, these initiatives were not funded for pandemic response, which therefore needed to be done at the cost of other research programs. This basis nonetheless offers essential building blocks for a longer-term sustainable preparedness research and response network, complementary to the ECDC-MS public health networks. The prepositioned EU funded research preparedness initiatives were underutilized at level of Members States which delayed clinical trials. Although the network activities provided crucial information, they were not connected to the formal pandemic response, including the ECDC risk assessment group and networks. The use of the EU open data portal should be stimulated. This includes access to public health data.

18. The massive incursion of private sector companies during the pandemic constitutes a risk for health system strengthening, as these focus on profitable parts of the care sector at the cost of rare but essential facilities that are needed for preparedness (e.g. large-scale routine testing versus customized care).

19. The establishment of HERA is important in that it recognizes the need for investment in preparedness. However, based on current budgets, this seems to be a very small investment (e.g. 100 million for medical countermeasures, 80M for vaccines).

Which key aspects should be taken into account in developing a multilateral and globally coordinated response to building preparedness? What could be the role of the EU in this process, including in terms of its participation in the World Bank's PPR FIF? How can the inclusion of social, political and economic and equity considerations be ensured in the response at global scale?

20. The organisation of research networks in the European research space has contributed to the building of collaborations that have been a strong backbone for the research response during the pandemic and as such provides an interesting model for future strengthening. However, the networks had to work through full funding applications during crisis response, which is not a sustainable model. For proper pandemic research response, contingency budgets that can be released immediately are needed.

21. There is a disconnect between biomedical and social sciences research, which is a key gap. While these fields have focused research priorities by themselves, there are key knowledge gaps in for instance assessing impact form pandemic control measures against societal impact, with an evidence base that is suitable for policy advise.

Coordinative Europeanisation: The EU Institutional Architecture in the COVID-19 Response, Dr. Stella Ladi (Queen Mary University, London)

The EU has demonstrated a fair amount of adaptability to the COVID-19 pandemic by drawing lessons from previous crises. The EU institutions and Member States seem to have come into terms with poly-crisis and in the first instance reacted in a coordinated manner making important decisions such as the NextGenerationEU and the EU Vaccines Strategy. This new phase can be best described as coordinative Europeanisation which is characterised by a bottom-up approach to the participation of EU Member States in the design of emergency policies by EU institutions. The argument is illustrated by drawing in to sectors not related to health policy but very central to the COVID-19 crisis: The NextGenerationEU and the freedom of movement in Schengen. The first seems to be pathbreaking and is undoubtedly one of the brightest moments in the EU's response up to now. The second, although it has managed to corroborate the EU solidarity among Member States, faces important challenges during its implementation. A new coordinative relationship between the EU institutions and its member-states is in the making but the challenge is to improve mutual trust, a value and principle that is undergoing important changes with the pandemic.

Coordinative Europeanisation indicates a shift from coercive Europeanization (Ladi and Graziano, 2014) or earlier uploading of good practices (Boerzel, 2002). **I**t is a bottom-up process where the Member States are actively involved in the policy making process early on in order to guarantee the highest level of implementation possible. This involvement during the COVID-19 crisis was often informal and online. The COVID-19 crisis led to a deeper understanding of interdependence between the Member States and EU institutions. It was accepted that solutions are often good enough, but it is important to act. The European public would not accept a lack of coordinative response during COVID pandemic, and this made European leaders focus and compromise recognising that COVID-19 apart from a health crisis was also an existential crisis for the EU project. It is important to note that coordinative Europeanisation takes place in parallel with intergovernmental and supranational tendencies.

EU's Institutional Response to COVID-19

- Slow at the beginning because of uncoordinated response and because of change in pattern of work but eventual speeding up in various areas: RRF, vaccines strategy, etc.
- Co-ordinating role of the European Council has been central similarly to other crises.
- The European Commission has also been central with increase of powers and day-to-day management but also because of Brussels reached out to the national capitals via online meetings (Commission - Capital networks)
- The **Council of Ministers** found it harder to adjust and most of the work took place at the COREPER
- The **European Parliament** also had a harder time adjusting but played an important role in the negotiation of the MFF and as a result the RRF

Conclusions – Policy Recommendations

- The nature of the crisis (existential and threat to human life) was central in leading to quick solutions.

- Co-ordination during crisis between Member States (capitals) and the EU institutions at an early stage is central in order to have solutions that can be implemented and produce immediate results.
- Foresight and strategic crisis management are central for future preparedness (see Chief Scientific Advisors Report, 2022)
- Critical infrastructure and institutions (e.g. national health systems, ECDC, HERA) need to be strengthened and be closely connected to be able to respond to future health crises.

Governance of the European pandemic response mechanism: review and prospects, Prof. Claude Blumann (Paris-Pantheon-Assas University)

Recent EU regulations and legal bases. The EU suffers from the weakness of its competence in the field of public health, hence the use of what might be called 'legal expedients'. In other words, uncertain legal bases were used[11]. Recently, three important texts completed the legislation: the Regulation on the ECDC, the Regulation on the legal framework for HERA, and the Regulation on serious cross-border threats to health. These three texts are direct extensions of the COVID-19 crisis. The legal bases chosen for these acts are questionable. Article 168(5) TFEU only allows the adoption of incentive measures, excluding harmonisation of national legislation. It is however clear from the text of the Regulation on serious cross-border health threats that this novel legislation goes beyond the TFEU's mandate. The consensus among Member States in the Council and the favourable vote by the EP are not sufficient. As for the establishment of HERA, its legal basis has the disadvantage of leaving the EP out of the procedure. Furthermore, the establishment of HERA is at odds with the objectives of Article 122 TFEU, whose centre of gravity is economic and not public health. As a result, these pieces of legislation are fragile. There is no risk of annulment considering that the time limit for appeal has expired, but there could be exceptions of illegality pursuant to Article 277 TFEU. The solution could be to extend the EU's powers via a simplified revision procedure of the TFEU.

EU preparedness to respond to public health crises. The EU has learned a great deal from the health and food crises that have hit it over the last few decades. In financial and material terms, the balance sheet is generally positive. In the 2021/2027 multiannual financial framework, public health inherits EUR 5.3 billion, including what comes from the "Next generation EU" recovery plan, compared to 450 million for the 2014-2021 period. This is a twenty-fold increase, which is considerable.

In terms of staff, DG SANTE employs 731 people (2.3% of total staff), in addition to DG ECHO (civil protection), 877 staff, or 2.7% of the total. DG ECHO deploys many units in the field (more than 1,400 rescuers and 100 search dogs, 29 search and rescue teams, 6 medical teams) and played an important role in the COVID crisis. It has enabled the exchange of masks and various medical equipment between EU regions and has sent personnel in support of the Member States. In my opinion, the EU has sufficient resources to accomplish its tasks. To this must be added the ECDC, whose budget has tripled between 2020 and 2021 (€179 million) and which employs around 350 staff. The system seems quite robust.

However, there is no comparison with a Member State (in France the annual health budget amounts to 227 billion euros and represents 9.1% of GDP). The EU administration is not a field administration and the competence of the EU in the field of health remains quite minimal. What can be improved? Progress can be made in simplifying the legislation and rationalising the prevention and reaction bodies. As regards the cross-border health threats and thus the actions provided for by Art. 4(b) to (d) of Regulation 2021/522, it could be possible to direct about 50% of the credits abovementioned towards medical countermeasures and aid for the constitution of national stocks.

Multiplication of structures to combat pandemics and the resulting complications. In addition to the coordination of national networks, the new texts multiply the number of

[11] Articles 196 (*civil protection*), 168(5) (*public health*), and 122 (*economic policy*).

structures. In this respect, Regulation 2022/2370 on the ECDC extends its tasks, even though this body encountered numerous difficulties during the COVID crisis. In addition, the appropriateness of entrusting the management of the early warning system (EWRS) to the ECDC is debatable. For food products (Rapid Alert System for Food and Feed) and industrial products (Rapid Exchange of Information System), the Commission is responsible and better equipped to do this. However, the EWRS is not regulated by the ECDC Regulation but by the Regulation of cross-border health threats.

Regulation (EU) 2022/2372 provides a legal framework for the adoption of medical countermeasures in the event of a crisis and is particularly relevant to HERA (equivalent to a Directorate-General). HERA deals with monitoring and research, but its main role is the management of contracts, such as the purchase of medicines, vaccines and other medical devices ("medical countermeasures"): a pooling function that was assigned to the Commission during the emergency of the COVID crisis. The management of medical countermeasures is the responsibility of a Health Crisis Management Board composed of representatives of the Member States and the Commission. The Council is chaired by the Commission and the Member State holding the rotating (EU) Council Presidency. The Board plays a key role as it "ensures the coordination of the action of the Council, the Commission, the competent bodies and organisations of the Union and the Member States...". It also works in conjunction with the ECDC and the EMA. In addition, a (comitology) committee assists the Commission in decision-making.

The Regulation on cross-border health threats appears to duplicate the HERA Regulation. It also takes up the requirement for coordination between all partners. It also returns to the measures for joint procurement of medical products and others on medical countermeasures. It is difficult to see the demarcation between what comes under HERA and what comes under Regulation 2022/2371. One of the original features of the regulation is that it allows for the establishment of a sort of crisis mechanism enabling official recognition of a public health emergency at the EU level. This will enable medical countermeasures to be activated, the European Medicines Agency to be called upon and the controls carried out by the ECDC to be reinforced. The regulation is also characterised by a number of bodies, including the Health Security Committee (HSC), which is made up of representatives of the Member States. "It coordinates in liaison with the Commission" is a recurring phrase. But it is the Commission that adopts the plans for prevention, preparation and response to health threats and emergencies, which are also supposed to coordinate the national plans. In addition, there is a committee of independent experts to give its opinion on the preparation of cooperation, preparedness and response plans. It is composed of independent experts. In addition, there is a comitology committee when the Commission has to take implementing measures in the legal sense of the term. In conclusion, there seems to be an excess of legislative and regulatory texts that tend to repeat themselves and overlap. Coordination is everywhere but a body will have to be appointed to coordinate the coordinators.

International developments. The EU is not a WHO member but a main contributor and has an unofficial observer position. The Regulation on cross-border health threats notes the EU's commitment to participate in the development of an international convention under the aegis of the WHO on pandemic prevention, preparedness and response. The Council of the EU authorised the opening of negotiations by the EC on 21 March 2021.

The EC can negotiate on issues falling within the competence of the EU (rather small it should be recalled, Art. 168 TFEU). But the negotiating directives are not public (see TTIP). However,

the question of the EU's competence remains: can the EU become a contracting party to this convention? Although the EU's competence in public health matters is limited, the answer is probably positive (e.g. the UN Convention on the Law of the Sea and the case law of the ECJ).

An intergovernmental negotiating body has been set up within the WHO, made up of all WHO member states and a secretariat provided by the WHO. A draft is already very advanced, but the conference seems to be heading towards a North-South confrontation, especially since the second session in June 2022 which decided in favour of a binding legal instrument. This also raises the problem of the legal basis for the future treaty (probably Article 19). The future convention could be governed by a body called the "Conference of the Parties" (COP) composed of all the contracting parties to the convention. A Bureau of the Parties, a small executive, will be elected by the Conference.

The EU is not a member of the World Bank either, but nothing prevents its participation in the implementation of the Financial Intermediary Fund (FIF) for Pandemic Prevention, Preparedness and Response (PPR) (June 2022), intended to support developing or low-income countries. The EU is even one of the founding contributors and preceded some of its Member States. The technical management of this new fund should be entrusted to the WHO, while the EU and other participants will sit on a board of trustees. A total of USD 1.3 billion has been mobilised so far and the EIB would have the status of an implementing entity.