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Delegations will find attached document COM(2022) 669 final.

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ANNEXES 1 to 2

ANNEXES

to the

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

State of Health Preparedness Report

Annex.1 – State of implementation of medical countermeasures preparedness actions

	Action Number	Main actions planned	Current level of implementation			
			Level 0	Level 1	Level 2	Level 3
Threat assessment and intelligence gathering	*1.1*	*Develop a list of threats priorities and work on threat scenario-building*				
	1.2	*Develop a list of critical medical countermeasures*				
	1.3	*Establish an MCMI Platform*				
	1.4	*Establish and operate a network of laboratories and research institutes*				
	1.5	*Consolidate wastewater surveillance capacities in the EU*				
Advanced research and development of medical countermeasures	*2.1*	*Reinforce horizon scanning capacities for emerging innovations and technologies in the field of medical countermeasures*				
	2.2	*Develop a Strategic Research and Innovation Agenda on pandemic preparedness*				
	2.3	*Consolidate EU trials networks*				
	2.4	*Increase financing for high-risk R&D projects via so-called "HERA INVEST"*				
	2.5	*Invest in next generation vaccines*				
	2.6	*Develop a roadmap to support research of new and repurposed antivirals*				
	2.7	*Support the development and access to medical countermeasures, including medical devices and diagnostics*				
Access to medical countermeasures – resilient supply chains and	*3.1*	*Develop a medical countermeasures supply chain risk management framework*				
	3.2	*Increase manufacturing capacity in the EU with EU FAB*				
	3.3	*Establish EU level stockpiles of critical medical countermeasures*				

production capacities	*3.4*	*Develop an EU strategic approach to stockpiling medical countermeasures*				
	3.5	*Revise the joint procurement mechanisms for medical countermeasures*				
International coordination and global activities	*4.1*	*Expand strategic partnerships in health and preparedness at the regional level*				
	4.2	*Support LMICs to build capacity and expertise in preparedness, response and local manufacturing*				

- Level 0: Development phase
- Level 1: Preliminary/study phase
- Level 2: Pilot phase
- Level 3: Implemented

Annex.2 – 10 Lessons learned from the COVID-19 pandemic, progress and development underway

10 Lessons learned	Progress so far	Further development
#1: Faster detection and response depends on stronger global surveillance and more comparable and complete data	• Launch of EpiPulse[1]- the European surveillance portal for infectious diseases - by ECDC in 2021. • Reinforcement of surveillance and pathogen sequencing capacities in Member States, including the EUR 77 million worth of ECDC grants with extra funding from the European Commission. • Technical support to the development of the Epidemic Intelligence from Open Sources (EIOS) initiative[2] • Collaboration with Africa CDC to ensure rapid threat detection and validation through the "EU for Health Security in Africa - ECDC for Africa CDC" project. • Implementation of automated processes by ECDC for more rapid data collection from public sources. • Strengthening and integration of tools used by ECDC for the rapid detection of threats through Epidemic Intelligence (e.g. Epitweetr[3], EIOS)	• Integration of molecular and genomic typing into EU level surveillance and outbreak preparedness according to ECDC strategy[4] • Further use of artificial intelligence in ECDC epidemic intelligence activities
#2: Clear and coordinated scientific advice facilitates policy decisions and public communication	• Increased ECDC evidence assessment and data analysis capacity and capabilities, including infectious disease modelling and forecasting and launch of the European COVID-19 Forecast Hub and the European COVID-19 Scenario Hub	• Further strengthening of ECDC evidence assessment and data analysis capacity and capabilities and expansion to other diseases • Capacity building and training by ECDC for evidence assessment and scientific

[1] https://www.ecdc.europa.eu/en/publications-data/epipulse-european-surveillance-portal-infectious-diseases

[2] The Epidemic Intelligence from Open Sources (EIOS) initiative is a unique collaboration between various public health stakeholders around the globe. It brings together new and existing initiatives, networks and systems to create a unified all-hazards, One Health approach to early detection, verification, assessment and communication of public health threats using publicly available information. Since January 2022, the lead of the EIOS initiative is hosted within the new WHO Hub for Pandemic and Epidemic Intelligence. https://www.who.int/initiatives/eios

[3] epitweetr tool (europa.eu)

[4] ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations – 2019–2021 (europa.eu).

	• COVID-19 vaccine effectiveness studies as part of the VEBIS project, scientific advice on vaccination strategies, launching the Vaccine Monitoring Platform (ECDC/EMA) • Provision of ECDC Rapid Risk Assessments on COVID-19 since January 2020 (19 RRA) and on other identified threats as required. • The EMA provides scientific advice *to developers* of vaccines and therapeutics. As of 19 October 2022 and in the context of the COVID-19 pandemic, 48 advices for vaccines and 111 for therapeutics were provided.	advice development to EU MS, pre-accession countries, and European Neighbourhood Policy countries • Ongoing revision of ECDC procedure for scientific opinions (Art. 7 of ECDC extended mandate) • Continuation of the ECDC VEBIS project (COVID-19 vaccine effectiveness monitoring) • Continuation of the work of the Vaccine Monitoring Platform (ECDC/EMA) • Updating ECDCs Rapid Risk Assessment methodology. • EMA and its Emergency Task Force (ETF) to continue to provide scientific advice to developers of medicines that could address the public-health emergency
#3: Preparedness needs constant investment, scrutiny and review	• ECDC Expert Consultation on the implementation of non-pharmaceutical interventions • Development of ECDC guidance and provision of training for In-Action Reviews and After-Action Reviews • After-Action Reviews (AARs) conducted by ECDC in multiple European countries focused on evidence-based advice-making • ECDC COVID-19 lessons learnt country visits in multiple European countries ECDC technical report on The EU experience in the first phase of COVID-19: implications for measuring preparedness	• Regular threat assessment • EU4health Programme funding for the implementation of the Regulation on serious cross-border threats to health and ECDC and EMA mandates. • ECDC capacity building and training for epidemic intelligence, preparedness and response activities to be provided to EU MS, pre-accession countries, and European Neighbourhood Policy countries • Development of ECDC e-learning courses on Emergency Preparedness • As provided for in the Regulation on serious cross-border threats to health, the Commission in cooperation with Member States and the relevant Union agencies, such as ECDC, will establish a Union health crisis and

		pandemic plan, there will be collection and analysis on a regular basis of preparedness and response planning; development of indicators to monitor progress as well as to assess the level of prevention, preparedness and response planning in the Member States.
#4: Emergency tools need to be ready, faster and easier to activate	• Establishment and operation of the European Federation Gateway Service (EFGS) for cross-border interoperability of mobile contact tracing applications • Establishment and operation of the EU Digital COVID Certificate system	• Drawing lessons learned from the EU cooperation on digital contact tracing • Work on a model for continuous and sustainable operation of digital health trust networks for the authentication of health-related certificates and other documents at the EU and possibly at the international level • ECDC protocols to be rapidly implemented to assess the epidemiology and risk factors related to novel health threats • ECDC protocols to be rapidly implemented to assess the effectiveness of implemented response measures
#5: Coordinated measures should become a reflex for Europe, reinforced public-private partnerships and stronger supply chains are needed for critical equipment and medicines.	• Adoption of the Regulation on serious cross-border threats to health. • Establishment of HERA • Extension of the ECDC and EMA mandate • Coordination with all actors involved in health threats preparedness and response through HERA Board, HERA Advisory Forum, Civil Society Forum and Joint Industrial Cooperation Forum • Regulation 2022/123, extended the mandate of the European Medicines Agency, entered into force on 1 March 2022. The legislation provides EMA with a role in monitoring and mitigating shortages of critical medicines, in the context of a public health emergency or major event, and	• Restoring and expanding production capacity for medical countermeasures (EU FAB) • Developing European stockpiling capacity • Identification, anticipation, and defining ways to address bottlenecks in medical countermeasures supply chains • The provisions on monitoring and mitigating shortages of critical medical devices will apply as of 2 February 2023. • Interoperable Medical Countermeasures Intelligence platform and increased private investments in high risk medical countermeasures via so-called “HERA INVEST”

	formally establishes the Medicines and Medical Devices Shortages Steering Groups and the Emergency Task Force.	
#6: Reinforced public-private partnerships and stronger supply chains are needed for critical equipment and medicines	• Structured Dialogue on security of supply of medicines, with stakeholders, in 2021 • 2022 Publication of a Commission Staff Working Document – Vulnerabilities of the global supply chains of medicines – Structured dialogue on the security of supply of medicines supply[5].	• The Commission will now continue its reflection, notably in the context of the upcoming reform of the pharmaceutical legislation, in order to formulate policy options and put forward actions to strengthen the continuity and security of supply in the EU, in particular for those medicines considered to be most critical to health systems
#7: A pan-European approach is essential to make clinical research faster, broader and more effective.	• As of January 2022, with the entry into application of the Clinical Trials Regulation, the assessment and supervision of clinical trials throughout the EU have been harmonised, notably via a Clinical Trials Information System (CTIS). • The Emergency Task Force, established as part of the by Regulation 2022/123, provides advice on clinical trial protocols, including joint clinical trials, to developers of clinical trials that are carried out in the Union. • Regulations (EU) 2017/745 on medical devices and 2017/746 on *in vitro* diagnostic medical devices, which entered into application in 2021 and 2022 respectively, provide a more harmonised framework for clinical investigations and performance studies. • Horizon 2020-funded project CORE-MD on clinical evidence for medical devices, performed by a consortium of healthcare professionals, notified bodies, academics, patients and regulators	• Over the coming years, the new European regulatory environment for clinical trials will facilitate, streamline, speed up and increase transparency for multinational clinical trials also for possible new COVID-19 therapeutics and vaccines. • Moreover, it will ensure that the EU offers an attractive and favourable environment for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants. • This scientific advice by the Emergency Task Force should be taken into account by Member States when authorising a clinical trial application. Ultimately, the advice will facilitate the timely development and authorisation of medical products such as vaccines and treatments and improve overall clinical trial coordination in Europe.

[5] Staff Working Document on Vulnerabilities of the global supply chains of medicines – Structured Dialogue on the security of medicines supply (europa.eu)

	• Support VACCELERATE and EU-RESPONSE clinical trials network, to assess new medicines and medical countermeasures (i.e.: during the monkeypox outbreak). • Increasing the link between threat assessment, R&D and procurement of medical countermeasures	• Continue work with Member States and stakeholders to develop common understanding and tools for medical device clinical investigations and performance studies. • Reinforce HERA horizon scanning capacities in the field of medical countermeasures • Consolidate EU clinical trials networks, to enable the conduct of perpetual platform trials and perpetual strategic cohorts in order to pivot to emerging diseases if an epidemic strikes
#8: Capacity to cope in a pandemic depends on continuous and increased investment in health systems (including their digital transition)	• Support to Member States to strengthen the overall resilience of health systems as part of their Recovery and Resilience Plans. Under currently adopted Plans more than EUR 40 billion are earmarked for national health systems. Almost one third of this amount is dedicated to drive the digitalisation of health systems. • In addition, the latest country-specific recommendations – adopted in July 2022 as part of the European Semester – addressed health systems in eight Member States and stressed the need for better prevention and primary healthcare, as well as tackling workforce shortages. • Support, through the EU4Health Programme, in partnership with the OECD and the European Observatory on Health Systems and Policies to bolster systems' preparedness for infectious disease outbreaks and other types of shocks. In particular, this regards the design of resilience tests to enable Member States to regularly review health crisis preparedness and check their health systems' resilience against specific high-pressure scenarios and long-term structural	• Continue the support to national Recovery and Resilience Plans ensuring their implementation during the Recovery and Resilience Facility lifetime (2021-2026) • Continue the assessment of the resilience of national health systems under the European Semester, including as regards investments levels and relevant reforms. • Continue supporting Member States in addressing health workforce challenges related to shortages and skills mismatches. This involves the Joint Action Heroes on health workforce planning and forecasting, which will kick off in the beginning of 2023 and actions on skills, including rolling out the Health Workforce Pact for Skills Partnership and training projects with a focus on digital skills under the EU4Health Programme. • Complete the health system resilience testing methodology and publish it in a handbook by

	challenges	mid-2023.
#9: Pandemic preparedness and response is a global priority for Europe.	• ECDC collaboration with Global Outbreak Alert and Response Network (GOARN) • ECDC collaborates with other Centres for Disease Control (CDCs) in non-EU countries, including US, Canada, China, Israel, Mexico, United Kingdom and Korea. Additionally on the initiative of the ECDC a Network of major CDCs across the globe including Africa, Australia, Canada, Caribbean, China, Israel, Korea, Mexico, Singapore, Thailand, UK and US has been established in 2019 to exchange information and expertise to respond effectively to threats posed by communicable diseases. The Network has proven to be particularly useful during the COVID-19 pandemic. • ECDC contribution to global discussions on governance frameworks for pandemic preparedness • ECDC regional initiatives such as enhanced provision of support to Africa CDC, the EU Initiative on Health Security and preparatory measures for the participation of EU candidate countries and potential candidates in ECDC work	• Continued ECDC regional and bilateral initiatives such as the EU Initiative on Health Security • Intensified global collaborations, such as between ECDC and Africa CDC • Establishment of an EU Health Task Force coordinated by ECDC
#10: A more coordinated and sophisticated approach to misinformation and disinformation should be developed	• Proactive communication, social listening and exchange to anticipate new threats • ECDC report "Countering online vaccine misinformation in the EU/EEA" • JRC report "COVID-19 misinformation: Preparing for future crises" • New Code of Practice on Disinformation • Digital Services Act • Transparency of political advertising proposal • European Media Freedom Act	• Review of European Democracy Action Plan planned for 2023; • Implementation of Digital Services Act • Work towards a FIMI Data Space (as called for in the Strategic Compass) • Continued engagement with stakeholders on the proposed common conceptual definition of FIMI and within the crisis situations sub-group of the nEw Code of Practice on Disinformation;

	• European Digital Media Observatory • Foreign Information Manipulation and Interference (FIMI) toolbox • EEAS Special Reports on COVID-19 Disinformation • Work on a common analytical framework and methodology to identify foreign information manipulation and interference • Close cooperation with Member States through the Rapid Alert System (RAS) and with international partners, in particular G7 Rapid Response Mechanism and NATO, as well as with civil society and private industry • Development of an ECDC study and an e-learning on countering online vaccine misinformation • Development of ECDC guide and related e-learning on facilitating COVID-19 vaccination acceptance and uptake, including strategies on providing accurate information and address mis- and disinformation.	• ECDC enhancing access to trusted sources of health information, including further development of the European Vaccination Information Portal (EVIP) • Enhancing healthcare workers' capacities to communicate with patients on vaccination (ECDC)