



Council of the  
European Union

Brussels, 20 September 2021  
(OR. en)

11958/21  
ADD 1

SAN 556  
PHARM 172  
MI 684  
IPCR 121  
COVID-19 343  
RECH 411  
COMPET 644  
PROCIV 118

#### COVER NOTE

---

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 16 September 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

---

No. Cion doc.: COM(2021) 576 final

---

Subject: ANNEX to the Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union

---

Delegations will find attached document COM(2021) 576 final.

---

Encl.: COM(2021) 576 final



Brussels, 16.9.2021  
COM(2021) 576 final

ANNEX

**ANNEX**

*to the*


**Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions**




**Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union**




## ANNEX

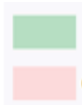
### *Comparative overview of competences – HERA, ECDC and EMA*

The below provides a comparative overview of the roles and functions that are envisaged for HERA, ECDC and EMA during the preparedness and crisis phase, covering different aspects of work related to preventing and addressing health emergencies. It takes into account existing roles and functions as well as future ones based on the EU Health Union proposals.

		HERA	ECDC	EMA
PREPAREDNESS PHASE		<ul style="list-style-type: none"> <li>• Threat anticipation and prioritisation</li> <li>• Horizon scanning</li> <li>• Consequence management</li> <li>• Identifying MCM requirements</li> <li>• Mapping of capacities</li> <li>• In-house expertise on medicines and medical devices</li> </ul>	<ul style="list-style-type: none"> <li>• Epidemiological intelligence and analysis</li> <li>• Epidemiological surveillance system</li> <li>• Harmonised health data sets and tools</li> </ul>	<ul style="list-style-type: none"> <li>• Monitoring/mitigating the risk of shortages of critical medicines and medical devices</li> <li>• Scientific advice on clinical trials design and product development as well as the ‘rolling’ review of emerging evidence on MCMs</li> <li>• Medical device expert panels</li> </ul>
CRISIS PHASE	 <b>INTELLIGENCE GATHERING &amp; ANALYSIS</b>	<ul style="list-style-type: none"> <li>• Inventory of crisis-relevant MCMs production</li> <li>• Production facilities</li> <li>• Crisis-relevant raw materials, consumables, equipment and infrastructure</li> <li>• Monitoring of crisis-relevant MCMs</li> <li>• Provision of non-binding recommendations on MCMs</li> <li>• Emergency research and innovation plans</li> </ul>	<ul style="list-style-type: none"> <li>• Epidemiological intelligence and analysis</li> <li>• Provision of non-binding recommendations and options for risk management (advice on application of health measures, e.g. masks, social distancing, testing strategies, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Update list of critical medicines and medical devices</li> <li>• Monitoring supply and demand of those products</li> <li>• Scientific advice on new/repurposed MCMs</li> <li>• Coordination clinical trials</li> <li>• Studies assessing vaccine safety and effectiveness</li> <li>• recommendations on most advanced MCMs</li> </ul>


	HERA	ECDC	EMA
 <p><b>PANDEMIC PREPAREDNESS &amp; RESPONSE PLANNING</b></p>	<ul style="list-style-type: none"> <li>• Pandemic preparedness and response planning with a focus on MCMs in close coordination with the pandemic preparedness research and innovation partnership</li> <li>• Annual State of Preparedness report</li> </ul>	<ul style="list-style-type: none"> <li>• EU pandemic preparedness and response plan</li> <li>• Stress tests</li> <li>• Audits</li> <li>• EU reference laboratories network</li> <li>• EU network for substances of human origin</li> <li>• Automated contact tracing system</li> </ul>	N/A
 <p><b>DEVELOPMENT CAPACITIES</b></p>	<ul style="list-style-type: none"> <li>• IT platforms for MCMs</li> <li>• End-stage research and clinical trials as part of the pandemic preparedness research and innovation partnership</li> <li>• Intellectual property access</li> </ul>	N/A	N/A
	<ul style="list-style-type: none"> <li>• Emergency funding instruments and requirements</li> </ul>		<ul style="list-style-type: none"> <li>• Emergency Task Force</li> <li>• Regulatory support for marketing authorisations</li> <li>• Acceleration of regulatory processes</li> </ul>
 <p><b>PRODUCTION CAPACITIES</b></p>	<ul style="list-style-type: none"> <li>• EU FAB</li> <li>• Cooperation mechanism with EU industry</li> <li>• Contributing to ensure sufficient EU manufacturing capacities</li> </ul>	N/A	N/A
	<ul style="list-style-type: none"> <li>• Emergency funding instruments and requirements</li> </ul>		<ul style="list-style-type: none"> <li>• Sub-networks of single points of contact from marketing authorisation holders, medical device manufacturers and notified bodies based on the products included on the critical medicines and medical device lists</li> </ul>

	HERA	ECDC	EMA
 <b>PROCUREMENT CAPACITIES</b>	<ul style="list-style-type: none"> <li>• Management of a portfolio of EU procurement tools</li> </ul>	N/A	N/A
	<ul style="list-style-type: none"> <li>• Emergency funding</li> <li>• Central purchasing body</li> </ul>		
 <b>STOCKPILING AND DISTRIBUTION CAPACITIES</b>	<ul style="list-style-type: none"> <li>• IT platforms for EU/national MCM stockpiles and supplies</li> <li>• EU level stockpiling or supply network of critical raw materials</li> <li>• Logistical infrastructures</li> <li>• MCMs management/ deployment</li> </ul>	N/A	N/A
	<ul style="list-style-type: none"> <li>• Efficient re-organisation of supply chains and production lines</li> </ul>		
 <b>TRAINING AND CAPACITY BUILDING</b>	<ul style="list-style-type: none"> <li>• Twinning partnerships</li> <li>• Expert exchanges and centres of excellence</li> <li>• Capacity-building forum</li> <li>• Skills in biopharmaceutical science and bio-manufacturing</li> </ul>	<ul style="list-style-type: none"> <li>• Training for healthcare staff on pandemic preparedness and response planning</li> </ul>	<ul style="list-style-type: none"> <li>• Training on innovative medical technologies</li> <li>• Training on regulatory aspects</li> </ul>



PREPAREDNESS PHASE

CRISIS PHASE

	HERA	ECDC	EMA
 <p><b>INTERNATIONAL ENGAGEMENT AND REINFORCEMENT</b></p>	<ul style="list-style-type: none"> <li>• Global needs assessment for MCMs</li> <li>• Global surveillance capacities gaps assessment</li> <li>• Technical assistance for global capacity building</li> <li>• Global alliances with HERA like structures</li> <li>• Distribution of HERA procured/financed MCMs at international level</li> <li>• International twinning partnerships, expert exchanges and centres of excellence</li> </ul>	<ul style="list-style-type: none"> <li>• Engagement with other Centres for Disease Control and capacities</li> <li>• Deployment of experts in international response teams</li> <li>• Deployment EU Health Task Force to support local responses in Member States and third countries</li> </ul>	N/A
	<ul style="list-style-type: none"> <li>• Trigger activation of the necessary preparedness plan/cooperation with identified third countries as source countries</li> <li>• Cooperation on availability and deployment of crisis-relevant MCMs and raw materials</li> </ul>	<ul style="list-style-type: none"> <li>• Engagement with other CDCs and capacities</li> </ul>	<ul style="list-style-type: none"> <li>• Liaise with counterparts regarding authorised medicines or products under development</li> <li>• Liaise with counterparts to mitigate shortages of critical medicines or their active pharmaceutical ingredients</li> <li>• Liaise with counterparts to mitigate shortages of critical medical devices or their component parts</li> </ul>