JEAN MONNET Centre of Excellence
New Visions of the European Union's Role in Global Health (EU4GH)

EU4GH Summer School

«Equitable access to medical countermeasures in times of emergency: EU perspectives»

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Emanuele Cesta

Salerno, June 4, 2024

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EU regulatory actions to face health threats

Communications and proposals of the European Commission of November 11, 2020

724: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions - Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats

725: Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

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EU regulatory actions to face health threats

Communications and proposals of the European Commission of November 11, 2020

726: Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control (ECDC)

727: Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU

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Decision no. 1082/2013/EU

The provisions on health safety laid by Decision no. 1082/2013/EU (relating to serious cross-border health threats) provided a limited legal framework for coordination at EU level, essentially based on the **Early Warning and Response System** (**EWRS**) and the exchange of information and cooperation within the Health Security Committee (**HSC**).

Proposal 727, based on the lessons learnt by the COVID-19 crisis to strengthen existing structures and mechanisms for better **protection**, **prevention**, **preparedness** and **response** against all health risks, aims at establishing a stronger and more comprehensive framework to enable rapid reaction and implementation of preparedness and response measures to cross-border health threats across the EU in the form of a regulation, through the development of an **EU preparedness plan for health crises and pandemics.**

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Decision no. 1082/2013/UE and proposals 725, 726 e 727

The three update proposals aimed at:

- coordinating and strengthening **Joint Procurement mechanisms** for vaccines;
- expanding the mandate and powers of the **European Medicines Agency** (EMA), to stabilize the exceptional measures taken during the pandemic in collaboration with Member States by implementing models and structures with defined competences (e.g. Steering Groups on Shortages);
- strengthening the tasks of the **European Center for Disease Prevention and Control** (ECDC) in preparing for and responding to health crises, to achieve integrated real-time epidemiological surveillance systems (EU4Health programme).

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The communication of 11 November 2020 proposes the development of a **binding EU Plan for preparation and response to health crises/pandemics**, based on:

periodic full-scale exercises

reporting and auditing process of EU capabilities by individual MS

reviews of actions to introduce corrective and improving measures

a EU **Authority for preparedness and response to health emergencies**, ensuring the availability of medical countermeasures

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Communication from Commission to the European Parliament, the European Council, the European Economic and Social Committeee and the Committee of Regions of **June 15, 2021 - Drawing the early lessons from the COVID-19 pandemic**

«Lacking a robust EU system to declare an emergency situation and trigger the coordination required, governments were already trying to catch up with the reality, and it proved difficult to bring together a consistent and effective early response.
There was a clear shortfall in pandemic preparedness and planning**, with few tools already in place to respond swiftly and effectively as soon as the pandemic broke out.**
This was true at global, European, national and local level but was perhaps more acutely felt in Europe, where we had not been tested by the epidemics or outbreaks seen in other parts of the world in recent decades.»

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COM (2021) 576 final of 9/16/2021: Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union (Annex)

Ø HERA was established as a direct consequence of the lessons learned from the initial management of the COVID-19 pandemic, to ensure a solid Union response to serious-cross border health threats and secure ready availability and accessibility of MCMs;

Ø HERA's responsibility is to ensure that the EU and Member States are ready to act in the face of cross-border health threats, its mandate covers both the strengthening of preparedness in advance of future emergencies and the implementation of a swift and efficient response once crisis hits;

Ø HERA's international cooperation agenda aims to build strong relations with bilateral and multilateral partners to ensure the availability and accessibility of MCMs globally, bolstering **preparedness** and **resilience** against potential health crises in the future, supporting projects that strengthen preparedness and response capacities in the field of health

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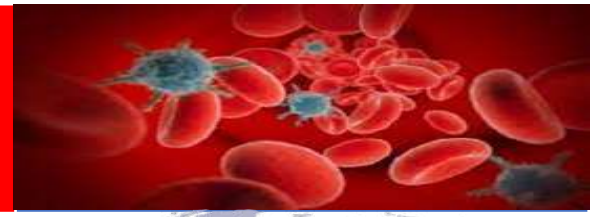
On 12 July 2022, HERA presented the list of the **3 main health threats** requiring coordination at EU level in the context of medical countermeasures, potentially lethal or, in any case, seriously harmful threats at risk of spreading in the Member States:

I	**Pathogens with high pandemic potential**	**mainly families of RNA respiratory viruses**	
II	**Chemical, biological, radiological and nuclear threats**	**Based on likelihood of release and potential impact on human health**	
III	**Anti Microbial Resistance**		AMR Antimicrobial Resistance

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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.

PREPAREDNESS PHASE / CRISIS PHASE	HERA	ECDC	EMA
INTELLIGENCE GATHERING & ANALYSIS	• Threat anticipation and prioritisation • Horizon scanning • Consequence management • Identifying MCM requirements • Mapping of capacities • In-house expertise on medicines and medical devices	• Epidemiological intelligence and analysis • Epidemiological surveillance system • Harmonised health data sets and tools	• Monitoring/mitigating the risk of shortages of critical medicines and medical devices • Scientific advice on clinical trials design and product development as well as the 'rolling' review of emerging evidence on MCMs • Medical device expert panels
	• Inventory of crisis-relevant MCMs production • Production facilities • Crisis-relevant raw materials, consumables, equipment and infrastructure • Monitoring of crisis-relevant MCMs • Provision of non-binding recommendations on MCMs • Emergency research and innovation plans	• Epidemiological intelligence and analysis • Provision of non-binding recommendations and options for risk management (advice on application of health measures, e.g. masks, social distancing, testing strategies, etc.)	• Update list of critical medicines and medical devices • Monitoring supply and demand of those products • Scientific advice on new/repurposed MCMs • Coordination clinical trials • Studies assessing vaccine safety and effectiveness • recommendations on most advanced MCMs

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PREPAREDNESS PHASE

CRISIS PHASE

	HERA	ECDC	EMA
PANDEMIC PREPAREDNESS & RESPONSE PLANNING	• Pandemic preparedness and response planning with a focus on MCMs in close coordination with the pandemic preparedness research and innovation partnership • Annual State of Preparedness report	• EU pandemic preparedness and response plan • Stress tests • Audits • EU reference laboratories network • EU network for substances of human origin • Automated contact tracing system	N/A
DEVELOPMENT CAPACITIES	• IT platforms for MCMs • End-stage research and clinical trials as part of the pandemic preparedness research and innovation partnership • Intellectual property access	N/A	N/A
	• Emergency funding instruments and requirements		• Emergency Task Force • Regulatory support for marketing authorisations • Acceleration of regulatory processes
PRODUCTION CAPACITIES	• EU FAB • Cooperation mechanism with EU industry • Contributing to ensure sufficient EU manufacturing capacities	N/A	N/A
	• Emergency funding instruments and requirements		• Sub-networks of single points of contact from marketing authorisation holders, medical device manufacturers and notified bodies based on the products

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PREPAREDNESS PHASE

CRISIS PHASE

	HERA	ECDC	EMA
PROCUREMENT CAPACITIES	• Management of a portfolio of EU procurement tools • Emergency funding • Central purchasing body	N/A	N/A
STOCKPILING AND DISTRIBUTION CAPACITIES	• IT platforms for EU/national MCM stockpiles and supplies • EU level stockpiling or supply network of critical raw materials • Logistical infrastructures • MCMs management/ deployment • Efficient re-organisation of supply chains and production lines	N/A	N/A
TRAINING AND CAPACITY BUILDING	• Twinning partnerships • Expert exchanges and centres of excellence • Capacity-building forum • Skills in biopharmaceutical science and bio-manufacturing	• Training for healthcare staff on pandemic preparedness and response planning	• Training on innovative medical technologies • Training on regulatory aspects

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PREPAREDNESS PHASE

CRISIS PHASE

	HERA	ECDC	EMA
INTERNATIONAL ENGAGEMENT AND REINFORCEMENT	• Global needs assessment for MCMs • Global surveillance capacities gaps assessment • Technical assistance for global capacity building • Global alliances with HERA like structures • Distribution of HERA procured/financed MCMs at international level • International twinning partnerships, expert exchanges and centres of excellence	• Engagement with other Centres for Disease Control and capacities • Deployment of experts in international response teams • Deployment EU Health Task Force to support local responses in Member States and third countries	N/A
	• Trigger activation of the necessary preparedness plan/cooperation with identified third countries as source countries • Cooperation on availability and deployment of crisis-relevant MCMs and raw materials	• Engagement with other CDCs and capacities	• Liaise with counterparts regarding authorised medicines or products under development • Liaise with counterparts to mitigate shortages of critical medicines or their active pharmaceutical ingredients • Liaise with counterparts to mitigate shortages of critical medical devices or their component parts

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What about the ECDC?
Does PHEs management is «only» a matter of MCMs?

Public health and social measures (PHSMs) refer to non-pharmaceutical measures implemented in community settings to abate the spread of infectious disease.

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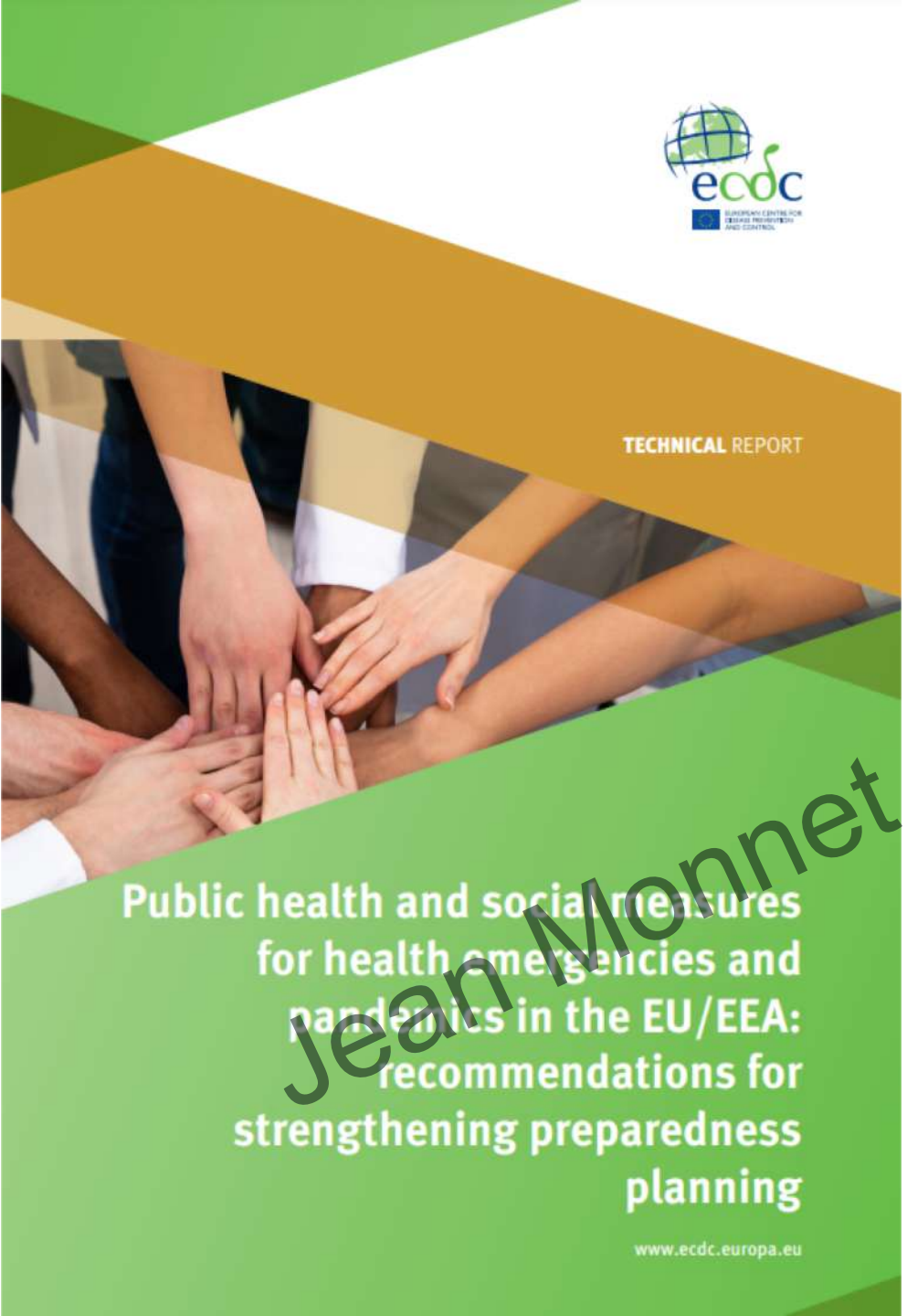

The potential future implementation of Public Health and Social Measures (PHSM) requires careful consideration – informed by lessons learned from the COVID-19 pandemic – and should be explicitly addressed by **national pandemic preparedness plans**. During future epidemics and pandemics, there may be a period of time before the widespread availability of medical countermeasures where PHSMs may again be relied upon to reduce disease transmission, and mitigate deleterious health impacts. The public health objective of reducing overall harms to population health should continue to apply in crisis situations.

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«measures with the highest level of acceptability/feasibility and the lowest negative consequences could be introduced first and removed last, while the early implementation of some measures will yield the highest effectiveness».

During large-scale respiratory disease outbreaks or pandemics, the application of PHSM or their deployment may consent, for example, to control sexually transmitted infections or mosquito-borne disease.

The use of PHSMs were the primary public health response during the initial phase of the COVID-19 pandemic, until vaccines became widely available, and it is likely that PHSMs will be relied upon in the early phases of future pandemics. However, their effectiveness may be affected by timeliness of decision-making and may vary across different contexts. Additionally, there has been much less investment in research focused on assessing the effectiveness and impact of PHSMs than there has been for drugs and vaccines. By as early as autumn 2020, the social and economic costs associated with the COVID-19 pandemic had already far exceeded past investments in preparedness and response.

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The lessons learned and future knowledge around PHSMs should be integrated into pandemic preparedness plans in a way that informs decision-making and action during health crises.
In the EU context, this should also be done in a manner consistent with:
- the provision of Regulation (EU) 2022/2371;
- the International Health Regulations (IHR), and
other global agreements around pandemic prevention, preparedness and response.

Article 3 of Regulation (EU) 2022/2371 does not explicitly define 'non-pharmaceutical interventions' but states that a '**public health measure**' means **a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combatting severe risks to public health or mitigating their impact on public health.**

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Regulation (EU) 2022/2371 on serious cross-border threats to health is aligned with the IHR and aims to strengthen EU coordination in preparedness and response to infectious disease threats. Mechanisms to do so include the **Health Security Committee** (Articles 4, 21, the **Union prevention, preparedness and response plan** (Article 5), coherence across countries and the Commission on national prevention, preparedness and response plans (Article 6), **alert notification of public health measures** intended to be taken at national levels (Article 19, par. 3(g), Article 21, par. 3), the **recognition of public health emergencies at Union level** (Article 23) and an **Advisory Committee on public health emergencies** (Article 24)

Article 22 of Regulation (EU) 2022/2371 notes that the Commission could complement the action of Member States through adopting recommendations on common temporary public health measures, noting that these shall be '**necessary**, **suitable** and **proportionate** to the public health risks' and 'avoiding any unnecessary restriction on the free movement of persons, of goods and of services', also promoting 'coordination of measures between Member States.

It would be useful for public health workers to undergo **ethics training**. A specialized training could help them become acquainted with fundamental ethical principles, understand how to apply ethical considerations in developing and implementing public health interventions, enhance their ability to identify ethical dilemmas and, if relevant, make informed decisions

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ECDC Recommendations

- National pandemic preparedness plans for EU/EEA countries are aligned with IHR and with Regulation (EU) 2022/2371, and are revised based on lessons learned from the COVID-19 pandemic;
- Pandemic preparedness plans account for the implementation of PHSMs, including outlining mechanisms and/or capacity for monitoring the impact and effectiveness of PHSMs;
- Countries assess the need to review which PHSM can be implemented under national law, and if necessary, consider updating national communicable disease or other laws to ensure alignment with pandemic preparedness plans;
- Pandemic preparedness plans account for the provision of support to socially vulnerable groups prior to and during pandemics;
- The European Commission, ECDC and Member States conduct stress tests of PHSM provisions in pandemic preparedness plans to assess coordination across the EU;
- Organizations dealing with public health crises would benefit from having dedicated ethical training offered to their staff - to effectively incorporate ethics into emergency response, Ethicists could also play an active role in the decision-making process during emergencies by participating in policy formulation

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European pharmaceutical strategy
COM(2020)761 of November 25, 2020

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Formally announced by the EU on 26 April 2023, the Communication focused on:

- ensure patients have **affordable access to innovative medicines** and **address unmet medical needs** (AMR, cancer and rare diseases);
- promote competitiveness, innovation capacity, sustainability and resilience of the EU pharmaceutical sector and the manufacturing of high-quality, safe, effective and more environmentally sustainable medicines;
- strengthen the mechanisms for **preparing and responding to health emergencies** and addressing **security and diversification of supply chains** (shortages of medicines and MDs;
- ensure a solid position of the EU on the world stage by promoting high standards in terms of quality, safety and effectiveness (art. 167 TFEU);
- supporting **patient-centred innovations** and digital and technological changes to remain attractive for investment and maintain the EU's role as a world leader in medicines development

The proposals follow the "**Council Conclusions on access to medicines and to medical devices for a stronger and more resilient EU**", of July 2021, which highlighted that access to medicines and medical devices, their availability and affordability are fundamental objectives for achieving **universal health coverage** (a WHO priority target).

Long before, with Resolution of 17 September 2020 on the shortages of medicines "how to address an emerging problem", the European Parliament had also underlined "*the geostrategic imperative for the Union to regain its independence in healthcare, secure rapidly and efficiently its supply of affordable medicines, medical equipment, medical devices, active substances, diagnostic tools and vaccines,* ***and to prevent shortages thereof****, prioritising the interest and safety of patients; stresses the importance of ensuring that all Member States have fair access to the supply chain; highlights, to that end, the need for the Union's pharmaceutical industry to have a diversified supply chain and a medicine shortage risk mitigation plan to cope with any vulnerabilities and risks to their supply chain*".

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97. Calls on the Member States to implement the '**green lanes**' proposed by the Commission in its guidelines for border management measures to protect health and ensure the availability of goods and essential services in order to allow the smooth running of the transport not only of medicines but also of raw materials, intermediate products and related materials, including packaging; stress the need to maintain **open borders** via green lanes so they can be used to address future unexpected events;

Notes the importance of the careful management of ambient and cold-chain warehouse capacity in inbound and outbound transport infrastructure;

Highlights the importance of IT systems in facilitating the traceability, supervision and timely delivery of medicines and the exchange of information between the various actors involved in the transport logistics chain, including customs authorities;

Resolution of 17 September 2020 on the shortages of medicines

"how to address an emerging problem"

Stresses the need to eliminate barriers to access to medicines, medical devices and protective equipment for all citizens, especially those living in Member States that, due to their small size or remote location, rely heavily on imports and do not have easy access to the supply chain;

Emphasises the need for a more efficient and sustainable transport and logistics network and a reduction in the length of transport routes, which would lead to a reduction in emissions, mitigating the impact on the environment and on the climate, improving the functioning of the internal market and reducing administrative barriers;

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25/01/2022 – adoption of Regulation (EU) 2022/123 on a strengthened role of the EMA in crisis preparedness and management of medicines and medical devices

- **MSSG + MDSSG**: response and coordination of urgent actions within the EU to manage supply problems, creation of lists of 'critical' medicines and medical devices, communications with MA holders and stakeholders to receive information on actual or potential shortages of critical medicines
- **European Shortage Monitoring Platform (ESMP)** to monitoring shortages of medicines and medical devices (within February 2025)
- **Emergency Task Force (ETF)** to ensure the development and provision at EU level of quality, safe and effective medicines with the potential to address PHEs
- **Data Analysis and Real World Interrogation Network ("DARWIN EU"),** coordination center to provide reliable and timely evidence on the use, safety and efficacy of medicines for human use from EU health databases

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December 6, 2022 – publication in the OJEU of the 3 Regulations aimed at strengthening EU action to combat health emergencies

Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (**ECDC**) (ex art. 168 TFUE)

Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (ex art. 168 TFUE)

Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (ex art. 122, par. 1, TFUE)

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Council Regulation (EU) 2022/2372

Regulation (EU) 2022/2372 seeks to facilitate the purchase of medicines, vaccines and raw materials, activate emergency funding and enable the monitoring of production facilities in case of a public health emergency (PHE)

Monitoring of crisis-relevant countermeasures

In case of a health emergency, the Commission will be tasked to draw up a list of crisis-relevant medical countermeasures and raw materials and to monitor their supply and demand. The Commission, supported by the EMA, will set up a system to monitor relevant information concerning the supply and demand of crisis-relevant medical countermeasures and raw materials within and outside the Union.

Health Crisis Board

In case of an emergency, a Health Crisis Board will coordinate actions by the Council, the Commission, EU bodies and member states to ensure the supply of and access to crisis-relevant medical countermeasures. The Board will be composed of the Commission and one representative from each MS. Among other things, the Commission will have to consult the Board whenever possible before taking action.

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Council Regulation (EU) 2022/2372

Procurement and production

In case of purchases of countermeasures and raw materials, the MSs may mandate the Commission to act as a central purchasing body. When it intends to conclude a contract, the Commission will inform the MSs. In particular cases, MSs have the right to opt out of the deal.

The new rules provide for the possibility to activate EU-FAB - a network of ever warm production capacities for vaccines and medicines manufacturing, allowing the EU to make quickly available reserved surge manufacturing capacities and avoid problems of insufficient manufacturing capacities.

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April 26, 2023 – European Health Union: the most far-reaching reform of EU pharmaceutical legislation in over 20 years

The EC proposal for a new Directive - COM(2023)192 - and a new Regulation - COM(2023)193 - aims at the following main goals:

- create a robust single market for medicines to ensure timely and equitable access to safe, effective and affordable medicines;
- continue to offer an attractive and innovation-friendly framework for medicines research, development and manufacturing in Europe;
- drastically reduce administrative burdens and timing of issuing marketing authorizations;
- improve medicines availability and ensure their supply to patients across the EU by improving and strengthening the supply chain;
- combat antimicrobial resistance (AMR);
- pursue the environmental sustainability of medicines following a "One Health" approach and in line with the European Green Deal.

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Thanks for you attent…ehm…

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Thanks for your attention (and patience)

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