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**Pharmaceutical Group of European
Union**

**Groupement Pharmaceutique de
l'Union Européenne**

**Position Paper on Health Emergency
Preparedness and Response Authority
(HERA)**

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.



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Executive Summary

The Pharmaceutical Group of the European Union (PGEU) welcomes the introduction of the Health Emergency Preparedness and Response Authority (HERA) which was first presented to the European Commission on 16 September 2021 (hereinafter, we will refer to the proposal by the Commission as the “HERA Proposal”). PGEU acknowledges that lessons learnt through COVID-19 pandemic shall be included in permanent decision-making streams to diligently act against future health emergencies.

In that regard, both the HERA Proposal and the proposal for a Regulation on serious cross-border threats to health (hereinafter, the SCBTH Regulation) have a clear goal: learning from the past to shape the future and ensure a timely and efficient supply of critical countermeasures. To that end, the EU needs a comprehensive, transparent yet actionable HERA.

It shall not be forgotten that community pharmacy has demonstrated its value for patients and healthcare systems during this crisis and is ready to further expand this contribution as part of sustainable collaboration models with other healthcare professions and providers in the community.

PGEU considers that it is necessary to ensure the presence of healthcare professionals in the HERA Crisis Health Board and for HERA to have a clear set of competences to avoid potential duplicities. Other recommendations are suggested to promote enhanced innovation, smart procurement and sufficient levels of governance and surveillance in HERA.

Lastly, PGEU believes that community pharmacists are well positioned to further expand their role in tackling and combating cross-border health threats and contribute, just as it has been proven during the COVID-19 crisis, to assisting patients and being a close and reliable source of information.



Introduction

The Pharmaceutical Group of the European Union (PGEU) welcomes the introduction of the Health Emergency Preparedness and Response Authority (HERA) which was first presented the European Commission on 16 September 2021 (hereinafter, we will refer to the proposal by the Commission as the “HERA Proposal”). PGEU acknowledges that mechanisms deployed, and lessons learnt through COVID-19 pandemic shall be included in permanent decision-making streams to diligently act against future health threats. From this perspective, HERA is essential to ensure better EU preparedness and response in terms of medical countermeasures to serious cross border health threats.

The pandemic highlighted the fragilities of health care systems worldwide, leveraging the need to rethink the way care is provided. Lessons must be drawn from the pandemic, learning from it and using it as an opportunity to improve preparedness and response of healthcare system to current and future increasingly complex challenges. Although materializing cooperation and setting a common framework for emergency decisions-making can be complex, is now more necessary than ever.

In that regard, it should be considered that during COVID-19 crisis, the network of pharmacies near people’s homes have been playing a vital role in supporting local communities and ensuring their continued access to treatments and care. Pharmacies, have been the first line of advice, treatment, and referral for many people in Europe on common ailments, successfully preventing unnecessary visits to emergency rooms. In many European countries, pharmacists have also been structurally involved in influenza and COVID-19 vaccination and testing strategies.

Furthermore, during this crisis, community pharmacists have played a key role in assisting the health authorities in distributing certified protective equipment such as face masks and providing advice to the public on their correct and safe use together with information on other hygiene measures to prevent the spread of the virus.



Community pharmacy has demonstrated its value for patients and healthcare systems during this crisis and is ready to further expand this contribution as part of sustainable collaboration models with other healthcare professions and providers in the community¹.

Therefore, PGEU believes community pharmacists are well positioned to further expand their role in tackling and combating cross-border health threats and contribute, just as it has been proven during the COVID-19 crisis, to assisting patients and being a close and reliable source of information.

¹ For further information on the role of community pharmacists in covid 19, please refer to PGEU Position Paper on the role of community pharmacists in COVID19 – Lessons learned from the pandemic, accessible [here](#).



1. ASSESSING THE FRAMEWORK OF HERA

In order to fully tackle public health emergencies and ensure the supply of crisis-relevant medical countermeasures at Union level it is of the utmost importance, to clearly identify and define an adequate working framework. Only with clear boundaries, adequate levels of governance, legal certainty and transparency can be ensured. At the same time, however, HERA shall be flexible enough to be able to adapt to every specific public health emergency detected.

a. Defining the scope of HERA and ensuring coherence with the Proposal for a Regulation on serious cross-border threats

- The scope of cross-border threats to health shall be, in both HERA Proposal and the SCBTH Regulation, broad enough to cover serious hazard to health of biological, chemical, environmental, climate or unknown origin for which coordination at Union level is necessary in order to ensure high levels of human protection, whilst respecting the differences in the organisation of healthcare systems across the EU.

In that regard, we welcome that under HERA not only pandemics but also other serious cross-border health threats such as antimicrobial resistance, a global public health concern that threatens the effective treatment of infectious diseases², can be addressed.

Under the current proposals, however, the relationship between a cross-border health threat and a public health emergency is not clearly defined. In that regard, the HERA Proposal and the SCBTH Regulation could increase their transparency and governance by including guidelines for the Commission on possible elements to be observed to declare a public health emergency to ensure full coherence of the system and the uptake of progressive measures.

² For additional information on the contribution that community pharmacists are making in tackling AMR and encouraging the prudent use of antimicrobials, please refer to the materials prepared by PGEU on the matter [here](#).



- An all-round approach shall be explicitly included in the HERA proposal for the preparedness phase. In order for the framework for health crisis preparedness and response at EU level to be able to address the weaknesses evidenced by the COVID-19 pandemic, preparedness shall be a multi-layered concept and include, at least, scientific, technical, financial and operational preparedness.

b. Interaction between HERA and other EU agencies

- PGEU welcomes that the presentation of the HERA Proposal is accompanied by an annexed communication consisting in a competence chart that addresses the role of HERA compared to the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).

However, it cannot be forgotten that the duplication of competencies is still a very legitimate concern that shall be further addressed. In particular, other pre-existing European Union agencies have some degree of impact in preparedness and planning (e.g., DG SANTE or DG-RTD). Therefore, and in order to give further formality to the agreed distribution of competences, PGEU recommends the definition of clear memorandums of understanding to coordinate agencies and EU-bodies effectively³.

c. Interaction between HERA and national health care systems.

- PGEU fully acknowledges the positive impact of proactive measures at EU level and the need to put in place permanent structures to prepare and respond to health threats instead of resorting to ad hoc solutions, as those may lead to partial or delayed responses in a cross-border crisis setting.

As set forth in the Inception Impact Assessment linked to HERA Proposal, *“the new body would provide added value by addressing the challenges that the Member States cannot efficiently and effectively address on their own, concerning preparedness, management and response to cross-border*

³ At the date of the drafting of this Position Paper, EMA has already set out their intention to enter into a memorandum of understanding with HERA.



health threats via action at various stages of the entire value chain for medical countermeasures. It will respect the competencies of Member States and relevant national authorities in this field and seek to ensure coordination of preparedness and response capacities of medical countermeasures for serious cross-border threats to health, undertaking tasks which take account of the reality that no one country can effectively prevent or tackle a cross-border public health crisis on its own.”

Therefore, we believe that the goal of strengthening health care systems shall throughout the process observe the necessary respect to the subsidiarity principal as set out in Article 5 of the Treaty on the Functioning of European Union, as well as Member States ‘competence and responsibilities to determine the organisation of the national health care systems.

As suggested by the Motion for resolution of the European Parliament of 10 July 2020 on “The EU’s public health strategy post-COVID-19”⁴, PGEU strongly supports the implementation of a ‘health in all policies’ approach, with the integration of health aspects in, and a systematic health impact assessment for all relevant policies and pieces of legislation.

⁴ https://www.europarl.europa.eu/doceo/document/RC-9-2020-0216_EN.html



2. Building a crisis preparedness and response infrastructure

The COVID-19 crisis has shown that HERA has the potential to fill a structural gap in the early detection, preparedness and response infrastructures at EU-level. To that end, it is of the utmost importance to build on European science, adopt mechanisms to implement timely and proportional measures and use public powers in an adequate manner, so that it enhances public health driven innovation as well as smart purchasing.

a. Healthcare professionals shall be represented at the HERA Health Crisis Board

- According to the HERA Proposal, HERA will be led by a board composed of Member States and the Commission, which will define its annual work program and coordinate actions, while the European Parliament would be mainly involved through the approval of HERA budget.

According to article 5.4 of the HERA Proposal “The Commission may invite experts with specific expertise, including representatives of Union agencies and bodies, national authorities including central purchasing bodies and health care organisations or associations, international organisations, experts from the private sector as well as other stakeholders, with respect to a subject matter on the agenda, to take part in the work of the Health Crisis Board or sub-groups on an ad hoc basis”

However, we believe that healthcare professionals should not be mere “invitees” when discussing health crisis. Even though the HERA work programme for 2022, as presented by the European Commission on February 10, 2022 enhances the aim to maintain “close cooperation” with stakeholders, no specific measures have been set out materializing such collaboration. HERA shall not miss the knowledge of a wide range of skilled and trained professionals who have demonstrated their added value and social commitment not only during the COVID-19 crisis but also from before. With



the aim of ensuring a transparent structure and governance, the optimization of the available resources as well as enhancing cooperation and coordination among all the involved stakeholders, healthcare professionals shall also be represented in the HERA Health Crisis Board.

b. Optimization of response mechanisms

- During the response phase, increased transparency, and timely communication on shortages to affected stakeholders shall be ensured. With a view to ensuring a continuous supply of medical countermeasures in times of crisis, it is crucial to set up a transparent yet timely mechanism to both detect and communicate shortages of medicines and medical devices to the affected stakeholders.

In this regard, PGEU welcomes the creation of the European shortages monitoring platform ('ESMP') and the establishment of the 'Medical Device Shortages Steering Group – MDSSG' under Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. The ESMP is established to process information on the supply of and demand for critical medicinal products during public health emergencies or major events and, outside of those situations, to allow for reporting on shortages of medicinal products that are likely to lead to public health emergencies or major events. To that end, mechanisms that ensure timely communication between EMA and HERA on the (foreseen) shortages of medical countermeasures shall be put into place so that coordinated actions to prevent or manage such shortages can be taken with respect to the competences of the respective EU bodies in this area.

As set out in depth in our Position Paper on the Revision of the General Pharmaceutical Legislation⁵, Community pharmacies could, where pharmacy-reporting systems are available or would become available in the future at national level, contribute to the collection of relevant information on medicines. Those measures could also, *mutatis mutandis*, apply on medical countermeasures when commercialized in a community pharmacy setting.

⁵ <https://www.pgeu.eu/wp-content/uploads/2022/01/PGEU-Position-Paper-on-the-revision-of-the-general-pharmaceutical-legislation.pdf>

c. Joint procurement schemes shall be further explored and developed.

- PGEU welcomes the measure included in article 7 of the HERA Proposal enhancing the role of the Commission as a central purchasing body for medical countermeasures. However, central purchasing by the Commission shall not result in the lack of monitoring mechanisms and opacity regarding the price schemes and conditions entered into with medical countermeasures providers.

Other recommendations in the field of joint purchasing, include the need to conduct a rigorous Health Technology Assessment where necessary, as part of the purchasing or tendering processes and the application of tools evaluating cost-effectiveness and added therapeutic value of new therapies. The goal of those material and procedural safeguards is to enhance transparency, incentivise innovation, foster cooperation and optimize cross-country pricing efforts.

d. Use of real-world data

- PGEU welcomes that the HERA Proposal contemplates the use of real-world data for the response of public health emergencies. We would like to highlight that community pharmacists already collect and generate in their daily practice real world evidence that can contribute to evidence-based health policy and best practices in patient care.

The collection of real-world data and the use of real-world evidence have already resulted in better outcomes, better adherence, and reduced costs for health services. The result of this gained knowledge can contribute, where necessary, to better decision-making processes throughout the preparedness and response phases.

However, under the current wording of the HERA Proposal the use of real-world data is still very limited in scope. According to article 8, when measures on emergency research and innovation plans are adopted in the emergency phase the Commission shall access to relevant data from clinical trials, but also to real-world data. Although PGEU fully welcomes this measure and supports the value of real-world data and evidence, late activation of such measures could result in hindering adequate timing in decision-making processes.



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Therefore, we would support the extension of measures promoting research and data generation during the preparedness phase, specifically in those cases where a cross-border health threat has been detected but has not yet achieved the status of public health emergency and always respecting the in-force procedural requirements as well as GDPR and other regulatory requirements.



Policy Recommendations

Community pharmacists contribute to the resilience of health systems in Europe. Therefore, their privileged position as a first line of referral and treatment as well as a trusted source of information for patients shall be further enhanced and duly remunerated during public health crisis.

In light of the abovementioned considerations, PGEU proposes the following policy recommendations regarding the establishment and functioning of HERA:

1. Assessing the framework of HERA

- Elements to shape the mission and vision of HERA, such as health threats, medical countermeasures and preparedness shall be further developed to set out an even playing field that allows HERA to be fully operational, progressive, and assist in the decision-making phases. For that purpose, legal certainty and flexibility shall be adequately balanced.
- All these concepts shall as well be coherent with the proposal for a Regulation on serious cross-border threats.
- HERA shall elaborate clear memorandums of understanding with other EU agencies or institutional bodies with competences in preparedness and response in order to ensure coordination and avoid possible duplicities.
- The functioning of HERA shall balance the need for preparedness and response structures with the EU principle of subsidiarity and competences and responsibilities of Member States.
- We believe HERA can provide an optimal framework to share national expertise and best practices but shall not go beyond addressing those challenges that Member States cannot manage effectively

2. Building a crisis preparedness and response infrastructure

- The foreseen composition of the HERA Health Crisis Board shall be amended to ensure the appropriate representation and involvement of healthcare professionals
- Timely communication on shortages of medicines and medical devices between EMA and HERA and to affected stakeholders shall be ensured.



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- PGEU welcomes the use of joint procurement and purchasing tools to ensure the supply of medical countermeasures. However, technical and economic quality of these proceedings shall be surveyed to ensure adequate levels of quality and transparency.
- PGEU acknowledges the potential of real-world data and welcomes its use in evidence-based policy decisions to tackle public health emergencies.