

Symbolic or real? Evaluating HERA's stakeholder engagement

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SUMMARY

The Health Emergency Preparedness and Response Authority (HERA), the European Commission's newest Directorate-General, has distinguished itself through a comparatively open and transparent strategy for stakeholder engagement. Its multilayered setup, comprising advisory bodies from a wide range of stakeholders, demonstrates a commitment to participatory governance but also highlights the complexity and ambition of HERA's mandate.

Stakeholder engagement is an important means through which policymakers can enhance legitimacy, democratic accountability, and access to specialised knowledge. However, such engagement is often criticised as symbolic: stakeholder engagement may give the appearance of transparency and responsiveness but offer stakeholders limited influence over policymaking.

This analysis looks at whether HERA's participatory mechanisms truly support decision-making or mainly serve as symbolic tools to project an image of responsiveness and legitimacy. It focuses on stakeholder engagement with Member States, civil society, and industry. It assesses engagement in terms of regularity, transparency, communication, and feedback.

Key areas for improvement include clarifying HERA's role, mandate, and powers, enhancing the quality of communications, and strengthening feedback mechanisms. Implementing measures in these areas will enable HERA to transform its innovative stakeholder engagement from the symbolic to the meaningful. It will also ensure that stakeholders' expectations are met, build trust, and improve collaboration, thereby maximising the impact of HERA's preparedness and response activities.



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EXECUTIVE SUMMARY

The Health Emergency Preparedness and Response Authority (HERA), the European Commission's newest Directorate-General, was established in September 2021 amid the Covid-19 pandemic. It has distinguished itself by a strategy of comparative openness and transparency in stakeholder engagement. This more open approach is partly driven by HERA's role, which inherently requires contributions from stakeholders.

HERA's multi-layered setup demonstrates a commitment to participatory governance, through the HERA Board and its advisory groups. Yet, this arrangement highlights the complexity and ambition of HERA's mandate.

Stakeholder engagement is an important way for policymakers to enhance legitimacy, democratic accountability, and access to specialised knowledge. Research shows that regulatory bureaucracies, including the European Commission, have shifted from primarily evidence-based (responsible) policymaking towards more responsive approaches attentive to stakeholder demands.

However, such engagement is often criticised as symbolic: structures for stakeholder engagement may give the appearance of transparency and responsiveness, but offer stakeholders limited influence over policymaking. This raises the question of whether HERA's participatory mechanisms truly support decision-making or merely serve to project an image of responsiveness and legitimacy.

We evaluate HERA's stakeholder engagement, focusing on EU Member States, civil society, and industry. We draw on stakeholder interviews and a review of publicly available information from HERA to examine engagement in terms of regularity, transparency, communication and feedback. We identify three main areas for improvement: the need for more clarity over HERA's role, mandate and powers, the quality of HERA's communications and the need for better feedback mechanisms.

Addressing these aspects will enable HERA to transform its innovative stakeholder engagement from the symbolic to the meaningful. They will ensure that the expectations of stakeholders are met, build trust and improve collaboration – thereby maximising the impact of HERA's preparedness and response activities.

1. Introduction

A new institutional endeavour prompts anticipation of a different approach and a more successful outcome. The Health Emergency Preparedness and Response Authority (HERA), the newest Directorate-General (DG) of the European Commission, was established in September 2021 during the Covid-19 pandemic. It arguably has one of the most innovative strategies for stakeholder engagement among EU institutions.

Despite the urgency under which it was launched, HERA has distinguished itself from the Commission's other internal services by involving stakeholders in a comparatively open and transparent way. This more open approach is partly driven by HERA's role, which inherently requires contributions from stakeholders. Only by engaging various types of stakeholders can HERA ensure that its actions are implementable and aligned with onthe-ground needs and capabilities.

A distinctive feature of HERA is its advisory mechanism, which is an open and perhaps ambitious approach. The HERA Board, composed of representatives from EU Member States and relevant agencies, contributes to HERA's strategic planning. The Board is supported by the HERA Advisory Forum, which in turn is advised by two independent consultative bodies: the HERA Civil Society Forum (CSF) and the Joint Industrial Cooperation Forum (JICF). This multi-layered structure not only demonstrates the Commission's commitment to inclusive and democratic governance, but also highlights the complexity of HERA's mandate.

Policymakers use stakeholder engagement to increase their legitimacy and democratic credentials, and to draw on specialised knowledge to inform their policies^{1, 2}. The literature on regulatory governance suggests that, amid growing politicisation, public contestation, and criticism of opacity and weak accountability, regulatory bureaucracies have shifted from a primarily responsible mode (focused on evidence-based policymaking) towards a more responsive one (attentive to stakeholder demands)³. The European Commission has undergone a similar shift in recent years⁴.

¹ Arras, S. and Braun, C. (2017), '<u>Stakeholders wanted! Why and how European Union agencies involve non-state stakeholders</u>', *Journal of European Public Policy*, Vol. 25, No. 9, pp. 1257-1275.

² Bunea, A. and Thomson, R. (2015), '<u>Consultations with interest groups and the empowerment of executives: Evidence from the European Union'</u>, *Governance: An International Journal of Policy'*, *Administration, and Institutions*, Vol. 28, No. 4, pp. 517-531.

³ Koop, C. and Lodge, M. (2020), 'British economic regulators in an age of politicisation: From the responsible to the responsive regulatory state?', Journal of European Public Policy, Vol. 27, No. 11, pp. 1612-1635.

⁴ Bunea, A. and Nørbech, I. (2022), '<u>Preserving the old or building the new? Reputation-building through strategic talk and engagement with stakeholder inputs by the European Commission</u>', *Journal of European Public Policy*, Vol. 30, No. 9, pp. 1762-1792.

A common criticism is that stakeholder engagement instruments – such as open online consultations, stakeholder conferences, and discussions in closed policy forums – are mainly symbolic exercises. They give policymakers the appearance of transparency and responsiveness, but offer stakeholders limited margin to shape policy outcomes⁵.

The Commission may face significant trade-offs when adding extensive participatory layers to its well-established, evidence-based policymaking, as it seeks to respond to public criticism and project an image of responsiveness. ⁶ Even in the context of stakeholder engagement, the Commission has prioritised preserving its reputation as an evidence-based decision-maker over its newer identity as a responsive policymaker⁷. In this light, the literature highlights the need to assess whether participatory instruments and procedures truly support responsive policymaking or primarily serve as symbolic tools to signal responsiveness. It is precisely this question that we explore in this analysis.

We examine HERA's stakeholder engagement activities and evaluate them in terms of regularity, transparency, communication and feedback. We focus on three main types of stakeholders: EU Member States, civil society (including research institutions), and industry. The analysis concludes with some recommendations for HERA and EU institutions in general.

⁵ Binderkrantz, A.S., Blom-Hansen, J., Baekgaard, M. and Serritzlew, S. (2022), '<u>Stakeholder consultations in the EU Commission: Instruments of involvement or legitimacy?'</u>, *Journal of European Public Policy*, Vol. 30, No. 6, pp. 1142-1162.

⁶ Bunea, A. and Nørbech, I. (2022), 'Preserving the old or building the new?', op. cit.

⁷ Ibid.

2. HERA'S GOVERNANCE AND ADVISORY STRUCTURES

HERA's stakeholder engagement strategy is more expansive and innovative than other Commission services. That is partly due to the need to involve a wider range of actors in the authority's governance and advisory structures and also the fact that the service has been set up relatively recently, allowing the European Commission to incorporate best practices and lessons learnt into its design.

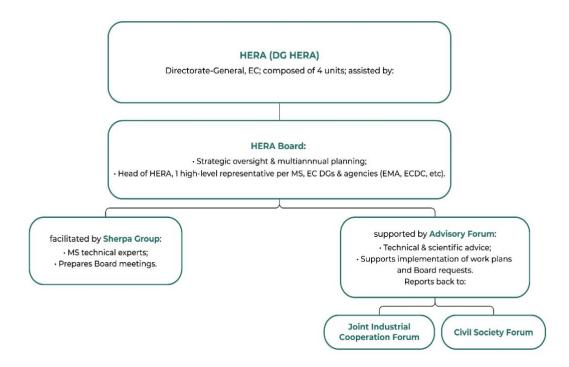
HERA operations are supported by <u>HERA's Board</u>, composed of representatives from Member States who guide the formulation of strategic decisions. It is the highest body within HERA, with high-level officials from Member States who can directly express their opinions about how their resources and capacities could be jointly deployed for the benefit of the EU as a whole. The HERA Board is facilitated by the Sherpa Group, in which deputies from Member States provide internal support to the organisation of the Board's activities and decisions.

The Board is also supported by an Advisory Forum, a group of experts from Member States competent in health security, chaired by HERA. Its role is to advise the HERA Board and support the implementation of HERA's work plans, facilitate exchanges with national competent bodies, and pool knowledge on medical countermeasures (MCMs). Two complementary bodies support its work:

- the JICF, co-chaired by HERA and DG GROW (on the Internal Market, Industry, Entrepreneurship and SMEs), which aims to foster collaboration with industry on preparedness and health crisis response;
- the CSF, intended to channel input from patients, consumers, and healthcare professionals, and to provide feedback on research as well as industrial and policy developments in health preparedness and response.

Figure 1 illustrates HERA's advisory structure with some brief descriptions.

Figure 1. HERA's advisory structure



Source: Authors' illustration based on official publicly available information.

2.1. HERA'S RELATIONS WITH MEMBER STATES

In the area of public health, the institutional relationship between the Commission and the EU Member States is complex⁸. While the Treaty on the Functioning of the European Union states that public health is mainly a competence of the Member States, the Covid-19 pandemic pointed to the deficiency of the then governance framework on public health security in the EU. The Commission quickly picked up the task to procure vaccines for the Member States but the result was not always appreciated. Some Member States were critical of the process, asserting that it was transparent⁹.

It was in this context that HERA was established. The Commission Decision setting up HERA outlines a governance framework that aims to ensure greater openness and accountability¹⁰. One important feature of the new framework is the elevated position of Member States in the procurement of MCMs. They will work closely with HERA through

⁸ Renda, A., Yeung, T., Vu, H., Arroyo, J., Kokalari, A. and Rékasy, P. (2024), <u>Health Emergency Response Governance in</u> the EU after the Covid-19 pandemic, CEPS In-depth Analysis, CEPS.

⁹ Arroyo, J., Del Giovane, C., Mizsei, B., Vu, H. and Yeung, T.Y.C. (2025), '<u>The EU Vaccines Strategy: A mixed bag of</u> achievements and discontent', *European Journal of Risk Regulation*', Vol. 16, No. 2, pp. 653-669.

 $^{^{10}}$ Commission Decision C(2021) 6712 final of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (HERA).

the HERA Board and participate in major decision-making at the Health Crisis Board during a health emergency. The recently published <u>review of HERA</u> identifies cooperation and coordination with national efforts as one of HERA's defining features.

HERA interacts with Member States primarily via the HERA Board¹¹. The HERA Board's <u>official mission</u> is to provide strategic direction and advice on health preparedness and response. It contributes to HERA's multiannual strategic planning and annual work plans, offers opinions on proposed activities, and facilitates detailed discussions with advisory forums. The Board also receives updates on HERA's key activities and provides input on major initiatives, including on stockpiling. The Board is supported by the Advisory Forum, which brings together Member State experts in health, research, and industrial policy to strengthen information exchange and knowledge generation¹².

HERA supports Member States in addressing gaps by sharing best practices, strengthening skills on the full cycle of MCM management, and providing tailored training and exercises¹³. Since 2023, this has included workshops on stockpile management and public procurement, complementing training by the European Centre for Disease Prevention and Control (ECDC) on epidemic intelligence and risk assessment. The review also highlights that HERA organises tabletop exercises to test coordination and interoperability between Member States and HERA, which requires close cooperation with national authorities and other Commission services.

2.2. HERA AND THE PRIVATE SECTOR

HERA is tasked with responsibilities that require substantial collaboration with the private sector. HERA is responsible for monitoring stocks of materials for essential MCMs throughout value chains. Still, such information is scattered among companies and authorities. Moreover, to a certain extent the information on stocks of essential materials is considered by companies to be a trade secret, which they have been reluctant to disclose to national authorities or HERA.

Meanwhile, HERA relies on pharmaceutical companies for their capacities to develop essential MCMs. Close collaboration is therefore key to the success of HERA. The use of public funds for MCM research and innovation is always controversial. The Covid-19 experience led commentators to urge governments to link their funding to conditions on

¹¹ See European Commission, <u>HERA Board</u>.

¹² European Commission (2025), <u>Review of the implementation of the operations of the Health Emergency Preparedness</u> and Response Authority (HERA), p. 5.

¹³ Ibid, pp. 10-11.

pricing and distribution^{14, 15}. At the same time, such conditions may weaken the incentives to bid for EU projects as the collaboration would mean sharing intellectual property rights with the Commission and maybe other developers.

Anticipating the need for involvement of the private sector, HERA set up the JICF, jointly with DG GROW, to support HERA's work. Twenty companies or organisations were selected following a public call for members in March 2022, joined by representatives from each EU Member State¹⁶. The first meeting was held on 13 July 2022. Based on the public information available on the official website, there have been a total of four meetings since its creation, with the latest held on 22 November 2023. Yet in 2024, HERA hosted workshops with industrial stakeholders to explore ways to tackle current barriers to more effective funding for MCM innovation.

Compared with other types of stakeholder engagement activities, the information publicly available about the JICF is less detailed. The minutes of the first three meetings are very short but the overall discussion's documentation significantly improved for the final meeting (22 November 2022).

The <u>2025 HERA Work Plan</u> states that HERA will continue to engage with industry through the JICF and reiterates the need to avoid supply chain issues, such as market failures and supply chain bottlenecks. HERA Industry Days were held on 2-3 June 2025, which brought together industry, innovators, and policymakers, to discuss key HERA and EU priorities for MCMs in the future. The two-day conference consisted of several plenary panels on the first day and some parallel sessions on the second day. Discussion topics included, but were not limited to, the role of industry in stockpiling, the future of vaccine development, and EU funding instruments.

2.3. HERA'S ENGAGEMENT WITH CIVIL SOCIETY AND RESEARCH INSTITUTIONS

HERA engages with civil society primarily through the CSF, intended as a channel for civil society organisations to contribute to HERA's work. The CSF was designed to provide input – through opinions, observations, and assessments – to support HERA's work and contribute to informed decision-making, while also acting as a contact point for stakeholders.

The CSF has a three-year mandate. A <u>call for applications</u> has recently closed for the selection of new members, targeting patients, consumers, and healthcare professionals,

¹⁴ Wouters, O.J., Forman, R., Anderson, M., Mossialos, E. and McKee, M. (2023), '<u>The launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving global pandemic preparedness?'</u>, *Health policy*, Vol.133, 104844.

¹⁵ Arroyo et al. (2025), '<u>The EU Vaccines Strategy'</u>, op. cit.

¹⁶ See the list of <u>JICF members</u>.

as well as their respective representatives. As stated in the call, HERA considers its engagement with civil society through the CSF to be successful and has therefore decided to renew its mandate for an additional three years.

The current composition of the CSF includes 23 European organisations¹⁷. Most of these are organisations for patients, consumers, healthcare professionals, hospital associations, public health, and advocacy. The CSF operates through thematic working groups (WGs), which focus on specific areas aligned with HERA's priorities. These groups are meant to adapt over time based on the development of tasks and priorities. For the present CSF, the groups are dedicated to the review of HERA (WG1), health threats (WG2), and training (WG3).

Notably, researchers and academics are not directly represented in the CSF and there is no plan to enable representation of universities or research institutes. That said, HERA frequently engages with the research community primarily through its funding programmes, particularly via research grants. In the early days of HERA, a <u>European expert group on SARS-CoV-2 variants</u> was created under HERA¹⁸. The group was tasked with establishing criteria to identify SARS-CoV-2 variants, as well as advising on vaccine development, reviewing scientific evidence, and guiding the Commission by providing recommendations. Members include 15 experts in public health and infectious diseases from the academic and research community.

The Commission Decision to create the group originally applied until 24 June 2022. Two amendments followed, one postponing the closure date to 2024¹⁹, and another postponing it to 2028²⁰. However, the group's last meeting took place in September 2023. This suggests that the meetings were no longer considered essential once the emergency had passed. At the same time it indicates that the expert group was seen as valuable enough for the Commission to keep it formally in place, given the likelihood of needing it in future emergency situations.

¹⁷ See the list of <u>CSF members</u>.

¹⁸ Commission Decision of 24.6.2021 setting up the European group of experts on SARS-CoV-2 variants C(2021) 4805 final.

¹⁹ Commission Decision of 23.6.2022 amending the Decision of 24 June 2021 setting up the European group of experts on SARS-CoV-2 variants as regards the composition of the group C(2022) 4176 final.

²⁰ Commission Decision of 24.6.2024 amending Decision of 24 June 2021 setting-up the European group of experts on SARSCoV-2 variants as regards its period of application C(2024) 4224 final.

3. Assessing HERA's current activities for stakeholder engagement

The recently published external study supporting the review of HERA provides useful insights into how HERA's stakeholder engagement is perceived²¹. The replies collected by the external study's targeted surveys paint a mixed picture, with notable support for HERA's coordination efforts, but also significant concerns about overlapping mandates and below-expectation engagement of stakeholders.

Among the respondents, 46% agreed that HERA had coordinated well with the Member States (15 out of 104 fully agree and 33 out of 104 somewhat agree). But this implies that 54% of the respondents either somewhat disagreed, fully disagreed or neither agreed nor disagreed with the statement²². When asked about HERA's engagement with industry, the research community, and civil society, 54% of the respondents (16 out of 104 fully agree and 40 out of 104 somewhat agree) held that HERA had coordinated well²³. The study notes that, overall, HERA's stakeholder engagement was viewed positively²⁴, but a deeper reflection points to considerable room for improvement.

The study remarks – based on secondary sources – that HERA has not sufficiently engaged civil society, researchers, or academia²⁵. Another observation concerned the depth of such engagement: interviewees suggested that the role of stakeholders should go beyond mere information exchange to include substantive involvement in preparedness and emergency response²⁶.

Respondents also expressed support for the creation of a scientific advisory committee within HERA's governance structure to better inform and guide priority setting²⁷. Such a body, they suggested, could provide expert guidance and strengthen decision-making²⁸. Yet, the study notes that the Sherpa Group within the HERA Board already fulfils this role²⁹. This mismatch points to a lack of stakeholder awareness of HERA's governance

²¹ European Commission: Health Emergency Preparedness and Response Authority, Open Evidence & PwC (2025), <u>Study supporting the review of the Health Preparedness and Emergency Response Authority (HERA) with regard to its operations, structure, and governance – Final report, Publications Office of the European Union.</u>

²² Ibid., p. 65.

²³ Ibid., pp. 62-63.

²⁴ Ibid., p. 64.

²⁵ Ibid., p. 65.

²⁶ Ibid., p. 93.

²⁷ Ibid.

²⁸ Ibid., p. 98.

²⁹ Ibid.

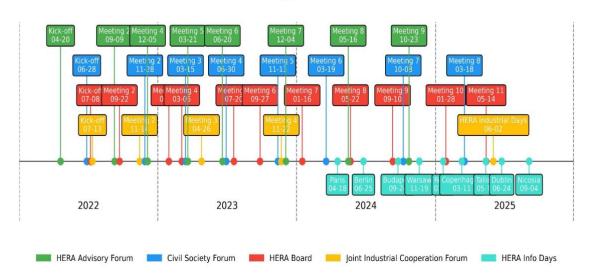
structures, highlighting possible shortcomings in transparency and communication between HERA and its stakeholders.

These perceptions largely resonate with the findings presented in the following analysis. It draws on stakeholder interviews and a review of the public information available on HERA, including the minutes of its Board and advisory forums, thereby building on and deepening the insights of the external study.

3.1. REGULARITY OF MEETINGS AND CONTINUITY OF DISCUSSIONS — KEEPING THE CONVERSATION ALIVE

HERA's meetings with stakeholders typically last between two and four hours, and are generally held on a regular basis, between two and four times per year, in online, inperson, or hybrid formats. Figure 2 provides an overview of the timeline of events, broken down by type of meeting. The JICF arranged meetings in 2024 and 2025 but certain information, including agendas and minutes, had not yet been uploaded at the time of drafting. In addition to regular JICF meetings, in 2024 HERA engaged with industry through in-person workshops to explore options for more effective funding for MCMs.

Figure 2. Timeline of HERA's events for stakeholder engagement



HERA Stakeholder Engagement Events and Dates

Source: Authors' illustration based on official information.

Note: The dates of JICF meetings in 2024 and 2025 have not been included in the figure, as they are not yet publicly available.

Although the frequency of meetings seems adequate, some stakeholders stressed that more is needed. An interviewed representative from the private sector emphasised the

need for sustained dialogue rather than one-off meetings to preserve momentum³⁰. Civil society stakeholders³¹ and a representative from a Member State pointed to the lack of exchanges between meetings, reinforcing the perception of fragmented dialogue³². These concerns highlight the need to strengthen engagement either by increasing the number of meetings or by complementing them with more continual interaction to foster a more effective exchange.

3.2. Transparency – what's there, what's missing

In general, HERA makes past agendas and minutes available on its official website, and these published minutes or summary reports are often detailed and comprehensive. This contributes to a relatively high level of transparency. However, industry stakeholders did mention that agendas are often not shared sufficiently in advance for them to adequately prepare for the meetings³³.

Transparency remains uneven across HERA's governance and advisory forums. For example, the Advisory Forum agendas were only made available up to June 2023, and participant lists appeared solely in the minutes of its first meeting. Similarly, JICF agendas have at times only been included in the minutes, and participant lists were published for just the first three meetings. The absence of participant lists limits the ability to assess who was engaged, how representation was distributed, and what influence different stakeholders might have had in shaping the discussions.

3.3. QUALITY OF COMMUNICATION — THE IMPORTANCE OF SPEAKING THE SAME LANGUAGE

3.3.1. Meetings and events – missed connections

The structure of the Board and advisory forum meetings is similar: presentations by authorities, including updates on HERA's activities, followed by Q&A sessions. The minutes show that, even though these sessions have primarily been intended as updates rather than feedback sessions, HERA has provided space for members to intervene, request clarifications, and share their views, demonstrating a commitment to an efficient and meaningful exchange. Based on the published minutes, participants' comments have often been documented, suggesting that the events have given room for participants to express their thoughts, although it is difficult to judge if the time allocated for these interventions has been sufficient.

³⁰ Interview with representatives from the industry sector, 19 August 2025.

³¹ CSF meeting minutes, 19 March 2024.

³² Interview with a representative from a Member State, 1 August 2025.

³³ Interview with representatives from the industry sector, 19 August 2025.

In a few instances, when time constraints have prevented in-depth discussion of specific topics raised by members, HERA has added them to the agenda of subsequent meetings. For example, following requests from the CSF, topics such as HERA's international relations (30 June 2023), collaboration with industry, and antimicrobial resistance (15 March 2023) were all addressed in later meetings. But not all agreements with members have been followed up. For example, at the Board meeting of 27-28 September 2023, it was agreed that HERA would organise a session on HERA Invest at the next meeting. Yet this never happened, though we cannot verify whether HERA followed up through other channels.

Sometimes, meetings of the Advisory Forum include debriefs from the HERA Board. While this shows HERA's intention to foster cross-group information sharing, an interviewed stakeholder expressed frustration about the duplication of topics discussed during these meetings³⁴.

Industry representatives expressed concerns about the current structure and effectiveness of the meetings³⁵. They emphasised that better preparation, more comprehensive information and cooperation would significantly improve outcomes. Additionally, they noted that interactions would be far more productive if topics were clearly separated and compartmentalised, to ensure that each conversation is targeted and purposeful.

On communications between meetings, minutes show that members are encouraged to provide feedback to HERA in written form. According to an interviewee, communications among members beyond meetings, as well as support from HERA, could be more effective. In March 2024, CSF members <u>enquired</u> about the creation of a collaborative platform for communication. Although the CSF Teams channel had been established a year earlier, it was not actively used, and HERA committed to looking into the matter. At the same meeting, members also raised the possibility of receiving more coordination support from the HERA Secretariat. Nevertheless, it is not clear whether these issues have been followed up. Similarly, a Member State official observed that, beyond the formal meetings, interactions among Board members are largely absent³⁶.

This suggests a communication gap that prevents members from engaging effectively between meetings, which may also limit their ability to collaborate, share insights, and prepare meaningful contributions ahead of discussions.

More positively, interactions with the industry sector go beyond JICF meetings. The recent closed-door workshops with industrial representatives adopted an interactive approach

³⁴ Interview with a representative from a Member State, 1 August 2025.

 $^{^{35}}$ Interview with representatives from the industry sector, 19 August 2025.

 $^{^{36}}$ Interview with a representative from a Member State, 1 August 2025.

that encouraged bilateral discussions and an exchange of ideas. Furthermore, the HERA Industrial Days lasted two days. The first was dedicated to a series of keynote speeches and panel discussions where representatives of companies and associations were invited on stage. The second day involved a series of parallel sessions with a wide range of speakers. The variety of the format of the events hints that HERA has been trying to enhance the quality of communications, though the perceived and actual effectiveness of these communications is unclear.

Another positive aspect that emerged in interviews with stakeholders was that they valued their bilateral exchanges with HERA, emphasising its openness and accessibility. In their view, HERA is a unique DG within the Commission due to its willingness to engage directly and hold one-to-one discussions.

Overall, while HERA demonstrates the ability to innovate and engage with partners in its formats and bilateral exchanges, gaps in preparation, follow-up, and between-meeting communication hinder the effectiveness of stakeholder engagement.

3.3.2. Clarity of roles and mandates – who does what?

Stakeholders perceive the roles and mandates of HERA's governance and advisory structures as unclear. One interviewee observed that, although expectations were well-communicated at the launch of these forums, the reality has been different: practical constraints limit members' ability to contribute meaningfully and engage in co-creation, with meetings primarily following a top-down format³⁷. Similarly, another stakeholder remarked that HERA Board meetings often function as channels for information exchange rather than venues for strategic dialogue³⁸. This stands in contrast with the Board's <u>formal mandate</u> to 'assist and advise HERA in the formulation of strategic decisions'.

An interviewed Member State official also highlighted challenges in clarifying the division of roles and responsibilities between HERA and the Member States³⁹. A central concern is the lack of clarity around 'who does what' when it comes to preparedness and response, particularly on issues such as stockpiling and MCMs. The interviewee noted that Member States often struggle to determine what they should handle at the national level and what should fall under the remit of HERA or the Health Security Committee⁴⁰.

Another layer of ambiguity highlighted by the official relates to HERA's position within the wider EU architecture for crisis preparedness and response. The division of

³⁷ Interview with a representative from the industry sector, 19 August 2025.

³⁸ Interview with a representative from a Member State, 1 August 2025.

³⁹ Interview with a representative from a Member State, 1 August 2025.

⁴⁰ Renda et al. (2024), <u>Health Emergency Response Governance in the EU after the Covid-19 pandemic</u>, op. cit.

responsibilities with other EU bodies – such as the European Medicines Agency (EMA) and ECDC – and different Commission services is not always clear. National authorities often find themselves questioning whether a given issue falls under HERA, DG SANTE, or the DG for Civil Protection and Humanitarian Aid Operations (ECHO).

This confusion about roles and responsibilities is amplified by the creation of overlapping activities. The stakeholders reported instances where new initiatives were launched simultaneously by different services, without sufficient clarity on who was leading and from what perspective. As an example, they referred to parallel developments on civil-military cooperation: the Health Security Committee initiated a technical working group on the issue, while HERA, during the same period, organised a workshop on civil cooperation from the MCM perspective. Such overlaps lead national authorities to question why a certain body is acting and from what perspective.

The lack of clarity over mandates and overlap of initiatives makes it harder for Member States to discern which topics they should collaborate with HERA on, and to send the right expertise to the table when strategic discussions take place. This also creates inefficiencies, such as having to respond to duplicate requests or attend overlapping meetings.

Likewise, industry representatives pointed to tensions between HERA and other Commission services⁴¹. They also noted that HERA's dual role as both a DG, which is meant to be policy-focused, and a funding body creates confusion about its focus and remit.

A prominent example is the Critical Medicines Alliance (CMA) – a consultative mechanism bringing together Member States, industry representatives, and civil society organisations to strengthen the supply of critical medicines in the EU⁴². An interviewee explained that when the Commission set up the CMA, HERA unexpectedly assumed a central role, which they perceived as going beyond its original mission of supporting product development. This involvement not only created confusion about roles but also diverted HERA's resources away from what had originally been conceived as its core mandate.

As a result, the persistent ambiguity surrounding mandates not only complicates collaboration between HERA and its stakeholders but also diminishes trust in the governance process and advisory roles. When formal responsibilities or promises are not reflected in practice, stakeholders may feel confused or sidelined. This gap between

 $^{^{\}rm 41}$ Interview with representatives from the industry sector, 19 August 2025.

⁴² The CMA was established to help ensure timely and equal access to medicines for all European patients, one of the core priorities of the European Health Union. More specifically, it was designed to address the industrial and competitiveness dimension of this challenge.

expectations and reality raises concerns about whether these structures can effectively shape Europe's preparedness and response agenda.

3.3.3. Visibility and access to information – the challenge of being seen

Stakeholders perceive HERA's activities and opportunities as not easily accessible with clarity. More specifically, civil society stakeholders highlighted the need to improve awareness of HERA and its activities among European public health professionals, suggesting that greater dissemination of information at events and conferences could enhance outreach.

Information availability and access are also seen as a challenge by researchers, in particular regarding funding opportunities. One interviewed researcher expressed frustration that information about EU-funded opportunities often fails to reach researchers⁴³. While expressing appreciation for HERA's grants, especially given that securing funding is becoming increasingly difficult for researchers, the interviewee also voiced some concerns. According to the stakeholder, many researchers are interested in exploring the outcomes of existing projects as well as upcoming funding opportunities, but this information is not presented in a way that allows for a clear and accessible overview of funding, activities, or partners. In addition, calls are perceived as complex and administratively burdensome, limiting researchers' ability to engage with HERA and leaving only a small circle of 'insiders' able to navigate the system successfully.

Similar concerns were voiced by an industry representative, who described calls as unclear, filled with EU jargon, and difficult to interpret in terms of expectations, objectives and available funding⁴⁴. Moreover, the time provided to apply for these calls is perceived as insufficient. Early visibility of funding opportunities and straightforward information on scope, budget, and requirements are lacking, thereby complicating participation and discouraging potential applicants.

These insights suggest that the quality and clarity of communication around opportunities remains suboptimal. Limited visibility and access to information, ranging from awareness of HERA's activities to the clarity of funding opportunities, pose significant barriers to participation and engagement, highlighting the need for more proactive and accessible communication with stakeholders.

⁴³ Interview with a representative from the research sector, 18 July 2025.

 $^{^{\}rm 44}$ Interview with a representative from the industry sector, 19 August 2025.

3.4. CONTRIBUTIONS AND FEEDBACK — FROM ADVICE TO ACTION?

During meetings with the advisory forums, members are requested to deliver presentations, share their views, or provide recommendations. While meeting minutes do not explicitly indicate when members' opinions or ideas have been considered, one could infer from other official documents whether such feedback has influenced HERA's direction.

One of the clearest examples is the recommendations from CSF Working Group 1 on the future of HERA. Some of them were reflected in the official review of HERA. These included the need to refine HERA's mandate and improve collaboration and cooperation with other EU institutions like the EMA and the ECDC (30 June and 13 November 2023), concerns about duplication (28 November 2022), and the call for a bigger and independent budget (30 June and 13 November 2023). It is important to note that these views reflect broader concerns shared by a wide range of stakeholders in the study supporting the review. HERA may therefore have been responding to a more widespread consensus rather than exclusively to the CSF's input.

In fact, the impact of contributions by members remains unclear. This was highlighted in the minutes of the CSF meeting on <u>8 October 2024</u>, where some members raised concerns about whether and how their contributions are considered in HERA's activities and decision-making. HERA responded that while all comments are reviewed, not all can be acted upon. It is reasonable that HERA should represent a broader range of interests than one particular type of stakeholder. Yet this points to a deeper issue that expectations between HERA and CSF members do not always align and the lack of expectation management may discourage further contributions and collaborations.

Similarly, industry stakeholders reported contributing to the development of novel funding tools and providing concrete recommendations⁴⁵. However, these efforts often appeared to vanish, with stakeholders left uncertain as to whether their input will ever translate into policy or changes to the funding mechanisms. A comparable situation has been observed in workshops: while participants gained a better understanding of HERA's priorities and improved communication, the outcomes frequently left them asking what would happen next. Despite investing significant time and effort, stakeholders felt that engagement in these processes seldom produced tangible outcomes.

Representatives from the private sector also voiced concerns about the limited involvement of industry in HERA's initiatives⁴⁶. HERA has often developed infrastructures and tools based on assumed needs, rather than in collaboration with the relevant

⁴⁵ Interview with representatives from the industry sector, 19 August 2025.

 $^{^{\}rm 46}$ Interview with representatives from the industry sector, 19 August 2025.

stakeholders. For example, certain calls for antibiotics were unsuccessful because they were not developed in consultation with industry: the language, funding amounts, and expectations regarding asset maturity did not align with what industry could realistically deliver. This mismatch was a direct consequence of not engaging with stakeholders early in the process. When feedback is requested, private sector representatives highlighted that consultation processes are often constrained by overly restricted timeframes, limiting their effectiveness.

A representative from the research community reports a similar experience when interacting with HERA. The interviewee notes that even if researchers are invited to comment on future calls and suggest improvements, it is unclear how a recommendation might translate into actual changes. The researcher described the process as a 'long chain' in which their recommendations have minimal visible impact on calls.

Overall, while HERA provides forums for stakeholders to share recommendations, the visibility and impact of these contributions remain uneven. Feedback occasionally shaped strategic decisions during the Covid-19 crisis, but beyond that, stakeholders often perceive their input as overlooked or disappearing in the policymaking 'black box'. Limited early involvement, short consultation windows, and inconsistent follow-up exacerbate this perception, creating uncertainty about the value of engagement. These challenges risk stakeholder disengagement and may undermine the effectiveness of HERA's advisory processes, reducing the potential for meaningful collaboration and co-creation.

4. RECOMMENDATIONS - MAKING ENGAGEMENT COUNT

1. Clarify HERA's role, mandate, mission, and powers.

A recurring theme among stakeholders is the lack of clarity around HERA's mandate and its division of responsibilities with other EU institutions (e.g. the EMA, ECDC, DG SANTE, and DG ECHO) and Member States. The ambiguities extend to HERA's governance and advisory structures, leaving stakeholders uncertain about their roles.

To address these issues, HERA should:

- coordinate with other EU services to clarify responsibilities and avoid duplication;
- clearly define, communicate, and act in line with the roles and responsibilities set by its governance bodies; and
- ensure stakeholder forums are used as genuine co-creation platforms rather than top-down information channels. Greater transparency and precision in mandates and roles will build trust, reduce duplication efforts, improve alignment, and enable stakeholders to engage in a more targeted and informed way. Without such clarifications, persistent confusion risks inefficiency, disengagement, and diminished collaboration.
- 2. Improve the quality of communication to strengthen engagement (information flow, transparency, continuity, and accessibility).

Stakeholders consistently reported challenges in communication, visibility, and access to information, limiting their ability to engage effectively.

To strengthen engagement, HERA should:

- simplify the language and structure of its calls and establish a clear, accessible platform for information on funding opportunities and activities;
- provide earlier communication on strategic priorities; and
- strengthen mechanisms for continuity between meetings, including better use of collaborative platforms for members and HERA Secretariat support. These steps would reduce barriers to participation, broaden the pool of stakeholders, and allow for more meaningful contributions, while fostering sustained dialogue rather than fragmented exchanges.

3. Strengthen the feedback loop and demonstrate the impact of stakeholder input.

While stakeholders are regularly invited to consultations and to provide feedback and input to the advisory forums, many of them express frustration that their input rarely translates into tangible outcomes.

To address this, HERA should:

- explicitly distinguish between agenda items that are open for input and those shared solely for information;
- ensure that workshops, consultations, and input from the forums result in actionable outputs; and
- provide systematic feedback after consultations and meetings with advisory forums, explaining how input has been used or why it has not been acted upon. This could be operationalised through periodic reports that summarise outcomes and highlight how stakeholder contributions have influenced decisions⁴⁷.

By closing the feedback loop, HERA can transform participation from a symbolic exercise into a meaningful driver of policy and preparedness. If not addressed, the lack of structured follow-up will continue to undermine confidence in the engagement process and risk stakeholder disengagement over time.

⁴⁷ Dell'Aquila, M., Grabova, O., Kostylew, M., Mizsei, B., Pőcze, J. and Yeung, T.Y.-C. (2025), <u>Mapping civil dialogue practices in the EU institutions</u>, European Economic and Social Committee.

5. Conclusions

HERA takes a transparent and expansive approach to stakeholder engagement. As a newly formed Directorate-General, HERA has benefited from a fresh perspective in designing the structure of its engagement strategy and processes from the ground up. Yet, while HERA's strategy sets a positive precedent for other EU bodies, certain aspects must still be improved. Persistent ambiguity and weak communication will undermine trust and hinder effective collaboration.

To strengthen stakeholder engagement, the Commission should clearly define the roles and mandates of HERA, as well as its relations with other internal services and EU institutions such as the EMA and ECDC. By improving communication and access to information, and by demonstrating how stakeholder input shapes decisions, HERA can foster trust, enhance collaboration, and ensure that its governance and advisory structures function effectively. Implementing these measures would not only reduce inefficiencies and duplication but also encourage sustained, meaningful participation from its stakeholders. This will ultimately increase the impact of HERA's preparedness and response efforts.

Rather than disappointing the high expectations of stakeholders regarding HERA's impact, the Commission should leverage them to achieve real change.



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