

COCIR Contribution

to the public consultation on the HERA Inception Impact Assessment

Introduction

COCIR – the European Trade Association representing the leading industries in the medical imaging, radiotherapy, electromedical and health ICT sectors, encourages the establishment of a European Health Emergency Response Authority ([HERA](#)) to protect the EU from potential future supply shortages in medicines and medical equipment, as part of the European Commission [EC] integrated approach to health crisis preparedness and response.

Scope of the Authority

In light of the lessons learnt from the current COVID-19 crisis, HERA would contribute to the ‘EU preparedness and response planning’, in the context of an effective monitoring, early warning of and mutualised actions against serious cross-border threats, as an equivalent to the US Biomedical Advanced Research and Development Authority, BARDA.

COCIR reminds that many of **our industry members have already a long-standing working experience with the US BARDA** and are willing to **share their insights with the EU policy makers**.

Policy Options

COCIR considers that **Policy Option 3**¹ is the most comprehensive one, but it should also include the ‘knowledge transmission and anticipation’-aspects, mentioned in policy option 1.

We welcome that **HERA will support the EU as global actor** to mitigate risks of uncontrolled epidemics through strategic partnerships that promote health capacity building in full transparency.

Problems and Remedies

HERA will attempt to address concerns that COCIR has been voicing throughout the pandemic. The Inception Impact Assessment highlights four main problems and two sets of remedying actions. Following on from that, COCIR places special attention to the three points below:

1. On **Upfront Investment**, as a possible remedy to the 4th challenge of ‘Development, financing and deployment of new countermeasures in times of crisis’ COCIR welcomes the EC initiative to mobilise ‘adequate and flexible’ upfront investment and parallel development processes and is willing to discuss ways to leverage EU funding tools to make this ambition a reality.
2. On the identified Objective of **Equitable [medical countermeasures] access, availability and distribution**, COCIR believes that the medical technologies industry experts would make invaluable contribution to the HERA ‘whole value chain approach’, not only on ‘knowledge’ creation & management and on ‘development & production capacities’, but also on ‘financing/procurement and distribution capacities’.

More specifically, medical technologies industry experts would provide invaluable contribution to a potential:

- **HERA capacity and supply monitoring group** to dynamically share information and adapt to market needs.

¹ Full end-to-end Authority & streamlining of EU level initiatives on medical countermeasures for serious cross-border threats to health.

- **HERA strategic planning group** to define and promote clear incentives for investment in cross-border R&I and ‘modern, flexible and easily scalable manufacturing lines’ for medical countermeasures, inter alia via EU funding tools and PPPs.
3. On **Training**, COCIR reminds of the benefits that digital literacy can bring to those implicated in the HERA implementation activities and urges the EC to include it in its draft legislative proposal.

Risk of overlapping actions

COCIR supports the HERA initiative to launch coordinated and mutualised actions to optimise MCM development and deployment. However, we consider that the roles of EU bodies, such as EMA, ECDC and even the EU’s Union Civil Protection Mechanism, should be clear enough to avoid overlapping actions and unnecessary duplication of work.

Preliminary assessment of expected impacts

COCIR will support HERA in achieving the positive impact it envisages, such as promotion of R&I, digitilisation and health systems innovation.

We are eager to see the expected Impact Assessment and, in addition to our contribution to the public consultations, we welcome an exchange of views on topics, such as [i] ‘crowding-in’ and crowding-out’ solutions, [ii] support to global competitiveness of the European medical technologies, or [iii] green production of medical countermeasures.

Final comments

The HERA inception paper showcases the EC commitment to prepare for future cross-border health threats. COCIR welcomes this initiative and reiterates its availability to participate in the dialogue on how to:

- promote long-term public-private collaboration in health, from discovery to distribution and use
- best channel research funds to ensure high-quality and safe medical products and market-ready health solutions.
- links to existing EU funding instruments, including the new partnership for health innovation under Horizon Europe.

[COCIR](#), together with its members, will continue to contribute to this European Commission initiative, providing our full support. Moreover, we call on the European Commission to organise a specific stakeholder consultation with our member industries and look forward to becoming informed about the results of the consultation and planned next steps.