

COCIR Contribution to the public consultation on serious cross-border threats¹

Introduction

COCIR – the European Trade Association representing the leading industries in the medical imaging, radiotherapy, electromedical and health ICT sectors, notes this **timely and necessary** European Commission [EC] [initiative](#) to **enhance** the ‘EU preparedness and response planning’, in the context of an effective monitoring, early warning of and **combatting serious cross-border threats**, and in light of the lessons learnt from the current COVID-19 crisis.

Indeed, **the proposed EU security health crisis preparedness package attempts to address the concerns that COCIR has been voicing throughout the pandemic.**

In addition, it targets **EU added value** by facilitating the cross-border cooperation planning and coordination in health crisis preparedness and response. It also fosters the **complementarity** of the relevant national plans, to achieve sustainable outcomes, and contribute to the implementation of a **European Health Union.**

Integrated approach to health crisis preparedness and response

In line with this notion, COCIR supports the European Commission [EC] **integrated approach** to health crisis preparedness and response. We applaud the change of instrument used, **from EU Decision to Regulation**, as this could significantly improve the effectiveness of the overall endeavour

We highlight the **opportunities** that arise from a Plan funded through the EU4Health programme and **synergising** with other EU instruments, such as ESIF, Horizon Europe, Digital Europe Programme, rescEU, ESI, ESF+, SMP, to support EU policies, such as on Cohesion, R&I and Digital Single Market.

We also promote the possibility of linking such actions with the **European Semester country specific recommendations** to avoid risks as underlined in the Proposal.

Upskilling and Digitalisation

COCIR welcomes the **training of health specialists** to manage public health crises in the context of grant agreements and procurements. We also place special attention on the **digital literacy** of healthcare professionals and their **training in ICT tools.** We then remind the significant role of **artificial intelligence and digitalisation** in managing the health crisis, as [i] they sustain **personalised care pathways** through **innovative healthcare solutions** with optimal results; [ii] they permit the **interoperability** of systems and structures within and across MSs; [iii] in line with the EU legislation on cybersecurity, personal and general data protection, they also **substantiate the management and exchange of sensitive personal and health data** in a safe, secure and lawful manner, which will be further enhanced by the establishment of a European Health Data Space; [iv] lastly, they enable an **Union-level integrated surveillance system** for better detection of early signals and accurate risk assessment and response.

Reference Laboratories Networks

In parallel, COCIR favours the establishment of **Reference Laboratories Networks** also considering the advantages from potential synergies with the existing **ERNs** -European Reference Networks.

EU Agencies

The pandemic highlighted the need for a more robust and structured Union-level health security framework. In this respect and in accordance with the principle of proportionality, **COCIR supports the strengthening of the EU’s key public health EU agencies** (the European Centre for Disease Prevention and Control, ‘ECDC’, and the European Medicines Agency, ‘EMA’), so as to sustain the Member States in better achieving the cross-border objectives of this Regulation. **However, we consider that the roles of these EU bodies should be clear enough to avoid overlapping actions and unnecessary duplication of work.**

¹ EC Proposal of 11.11.2020 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 [COM(2020) 727 final - 2020/0322 (COD)] [Link](#)

Medtech industry as full members of the EC health crisis advisory groups

COCIR urges the **EC to duly take into consideration the added value of medical technologies, devices and other products** is the establishment of the Health Crisis Preparedness Plan -at both EU and national levels.

In addition **to the public consultations**, we, therefore, call on the **EC to establish regular exchange with the medical technologies sector, where its experts could participate on equal footing with other stakeholders**. Such an exchange could indeed take the form of a **stakeholder forum**.

However, COCIR mostly supports the participation of industry experts in the **technical working group of Health Security Committee-HSC** as well as the standing **Advisory Committee on public health emergencies as full members**. The reason is that within such structures, the medtech experts could offer their technical insights into the management of health crises -e.g. measures for medical products and devices- as well as a complementary view to the 'mechanisms that monitor shortages of, develop, procure, manage and deploy medical countermeasures'.

Final comments

Lastly, COCIR would like to place the focus on the following five points:

1. Further to travel restrictions during the COVID-19 crisis, activities such as inspections and maintenance of medical devices were heavily disrupted. COCIR, therefore, urges the EC to take stock of the situation and plan measures that **ensure the smooth free movement** of people and goods in case of cross-border health crisis, without jeopardising the health of citizens.
2. On the '**Joint Procurement** and with a view to the advance purchase of medical countermeasures for serious cross-border threats to health', COCIR welcomes the EC proposal to extend the agreement to the EFTA and the Union candidate countries. We also call on the EC to consider **improvements in the Joint Procurement procedures**, whose coordination at EU level was deemed sub-optimal during the pandemic -mainly delays, insufficient information and incomplete procedures. Lastly, we **welcome the EC intention to strengthen such cooperation between the different EU programs**.
3. Regarding the '**Pharmaceutical strategy**', COCIR supports the EC intention to strengthen cooperation between the pharmaceutical and medical technologies sectors, considering such cooperation a building block of a patient-centric care.
4. COCIR encourages the establishment of a European Health Emergency Response Authority (**HERA**). We remind that many of our industry members, have already a long-standing working experience with the US BARDA, and are open and willing to share their insights with the EU policy makers.
5. Finally, a comprehensive and effective Union-level health crisis preparedness and response plan should include steps for patients suffering from non-communicable diseases [NCDs], such as cancer patients, whose screening and treatment saw serious delays during the first phase of the COVID-19 crisis. This resulted to a spill-over effect of greater occurrence of cancer patients, diagnosed in later stages of the disease, with limited successful treatment options. In light of the lessons learnt, COCIR, therefore, urges the **EC to ensure that no health crisis will impede NCDs prevention and care pathways in the future and therefore we propose including NCDs in the remit of an even more extended ECDC scope**.

[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 on the results of the consultation and planned next steps.