Brussels, 11 May 2022

COCIR Contribution to the European Commission Call for Evidence[1] regarding the setup of a new EU instrument to guarantee functioning of single market during emergencies -SMEI

COCIR – the European trade association representing the health technologies and devices industry – welcomes[2] the new ambitious and timely European Commission's initiative to improve the European Single Market resilience and preparedness for future health, natural and man-made cross-border emergencies with potential impact on demand and supply chains.

More specifically, COCIR would like to highlight the following:

1. On the SMEI – HERA synergy:

COCIR values the EC effort to put in place a new 'toolbox of targeted and temporary instruments' in synergy with other EU policy tools to ensure seamless EU Single Market operation in times of crisis.

However, we highlight the **risk of overlapping actions** and duplication of efforts between SMEI and HERA, as both instruments target coordinated communication between information channels at national and EU levels, as well as a structured emergency and crisis management layout[3]**.**

- COCIR recommends the European Commission to put in place **a plan that ensures efficient synergies** between the EU instruments to avoid duplication of resources.

2. On European industry intelligence and capacity

Despite the reference to the EU-US Trade and Technology Council, it remains **unclear how the EU can ensure a coordinated approach to key global trade issues**.
The assessment and comparison with global partners proposed in the relevant EU information document[4] require finetuning in close collaboration with the European economic operators to be pragmatic, pertinent, and successful. An **inclusive dialogue** with the European economic operators could ensure feasible and balanced outcomes for SMEI, since SMEI both targets and depends on them.

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[1] *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13181-Single-market-new-EU-instrument-to-guarantee-functioning-of-single-market-during-emergencies_en*

[2] *https://www.cocir.org/media-centre/position-papers/article/joint-cocir-euregha-recommendations-recovery-from-covid-19-driving-healthcare-resilience-in-the-eu.html*

[3] *Both instruments foresee the following crisis Prevention and Response measures: such as [i] targeted monitoring, [ii] strategic storage or stockpiling system(s), for increasing the availability of goods of key strategic importance such as critical raw materials, [iii] strategic storage or stockpiling system(s), for increasing the availability of goods of key strategic importance such as critical raw materials [iv] joint public procurement, and [v] targeted information requests to economic operators.*

[4] *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13181-Single-market-new-EU-instrument-to-guarantee-functioning-of-single-market-during-emergencies_en*

- To that end, COCIR calls on the European Commission to also foresee **bilateral interviews with the European industry players.**
  Such interviews could also be held in the context of 'targeted information requests to economic operators' and 'industry-led initiatives aiming at enhancing the resilience of strategic supply chains', such as ramping up production and availability, or coordinating the distribution of scarce goods when there are dire shortages of critical resources in times of crisis.
- In the same vein, it would be beneficial, if, besides the rather generic article 337 TFEU[5], the European Commission provided a **more targeted and action-specific legal basis** for the request for -potentially sensitive- data and intelligence from the industry.

3. On Stockpiling and allocation of critical supplies in priority

The COVID pandemic revealed that initiatives such as stockpiling of critical raw materials and supplies could be a pertinent measure to ensure the undisrupted functioning of the internal market in times of crisis.
Having said that, it is **difficult to stockpile raw materials that are critical for the health technologies and devices industry**, such as lithium, helium and cobalt 60, due to their short lifespan of around one year. Accordingly, semiconductors and medical devices evolve very fast; this entails the risk of stored material becoming obsolete in time of need.

- COCIR encourages the creation of **sustainable and predictable sourcing** in a coordinated and transparent manner together with the EU member states.
  This exercise should include also regular updates on their status. Evidently, a synergy between SMEI and HERA should be envisaged regarding critical medical devices and other equipment.

In the same vein, should a reliable stockpiling structure be set, it is pivotal **to prioritise the allocation of stored critical supplies to critical sectors** in an emergency.

- COCIR urges the European Commission **to include the health technologies and devices industry in the list of priority sectors**, in order to be among the first to receive critical supplies in emergency situations to ensure seamless provision of healthcare to the European citizens

4. On Joint Public Procurement

The recent reality check with the COVID pandemic showed that normal conformity assessment or standardisation procedures could be too slow to respond to sudden shocks in supply or demand.

Though **joint Public Procurement rules** include emergency provisions, their scope of application tends to be **unclear** to their addressees.

- COCIR calls on the European Commission to ensure that **national authorities unshakeably abide to their commitments** on joint procurement in times of crisis.
- COCIR urges the European Commission to engage in **an inclusive dialogue with the European economic operators to draw up a resilient yet flexible action plan** to deploy when needed.

[5] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E337:EN:HTML

5. Conformity assessment in crisis situations

The extraordinary measures put in place to fight the COVID-19 pandemic such as travel restrictions and quarantine orders, made it unpredictable and in many cases **neither possible nor safe for manufacturers to undergo the Notified Body audits** – which require by regulators to be carried out by physical presence.
In practice, manufacturers transitioning to the new Regulations had to either delay/suspend their certification processes or go back to working under obsolete Directives! **This resulted in delays in product launches or even shortages for medical devices.**

- COCIR calls for the New Legislative Framework -and all other [derived sectorial] legislation- to **allow Notified Bodies to undergo remote/virtual audits using the latest digital technologies**, especially in crisis circumstances, in order to ensure the seamless functioning of the European Single Market.
- In the same vein, COCIR recalls that, during the pandemic, **MDR Article 59[6] was often used as legal basis for bringing medical equipment to market.**

6. Free movement of goods and persons

In times of crisis, the free movement of workers can be disrupted for reasons of public health and security. However, the COVID pandemic revealed disproportionate and occasionally discriminatory national restrictions to international/cross-border workers, which impacted European societies and economies.
An illustrative example is the case of **non-EU citizens expert medical devices technicians, who either denied visa or received visas with very limited validity**. This created disruptions in the provision of field work with a spillover effect on the overall provision of healthcare in the EU Member States.

- COCIR calls for **critical staff – EU and third country citizens – to be able to deploy seamlessly** within the EU territory. COCIR encourages the European Commission to consider issues such as visa waivers for non-EU critical staff.
- COCIR urges the EU to establish an efficient **support mechanism for logistics and transport** of equipment, parts/components to run in case of emergency

Conclusion

COCIR, together with our members, are striving to provide new innovative solutions to meet evolving patient and clinical needs.
So that all European citizens profit from personalised care and cure, and sustainable outcomes. So that the whole of society benefits from improved patient experience, increased health professional satisfaction, better clinical pathways, and overall cost efficiency.
To this end, COCIR will continue to provide our full support to this initiative and look forward to the planned next steps.

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0519(01)&from=EN