

COCIR Feedback

Proposal for a European Chips Act

Introduction

COCIR appreciates the opportunity to provide feedback to the European Commission's proposal for a Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)¹.

As one of the consequences of the Covid-19 pandemic, the medical technology sector is suffering shortages of various materials and transport capacities. In particular, the availability of semiconductors has become an industry-wide concern. Semiconductors are a critical component of almost all devices in the COCIR members' product portfolio (medical imaging, radiation therapy, electromedical equipment, healthcare IT). Any medical equipment that can be plugged into an electric socket or has batteries depends on semiconductors to operate. Examples of medical equipment include but are not limited to Nuclear Medicine, Ultrasound, Patient Monitoring, Respiratory, Image Guided Therapy, Emergency Defibrillator, Contrast media injectors, X-Ray, Magnetic Resonance Imaging, and Computed Tomography devices.

The impact of the shortages on the production of medical equipment is serious. These difficulties are expected to continue throughout 2022, in some cases even 2023. However, we have analysed the European Chips Act primarily as a framework to tackle future crisis situations.

Feedback

We support the additional investment in research, development, and manufacturing of semiconductor technologies, via the Chips for Europe initiative as well as the set-up of Integrated Production Facilities and Open EU Foundries. Investment in key enabling technologies is important to ensure the continued supply of critical components for medical devices in the future.

We welcome that the proposed Regulation cites medical and diagnostic equipment as essential products used by critical sectors. Significant shortage of these devices would constitute a semiconductor crisis. In such a crisis situation, several mechanisms are available to the European Union.

You find here some recommendations to further improve the framework, in view of future application and implementation:

1. A clear definition and criteria for what constitutes a crisis should be developed. The processes and responsibilities for determining and announcing a crisis should be clear to allow for fast action when it is critical.
2. Companies along the semiconductor supply chain will be obliged to provide information on their production and the impact of disruption. Up-to-date information and monitoring of the market situation is key to assess if a supply shortage is arising. Of course, information provision needs to be proportional to avoid

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13405-European-Chips-Act-package_en

- unnecessary administrative burden on manufacturers. Only necessary data should be collected to avoid any misuse of information. The process for information gathering should be centralised as much as possible at European level to avoid overlapping or conflicting data from national authorities.
3. The Commission may oblige Integrated Production Facilities and Open EU Foundries to accept and prioritise an order of crisis-relevant products. A mechanism to ensure that manufacturers of medical equipment have priority access to critical components in a crisis is key to crisis preparedness. Similar mechanisms are available in other jurisdictions across the world, including the United States.
 4. The Commission may also, upon the request of two or more Member States, establish a mandate to act as a central purchasing body. It should be further clarified in the implementation how such a common purchasing process would be set up, including how the purchased semiconductors would be distributed to manufacturers in critical sectors. Care should also be taken that such a common purchasing process does not distort the market by giving priority to certain individual manufacturers.
 5. Support for research, development, and manufacturing should include a wide scope of technologies to keep up with the technological state-of-the-art, also in the medical equipment sector.
 6. The Act allows the Commission to introduce export restrictions when a significant shortage of an essential product is declared. The criteria for such a situation should be developed more concretely and carefully, as export restrictions may actually increase the risk of supply shortages, disrupt distribution channels, lead to imbalances between supply and demand, and risk a vicious cycle of retaliation.
 7. The Act sets up a European Semiconductor Board. Direct involvement of and engagement with industry beyond mere observer status is key. Both from the supplier and user side, industry is critical to provide the necessary technical and business expertise.

Conclusions

We look forward to working with the EU institutions in ensuring that the European Chips Act will support availability of medical equipment. Besides these activities at European level, we would also like to remind the European Commission of the importance of international trade for resilient supply chains. The medical technology sector supports any measures to facilitate trade with suppliers of critical components and raw materials by eliminating tariffs, enhancing regulatory and customs cooperation and reliance, and fight against localization measures for procurement outside the EU. We also ask for support of the Trade in Health initiative.