

Global Semiconductor Shortage Need for Prioritisation of Healthcare Capabilities

26 July 2022

I. A Growing Divergence of Supply and Demand

The ongoing global semiconductor shortage is severely impacting the manufacturing and assembly of medical technologies, i.e., medical devices and *in vitro* diagnostic (IVD). These industries combined use approximately 1% of the current global supply of semiconductors, and yet even this small amount is under threat of undersupply. The gap between supply and demand is likely to increase even further in the months and years ahead, as demand for medical technologies is expected to grow continuously.

Ramping up medical technology supply to meet demand is essential, if healthcare systems are to clear the significant COVID-19 related patient backlogs that still persist in many Member States, while continuing to tackle the chronic challenges of ageing population and the resulting prevalence of chronic conditions and the aspiration for a digital transformation of healthcare that is desired in order to ease these pressures.

It is therefore critical to ensure a continuous and sufficient supply of semiconductors, to meet the growing demand of healthcare systems for medical technologies needed to deliver patient care.

Call for Action:

Immediate global and European actions are needed to safeguard against harm to patients and healthcare systems stemming from the semiconductor shortage, including:

- (1) prioritised allocation of mature and advanced semiconductors to the healthcare sector, now and in the future**
- (2) measures to allow for transparency in the allocation of semiconductors,**
- (3) flexibility to incorporate varying semiconductor types under the medical device and IVD regulatory frameworks¹ in a swift manner, and**
- (4) incentives to increase global production of various semiconductor types, and to facilitate efforts of end-users to re-design medical technologies so they can use newer generations of semiconductors.**

¹ Regulation 745/2017 on medical devices (MDR) and Regulation 746/2017 on *in vitro* diagnostic medical devices (IVDR)

II. Semiconductors are an integral part of many medical technologies and systems

Semiconductors are an essential part of all electronic medical devices and IVDs, and thus are relevant for a huge number of healthcare services.

It is often well-established second or third-generation semiconductors of proven reliability that are used. They are usually supplied as part of pre-assembled electronic components or printed circuit electronic boards which in turn enable various critical components to function, such as: motors, power supplies, sensors, touchscreens, other displays cameras, lasers, data processors, memories, diodes and more.

These components are then integrated into medical technology products, such as:

- Analysers and big instruments that perform all types of diagnostic tests, such as molecular biology, immuno-assay, and bacteriology
- Antibiotic Susceptibility Testing and microbial identification
- Automated External Defibrillators (AED)
- Computerised Tomography (CT) Scanners
- Dialysis machines
- Diabetes blood glucose measuring and insulin delivery systems
- Power tools used for orthopaedic surgery for drilling, reaming, and sewing
- Infusion pumps
- Image Guided Therapy (IGT)
- Laboratory equipment for research, lab automation
- Magnetic Resonance Imaging (MRI) & Ultrasound
- Manufacturing equipment to produce medical technologies, including all types of orthopaedic implants
- Patient monitoring devices
- Pharmacy automation systems
- Surgical robot assistants used for knee, brain, and spine surgery
- Cardiac implanted pacemakers
- Cardiac implanted and external defibrillators
- Health monitoring devices
- Ventilators
- Sleep-apnoea monitoring and treating devices
- Automated external defibrillators for emergency use
- Epidemiology surveillance and pathogen agent tracking

There are many more medical technologies that rely on semiconductors. The list above demonstrates that semiconductors availability is important for effectively all disease and treatment areas within healthcare.

In addition, semiconductors are needed to produce the machines used in the manufacturing of medical technologies. Sufficient availability of those machines is needed too.

III. Short-term mitigation measures cannot compensate for the general shortage of semiconductors in the medical field

To allow for the continued production of needed medical technologies, despite the existing semiconductor shortages, manufacturers have already taken extraordinary mitigation measures in the past months, including:

- Using up any existing stockpiles
- Working with suppliers insofar as possible to ensure priority deliveries for essential medical technologies
- Providing longer forecasts to suppliers for their planning (>12-24 months)
- Accepting more stringent sales contracts from suppliers
- Exploring alternative sales channels, e.g., engaging with brokers of general electronics components
- Building strategic inventory and rationing
- Planning for re-design of products, where possible, to reduce longer-term dependency on semiconductors
- Re-allocating human resources towards more engineering, quality and regulatory resources to allow for re-engineering and re-certifying products, where this is possible

Some manufacturers also look to replace or re-engineer components in their products in order to move to alternative semiconductors, where possible and available. This however is not straightforward to do quickly, as it triggers the need for validation of the new semiconductors, which could trigger regulatory consequences under the sectorial medical technology legislation, i.e., the MDR or IVDR.

These mitigation measures already have a significant impact on the costs and lead time of medical technology production, and this creates unpredictability about when newly-manufactured products can in practice be delivered to the healthcare systems which need them.

While these short-term measures have for the most part enabled medical technology manufacturers to partially compensate in the past months for the ongoing semiconductors shortage, the challenges for the healthcare sector will continue to exacerbate if the situation is not resolved in the longer term. These short-term measures alone are not sufficient to keep the sector afloat in the months and years to come.

Broad and systemic measures are therefore needed to safeguard against further disruption of medical technology supplies to healthcare systems. We call on the European Institutions and Governments to facilitate tangible, bolder action.

IV. Actions to secure the supply chain resilience of medical technologies with regard to semiconductors

MedTech Europe suggests the European Union and Governments to take a range of actions to:

- (1) address the pressure on health products caused by the semiconductor shortage,**
- (2) strengthen the resilience of the medical technologies' supply chains and thus**
- (3) help securing the continuity of medical devices and diagnostic supplies:**

The most important measure is to:

1. Ensure priority allocation of semiconductors to the medical technology sector,

Further measures:

2. Define the medical technology and other healthcare industries as a distinct and self-standing 'critical sector' within any kind of allocation schemes.
3. Increase end-to-end transparency on the allocation of mature and advanced semiconductors in the EU for 2022-2023 and beyond.
4. Allow for the continued use of critical materials needed to manufacture semiconductors in Europe, for example through a strong alignment of the EU Chips Act and the EU chemical legislation.
5. Ensure that medical technologies can undergo needed changes from one semiconductor to another, without triggering recertification under the MDR/IVDR, provided that the change has no negative impact on the device's safety, performance or benefit-risk ratio.
6. Provide public financing for semiconductor production, to ensure critical sectors like medical technologies can be prioritised during shortages, for example providing premiums for semiconductor manufacturers that supply to critical industries.
7. Invest in a more diversified supply chain for semiconductors, including increasing the production of semiconductors within the European Union.
8. Facilitate stronger relationships and exchanges between the medical technology and semiconductor industries, for example through stronger collaboration in research projects to ensure the development and availability of key components for the medical technologies industry.
9. Provide guidance at European level to public hospitals and authorities concerning potential extensions to delivery terms in their purchasing/procurement contracts due to these exceptional circumstances.
10. Help Member States make full use of the [February 2022 Commission Recommendation](#) on a common union toolbox to address semiconductor shortages.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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