

BVMed factsheet

Increasing cost pressure on the manufacture of medical devices

Coping with the COVID pandemic and the Ukraine war have severely impacted global supply chains and manufacturing costs. The medical technology industry is struggling with rising costs while operating in a highly regulated market. There are often legal regulations and longterm contractual ties that make it even more difficult for companies to plan and to operate. The following issues are putting increasing pressure on medical device manufacturing:

Rising energy and commodity costs

The medical technology industry is energy and raw material intensive. The steep rise in international oil and gas prices has led to higher energy costs, which affect manufacturing costs. In addition, global commodity prices have skyrocketed, making all products and goods that rely on these materials more expensive. Furthermore, global shortages of key raw materials such as semiconductors, packaging materials, resins, plastics, and surgical alloys, all of which are important to the manufacture of medical technology, have contributed to significant price increases.

87 percent of medtech companies feel these burdens relatively strongly, according to a DIHK survey. **The proportion of companies citing energy and raw material prices as a risk is at a new all-time high of 72 percent in the medtech industry.**¹ The situation in the healthcare sector is worse than in the economy as a whole. The high energy and raw material prices have displaced the shortage of skilled workers from the number one risk factor in the healthcare industry.²

According to the Federal Statistical Office, energy prices rose by 86.1 per cent in June 2022 compared to the same month last year.³ Both the production and sterilization of medical devices needed for care and especially for surgery and operations are affected. Healthcare in Germany and worldwide is only possible with the necessary medical devices. Medical technology companies are systemically relevant and must be supplied with gas and electricity as a matter of priority, even in the event of a crisis.

The prices of metals important to the industry such as platinum (plus 43 per cent) or cobaltchromium (plus 119 per cent)⁴ have also risen considerably in the last two years. Examples are also the price increases of polyacrylate (superabsorbents) with 67 per cent⁵ (Propylene Europe Index), polyethylene (films) with 80 per cent⁶ (LDPE EU Index), and polypropylene (nonwovens) with 60 per cent⁷ (PP Europe Homo Index) as main components for the production of incontinence products.

42 percent of medical technology companies suffer from supply bottlenecks. **Important precursor products such as semiconductor (chips), but also steel, aluminum, and plastics are**

¹ <u>https://www.dihk.de/resource/blob/73350/4912206cdf7717fd3e770a3927f58537/gesundheitsreport-fruehsommer-2022-data.pdf</u> (last accessed on June 22, 2022)

² <u>https://www.dihk.de/de/themen-und-positionen/wirtschaftspolitik/gesundheitswirtschaft/energie-und-rohstoffkosten-belasten-auch-gesundheitswirtschaft--73246</u> (last accessed on June 22, 2022)

³ <u>https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22_309_61241.html</u> (last accessed on July 20, 2022) ⁴ <u>https://www.boerse.de/rohstoffe/Platinpreis/XC0009665545</u> (last accessed on June 22, 2022)

⁵ https://www.chemorbis.com/en/pp/polypropylene-indexprice (last accessed on June 22, 2022)

⁶ https://plasticker.de/preise/preise myceppi en.php (last accessed on June 22, 2022)

⁷ https://plasticker.de/preise/preise myceppi en.php (last accessed on June 22, 2022)

scarce. For manufacturers, these are more than just temporary interruptions in supply chains. These shortages result in huge price increases, or in the case of component unavailability, high costs incurred through product redesign.

All of this drastically increases costs for manufacturers – especially for intermediate inputs. For example, the cost of intermediate goods across all sectors increased by 22.3 per cent⁸ in June 2022 compared to the previous year.

In medical technology, 96 percent of the companies are affected by higher purchase prices for purchased goods and services.⁹

Rising logistics and freight costs

Global logistics processes have been significantly impacted by the COVID pandemic, leading to supply chain disruptions and instability in global production. Sea and air freight rates as well as container freight costs have risen sharply.

<u>For example</u>, the World Container Index¹⁰ currently puts the booking of a 40-foot container at US\$ 6,999, 454.6 per cent more than in September 2019 (US\$ 1,262). In September 2021, the price peaked at US\$ 10,375/container, an increase of 722.1 per cent compared to the September 2019 price.

On the busiest route to Europe (Shanghai – Rotterdam), booking a 40-foot container currently costs US\$ 9,182 per container. **Compared to September 2019 (US\$ 1,247 per container), this is 636.3 per cent more.** On this route, the price peaked in October 2021 (US\$ 14,558 per container). Compared to the price in September 2019, this resulted in an increase of 1,067.4 per cent.

Due to high fuel prices and the ongoing drivers' shortage, freight transport costs continue to rise. While the number of freight entries is still high so far, offers of cargo space are falling.

Due to the globally organized production and supply chain networks of the medtech industry, all these factors have a negative impact. Many medtech devices and components also require very specific transport conditions to ensure their safety and performance, such as to provide and safeguard the right temperature (for diagnostic tests), sterilization conditions (for medical PPE, surgical material, implants), or guaranteed expiry dates. As operational routes and freight volumes decline worldwide, freight availability and reliability, and the associated freight costs, have become a growing cost factor for medical device manufacturers.

Rising regulatory costs

Supply chain or system-related logistical challenges force manufacturers to redevelop and redesign devices and / or components. In the case of medical technologies, this often requires recertification to demonstrate the same level of safety and performance of the product, especially as the new EU Medical Device Regulation (MDR) has tightened and extended the legal requirements. **Thus, the industry is additionally affected by a higher certification and bureaucratic burden. Companies incur costs of € 300,000 – 500,000 per certification file.** In addition, there are delays due to a lack of transposition regulations and insufficient capacities at the Notified Bodies.

⁸ <u>https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22_309_61241.html (last accessed on July 20, 2022)</u>

⁹ <u>https://www.dihk.de/resource/blob/73350/4912206cdf7717fd3e770a3927f58537/gesundheitsreport-fruehsommer-2022-data.pdf</u> (last accessed on June 22, 2022)

¹⁰ https://infogram.com/world-container-index-1h17493095xl4zj (last accessed on July 20, 2022)

These issues represent a severe situation for many small and medium-sized enterprises, which leads to jeopardizing the security of supply with medical devices.

Rising labor costs

The medtech industry faces strong competition from other industries for highly skilled workers in areas such as engineering, IT, and regulatory specialists. Moreover, wage inflation affects areas such as warehousing, logistics, and distribution. **Thus, labor costs have increased significantly in recent months – and will increase even more in the months to come.**

Conclusion

In recent months and years, the medtech industry has also shown itself to be an innovative sector and a reliable partner in the pandemic, which was able to contribute significantly to the fight against COVID (in terms of protection) and to ease its results. In addition, with more than 235,000 employees and a total annual turnover of 36.4 billion euros in Germany, the sector is an important economic and labor market factor. The member companies of BVMed are aware of their responsibility in these macroeconomically and geopolitically tense times. It is their endeavor to ensure a reliable supply of medical technology in Germany and worldwide – also in the future.

Given the inflationary cost increases and systemic cost pressures on the medtech industry, we need short-, medium-, and long-term measures and mechanisms to ensure the security of supply of essential medical devices to people – and to address the challenges coming therewith.

BVMed – German Medical Technology Association

As of July 2022