Position Paper
on the German EU Council Presidency July to December 2020

From BVMed's point of view, the German EU Council Presidency in the second half of 2020 should be used to establish a uniform approach in the post-COVID-19 phase, to see medical technologies as part of the solution and to promote innovations.

1. Europe-wide solutions for appropriate care

Europe must move closer together, join forces and do everything possible to master the current challenges - especially in these difficult times. The drastic measures taken by European member states generally were the right ones to slow down the spread of the Sars-CoV-2 virus and to strengthen the healthcare systems. However, going alone at national level and restricting the free movement of goods is not the solution. Free movement of goods, open borders and solidarity with each other are essential to help each other in emergency situations.

> **Promote free movement of goods:** Logistics and supply chains were massively hindered by national reflexes at the beginning of the coronavirus crisis. We must remove trade barriers and simplify customs procedures to ensure free movement of goods. In the current crisis situation we see the importance of functioning trade routes and uninterrupted supply chains to maintain the supply of medical equipment. Europe-wide solutions must now be found for future demand-oriented supply including all necessary medical devices and medicines, which reflect the complexity of supply chains and production networks.

> **Increasing cross-border health security capacities, reducing external dependencies:** Due to social and economic interdependence, a single country cannot face the enormous challenges of combating the pandemic and coping with its consequences on its own. Rather we need closer cooperation between the European member states.

> **Protection against infection must be a permanent health policy priority:** In order to be able to jointly manage such pandemics in the future, it is important that we establish effective infection control in the member states on a sustainable basis. This requires the cooperation and efforts of all member states in establishing binding hygiene standards and their continuous and consistent implementation. In order to be able to guarantee the necessary transparency regarding the occurrence of infections within the EU, we strongly support the strengthening of the ECDC (European Center for Disease Control). This must be accompanied by ambitious target values for the reduction of e. g. nosocomial infections, which are regularly reviewed.

2. Understanding and strengthening medical technologies as part of the solution

The COVID-19 crisis has exposed the weaknesses of some European healthcare systems. At the same time, however, it has highlighted the contribution of the medical device industry in providing innovative and high-quality medical devices to patients throughout Europe. Even products that are relatively easy to manufacture, such as personal protective equipment, suddenly became a crucial ally in the fight against the spread of the virus or in the treatment of patients. Now the time has come to strengthen the European MedTech industry, which is strongly characterized by medium-sized companies, for the future.

> **Protect property rights and entrepreneurial freedoms:** Companies must be able to meet the needs of their customers across borders. State interventions such as confiscation of products, export bans, arbitrary pricing or disproportionate stockpiling at European member states' level

create an uneven distribution and bring medical care to a shutdown in the short term - with serious consequences for the affected patients.

> **Create legal certainty for companies:** With the planned directive on collective redress, the European Commission wants to strengthen the enforcement of consumer law. For medical devices and diagnostics, however, the MDR and IVD ordinances provide their own specific regulatory instruments. These already offer consumers and companies the necessary legal certainty. With this in mind and with the aim of avoiding legal uncertainties for companies, medical devices and in vitro diagnostics should be excluded from the scope of the planned guideline, as already intended by the European Parliament.

> **Secure and expand European production:** When calling for a relocation of production, it is often ignored that the EU is already one of the largest global manufacturers and the largest exporter of medical devices. However, high energy prices, environmental requirements and bureaucratic regulations are endangering the success of the medical device industry in Europe. With this in mind, the simplification of existing regulations should be examined and new proposals by the legislator should be evaluated for any negative effects on the industry and adjusted accordingly. A politically desired relocation of the production of certain drugs and medical devices must be funded by the EU and taken into account by the respective European health care systems in calls.

> **Increase security of supply in Europe:** The COVID-19 crisis has shown that the EU runs the risk of becoming dependent on a few non-European countries if the production of essential medical supplies is only centralized there. To address this, the EU must first work with manufacturers to examine possible weaknesses in supply chains. To avoid future bottlenecks, the EU should also expand its stock of medical equipment and make it available to member states that need it. A European strategic reserve of medical devices can be built up by making intelligent use of existing storage capacity. Considering that, the existing storage capacities must be networked online and intelligently controlled. Consequently, there will be no problems with the durability of the products because the stocks will be turned over regularly. As part of the German EU Council Presidency, BVMed is offering the European Commission close cooperation in establishing such a rotating system.

3. Drive innovation

Europe thrives on innovation - also in the field of health. To improve the framework conditions for research and development in the EU, a uniform European data strategy should be promoted and regulatory barriers should be removed.

> **Launching a European industrial and digital strategy:** Medical technology companies in Europe must be enabled to catch up with excellent research and development. The EU Trio-presidency of Germany, Portugal and Slovenia rightly speaks of the "innovation orientation" that is necessary to launch a European industrial and digital strategy.

Digital products and solutions for health care do not only play a fundamental role in the search for immediate solutions to crisis-related problems. They will be crucial for improving the long-term resilience and sustainability of European healthcare systems. In order to proactively shape the current technological change in healthcare systems within the EU and to fully exploit its potential, companies need the following:

- **Harmonisation of European health data and access to the European Health Data Space:** The COVID-19 crisis has shown that the collection of health data is essential for the real-time tracking of disease transmission, epidemiological research or the discovery and

identification of treatment options. In the EU context, the lack of harmonisation slows down the establishment of Europe-wide research initiatives. Data should be searchable, accessible, interoperable and reusable. The governance model of the Health Data Space should allow a secure data exchange, enabling citizens, public authorities and businesses to share critical findings under the highest ethical and technical standards within an agreed code of conduct.

- **Improving public acceptance and trust in digital health solutions:** This can only be achieved by informing, accepting and further increasing the digital literacy of citizens in the European Union. Here we refer to the announced action plan on digital education.

- **Telemedicine and better access of the population to "smart care":** The enormous increase in the use of telemedicine applications during the COVID-19 crisis has demonstrated the added value of these treatment options. This type of care must be expanded, especially with regards to an aging society.

- **Greater acceptance of real-world evidence:** Digital health solutions will deliver data volumes that are quickly available and directly reflect care processes. This data should be accepted for the proof of benefits respectively "outcomes" in health care systems.

- **EU programmes / initiatives for new reimbursement concepts for digital products and services:** If digital applications are to be established in European healthcare systems, they must also be reimbursable. Accordingly the EU should encourage member states to develop funding possibilities for these products.

  A concrete example that shows the important role of digital tools is the fight against cancer. The cancer plan announced by the EU Commission ("Europe's Beating Cancer Plan") must be adopted promptly. In doing so, the potential of digitization must be exploited, which is of crucial importance for improving cancer treatment. Programs for digital imaging and digital pathology can support cancer detection, artificial intelligence can promote comprehensive diagnosis and optimize therapies. These technologies require investment in improving digitization in patient care and promoting fast-track financing and reimbursement models.

> **Combating common causes of death through innovative MedTech solutions:** In particular, the prevention of cardiovascular diseases, as the most frequent cause of death in Europe, should be promoted through research by interdisciplinary expert groups. In times such as the COVID-19 pandemic, modern minimally invasive therapies for cardiovascular patients are just as appropriate as for other diseases, thus the capacity of the health care system is spared through reduced need for intensive care beds and a shorter general treatment period.

> **Getting the MDR system ready:** The EU institutions must make effective use of the one-year postponement of the EU Medical Devices Regulation (MDR) until May 2021 to make the system operational. For this further notified bodies must be notified under the MDR without delay. The certification of new products as well as existing products whose purpose is extended must be guaranteed. For this purpose, alternative assessment procedures must be developed, which do not necessarily require on-site audits. The expert bodies required for certification in the consultation procedure, must be established quickly. The missing legal acts and essential guidelines, which are urgently needed for the implementation of the MDR, must be made available without delay.

> **Take medical technologies out of the European HTA legislation:** The field of medical technologies must be removed from the planned European Health Technology Assessment

(HTA) legislation. The EU HTA proposal does not bring any added value for patient safety, but will lead to a further delay in the provision of advanced medical technologies to patients. Pharmaceuticals and medical devices cannot be regulated together due to their respective characteristics. The proven voluntary HTA procedure for medical devices at EU level should be continued.

The COVID-19 crisis has highlighted the importance of modern medical technologies for the diagnosis and treatment of diseases across Europe. We must invest more in technological solutions and gain digital progress. The medical technology sector can use its expertise to develop solutions for more efficient processes, improve treatments and their procedures, make interventions gentler and support cross-sectoral patient care. We Europeans want to produce innovations and not just import them.

Berlin, 16th June 2020