A European industry perspective on the German draft law on digital care modernisation (DVPMG)

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MedTech Europe would like to share some considerations on the German draft law on digital care modernisation ("Digitale Versorgung und Pflege Modernisierungs Gesetz, or DVPMG[1]), supporting the position of our German member association BVMed articulated on 15 March 2021.[2]

I. The European Context

MedTech Europe sees the draft law in the wider policy context of the European Health Data Space (EHDS) project, which seeks to harness the potential of health data for the advance of healthcare delivery and research. MedTech Europe supports the EHDS. The EHDS aims at making data "FAIR", namely findable, accessible, interoperable and reusable. Regarding interoperability, the European Commission can coordinate Member States' actions (for example with the European Electronic Health Record Exchange Format), but it is the responsibility of Member States to act. In its statement of February 2021, MedTech Europe shared the following recommendation on the EHDS:

> *MedTech Europe calls on governments and healthcare authorities to develop guidance, recommendations and mandates (in the form of digital health strategies, action plans, or other indicative statements) that advance interoperable data ecosystems consistent with, and based on, international consensus standards to avoid national and regional fragmentation.*[3]

The draft DVPMG law would be one of the first initiatives in Europe advancing interoperable data transfers in the context of the EHDS. MedTech Europe supports initiatives that aim to further advance national and European digital health infrastructure and to improve citizen and patient access to their health data. MedTech Europe believes these goals deserve to be pursued in an effective and efficient manner whilst avoiding the occurrence of any unintended effect.

Below we outline the challenges we see with the draft law, which could affect German patients' access to advanced medical technologies if passed as written. We also provide recommendations to address these challenges.

II. Concerns

Our concerns are:

- **Impact on Europe:** Given Germany's importance in Europe, the DVPMG law may offer a blueprint for health systems and providers in countries and regions in Europe and beyond. Therefore, it is important that the German law establishes efficient and feasible interoperability requirements that are consistent with the EHDS and can be replicated elsewhere.

[1] The text and background of the law is available on the German Ministry of Health's website.
[2] We refer to the BVMed 15 March 2021 position paper on the DVPMG's envisaged changes to Article 374a SGB V, available on the BVMed website.
[3] See *The European Health Data Space and the view from MedTech Europe*, 3 February 2021.

- **Connection of medical technologies with digital health apps:** The draft DVPMG law would mandate manufacturers to make changes to their connected medical devices to facilitate a direct data link between their device and a personal digital health application (DiGA)[4]. This approach is concerning because direct data links between devices and apps from different vendors and different regulatory classifications may raise a number of legal, regulatory, technical, economic, intellectual property (IP) and security challenges.[5]
- **European market fragmentation:** Medical technologies are designed to serve different healthcare systems in various countries according to internationally accepted standards and requirements. We are concerned that country-specific requirement to transfer health data to third parties could present a potential technical barrier to trade and could lead to the disruption of supply for the German market or the discontinuation of certain devices altogether. In many cases it will require the development of new devices, which takes time and effort.

III. Recommendations

To advance patients' access to their data, improve healthcare delivery, and support the implementation of the EHDS, we would suggest taking the following recommendations into account:

- **To allow for appropriate transition times.** The envisaged transition time of two years is too short, given that the development, testing and approval cycles for new medical devices take at least three to four years. Advanced connected medical technologies are made for a global market. Manufacturing devices to new specifications will present considerable barriers for the European and international medical technology industry to providing them to national healthcare systems. A transition period of a mere two years could lead to a disruption of supply for German patients.
- **To ensure compliance with international consensus standards.** Advanced connected medical technologies are designed for a global market. Country-level regulations requiring local adaptions to the device design to comply with additional local specifications present considerable challenges and constitute a barrier to the launch of medical technology solutions on the German market. The broader impact of the current draft requirements should be considered, and a regulatory approach is favoured where the German requirements are aligned with robust and recognised international consensus standards.
- **To work with industry.** When ensuring health data transfers, the medical technology industry should be considered a partner in the process. Instead of requiring manufacturers to create interoperable interfaces ("interoperable Schnittstellen"), we recommend that the law defines the objectives, and the Government supports the established interoperability organisations and mechanisms like those of Integrating the Healthcare Enterprise (IHE).[6]

[4] "DiGA", short for "digitale Gesundheitsanwendungen", are digital health applications that passed an official assessment for reimbursement by Germany's statutory health insurances; more information is available on the website of BfArM, the German Federal Institute for Drugs and Medical Devices.
[5] BVMed has discussed many of these challenges in its aforementioned 15 March 2021 position paper.
[6] Integrating the Healthcare Enterprise (IHE) is an international initiative by healthcare professionals and industry to improve the way digital health systems share information, by promoting the coordinated use of established standards to address specific clinical needs. Go to HE international, IHE Europe or IHE Deutschland.

We are ready to discuss any questions and look forward to supporting further improvements to the draft German “DVPMG” and Europe’s digital transformation of healthcare.

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 who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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