

Summary BVMed and VDPH White Paper on the Future Development of the MDR and IVDR

In cooperation with Erik Vollebregt – Axon Lawyers

Introduction and background

The MDR and IVDR have not delivered on their promise of a sound, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health protection and at the same time promotes innovation. There is broad consensus and evidence that the MDR and IVDR compromise lead to shortages of devices in medical care and slow the pace of innovation. The rules and procedures under the MDR and IVDR are experienced as complex and unpredictable, making it more difficult to develop and launch novel products in Europe. Data shows that there is a steep decline of the number of medical technology and IVD companies that would consider introducing new devices in Europe first. Many devices available under the previous EU directives have been taken off the market because obtaining a CE mark under the new regulations is too complex, time consuming and expensive.

BVMed and VDPH have drafted a white paper that discusses the consequences of the underperforming regulatory system for healthcare, innovation and the position of the CE mark for medical devices and IVDs internationally. The white paper proposes several solutions, grouped by the following categories:

- Measures to supplement the current regulatory system set out under the MDR and IVDR;
- Measures to increase efficiency and implement principles of good administration;
- Reform of the current five-year certification cycle;
- Increased international cooperation and regulatory reliance; and
- Centralisation of responsibility and policy within the regulatory system.

Measures to supplement the current regulatory system

Many jurisdictions in the world have fast track procedures for innovative devices, for orphan devices or devices testing for rare diseases and/or for niche devices with a proven track record that can be implemented in the MDR and IVDR. BVMed and VDPH propose dedicated procedures in the MDR and IVDR for these groups of devices by analogy to other jurisdictions to stimulate innovation for the benefit of small (often paediatric) patient groups and of patients with rare diseases.

Measures to increase efficiency and implement principles of good administration

The increased obligations for notified bodies and administrative formalities required under the MDR and IVDR have led to several challenges that are compounded by the inefficient notification designation process for notified bodies under the MDR and IVDR. BVMed and VDPH believe that consistent implementation of the principles of good administration in MDR and IVDR procedure is needed to ensure that the CE certification system under the MDR and IVDR continues to operate in a fair, transparent, lawful and predictable manner under administrative accountability in order to achieve:

- more predictable duration and cost of regulatory procedures under the MDR and IVDR;
- equal access to the regulatory system by all stakeholders;
- increased transparency and accountability for market access decisions;
- effective legal remedies against market access decisions in accordance with fundamental rights of stakeholders;
- better management of overlap of legislation applicable to medical devices and IVDs, both on EU and national level.

Reform of the five-year certification cycle

The CE certificates issued by notified bodies for devices are currently limited in duration to five years, which necessitates a costly and resource consuming re-assessment for a renewed certificate every five years. However, the much increased post-market surveillance and post market clinical / performance follow-up requirements for the device's life time enable a more efficient and risk-based certification approach. This approach leverages these data collected for devices under the MDR and IVDR, allowing for an efficient surveillance based certification approach rather than certification based on a time cycle, that benefits patients and manufacturers alike.

International cooperation and regulatory reliance

Until entry into force of the MDR and IVDR the EU CE marking system for medical devices was generally seen as the most (cost) efficient system of regulatory approval for medical devices in the world. The CE mark was (unilaterally) recognised by many jurisdictions. The MDR and IVDR have changed this, causing erosion of the international status of CE marking for medical devices and IVDs and the EU's international influence as a source of standards for medical devices and IVD approval.

BVMed and VDPH propose an increased international involvement of the EU in MDSAP to enable recognition of MDSAP audit reports by the EU for CE marking purposes under the MDR and IVDR. BVMed and VDPH see many opportunities for the EU to further recognition- and reliance practices internationally and to promote international convergence of regulation both under existing structures and under new structures. In dealings with other jurisdictions with a mature regulatory system for devices, the EU should increasingly facilitate the use of reliance and recognition mechanisms, as appropriate. An example would be reviving the existing EU-US

mutual recognition agreement for medical devices and re-establishing mutual recognition between the EU on the one hand and Switzerland and the UK on the other hand.

Centralisation of responsibility and policy within the regulatory system

As a result of inefficiencies and inconsistencies in the functioning of the decentralised MDR and IVDR governance system, patients are deprived of medical technology that can improve their outcomes and manufacturers are deprived of predictable conformity assessment options. BVMed and VDGH believe that establishing a central accountable managing structure for medical devices combined with consistent application of the principles of good administration would have important advantages over the current system laid down in the MDR and IVDR. It would result in:

- notified bodies being consistently managed under the same unitary policy and
- the principles of good administration being applied to decisions concerning certificate grant and certification status as is required under the EU Charter of Human Rights and the European Convention on Human Rights (ECHR).

An accountable managing structure would have an appropriate policy for SMEs and special categories devices such as niche or orphan devices or devices for testing for rare diseases. It would have predictable deadlines for procedures subject to principles of good administration that would better serve the public interest.

Impressum:

BVMed - Bundesverband Medizintechnologie e.V.

Reinhardtstraße 29b, 10117 Berlin

VDGH - Verband der Diagnostica-Industrie e.V.

Neustädtische Kirchstr. 8, 10117 Berlin