Biomedical Alliance in Europe

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Plans made in haste to change medical device regulations risk further neglecting the needs of patients who rely on medical technologies

Brussels: In the European Parliament Plenary Session on 9 October, the European Commission made a statement on the revision of the Medical Devices Regulation. During the debate, several Members of the European Parliament called to speed-up the evaluation of the Medical Devices Regulation, and asked the next Commissioner for Health and Food Safety to come with a new proposal within the first 100 days of being in office. The Biomedical Alliance in Europe, representing 35 medical and research societies, believes a careful review of the regulatory framework for medical devices and in vitro diagnostics cannot effectively be conducted in such a short time period and calls on European policymakers to base their re-evaluation on an analysis of the needs of patients and clinicians rather than short term political expediency.

Initial experience with the Medical Devices Regulation (EU 2017/745) and In-Vitro Diagnostic Device Regulation (EU 746/2017) demonstrates a remarkably complex system that is proceeding in the absence of basic scientific principles for clinical evidence generation. The time, cost and complexity of conformity assessments in both frameworks is now significantly more challenging than in other international regulatory systems, where market access can be achieved in a much more predictable, efficient and timely manner. In short, we are not achieving the fundamental goal of regulation in either of these frameworks, which is to protect public health and support innovation.

The inefficiency of the system can be attributed to its structure. This is not a problem arising from a lack of resources – the current regulatory system employs approximately 5,000 staff in notified bodies alone. Member State Authorities employ hundreds more staff. As a result, we employ twice as many regulators for medical devices and IVDs than the US FDA. Despite this, there is no scientific or public health coordination apparent within the European system. A pre-market clinical study or a post-market recall of a medical device is managed by each individual authority, resulting in an enormous replication of work.

The Biomedical Alliance has previously noted the growing fear that Europe is on track to a potential public health crisis, and as things currently stand, it is only a matter of time before patients, and particularly children, experience serious consequences of the unavailability of devices or may even have a higher risk of mortality. The Alliance agrees that immediate short-term measures are necessary to address pressing issues, including the limited availability of orphan and paediatric devices, but these should be separate from a structured and in-depth evaluation process of the MDR and the IVDR. We must take the time to do things right, and address longstanding issues in the system. If we rush through the process we may not be able to fully assess the impact of any new measures and to understand whether these measures are sufficient to address shortcomings in our regulatory system for medical devices and IVDs.

The single greatest cause of this current dysfunction is a lack of clarity concerning clinical evidence requirements. In simple terms, it is not clear whether a technology requires a clinical study, or how that study should be designed. This is vital for small and medium sized enterprises, which constitute the vast majority of organisations introducing innovative technologies.

In the absence of scientific principles for clinical evidence generation, developers rely on expert scientific advice. This is readily available in the United States, where the US FDA can provide clear advice on clinical evidence requirements in a consistent way. In the EU, advice structures are partial and uncoordinated, leading to a persistent ambiguity in the system.

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MEP Dr. Peter Liese has prepared a proposal for a draft amending regulation. The Biomedical Alliance understands that this will include changes to some reassessments of clinical and safety reports. The Alliance welcomes the intention to address regulatory challenges with urgency, however such changes require a clear rationale and impact assessment to understand the public health consequences. It believes that the proposal seeks to remove requirements for reassessing some products and post-market safety reports, however this is not supported by any rationale or impact assessment to consider the public health consequences. Furthermore, there is currently no proposal to address the unique and even more complex challenges faced by IVD developers and IVD users, including patients themselves.

BioMed Alliance therefore calls on policy makers:

- To support the detailed review of the regulations that the European Commission is currently undertaking.
- To avoid implementing short-term legislative measures without a careful diagnosis of the key shortcomings in the system.
- To address fundamental problems based on scientific principles.
- To ensure that revisions to the IVDR are considered separately, due to the different needs of the diagnostic sector.
- To plan for much greater use of clinical and scientific expertise within the current system to provide common specifications and predictable evidence-based decisions.
- To implement targeted short-term measures to reduce certification costs and mitigate shortages of medical devices, particularly of orphan devices and paediatric devices, separately from the more comprehensive review of the regulations.

About BioMed Alliance:

The Biomedical Alliance in Europe (BioMed Alliance) speaks as a common voice for 35 leading European medical and research societies. It shares the expertise of healthcare professionals and researchers to contribute to evidence-based policy making.