Transitioning into the new IVD Regulations

It's important to get it right

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THE PROPOSED IN VITRO DIAGNOSTIC (IVD) REGULATION under discussion at the European Parliament is a landmark piece of legislation for the medical device industry. It will define the way in which in vitro diagnostics are regulated and made available in European healthcare for decades to come.

Fundamental changes will need to be adopted by the IVD sector. In addition to an in-depth review of regulatory process for medical devices, the revised regulation for IVDs specifically will include an extensive technical review. This will consist of a complete overhaul of the classification and conformity assessment system, and establish critical new requirements for determining the clinical evidence for IVDs.

It is essential to ensure an adequate transition period for the upcoming legislative revisions. If the transition period is too short, implementation will be hampered, as there will be no sufficient resources or time for IVDs to meet new requirements, and therefore IVDs will not be available on the market. Equally, if authorities are not ready to implement and enforce new provisions, the revised legislation will fail to achieve its goals. As many of the provisions are being put in place to increase the safety of the system, undue delays in their implementation would needlessly weaken the regulatory system for in vitro diagnostics.

Unfortunately, determining the optimal transition period for the new IVD regulations will be challenging. This is why the industry welcomes the proposal put forth by the ENVI Committee to split the transition period and include rapid timelines for those aspects of the regulation which can be implemented faster. This will strengthen the ability of Authorities to control devices. Measures to be implemented rapidly include those that affect devices before their placement on the market, such as the much stricter control of notified bodies, and a closer collaboration between authorities. Additionally, it will enable a better control of the situation in the field after IVDs are made available, by reinforcing the vigilance provisions and installing a system of traceability through unique device identification.

There still remain provisions that will require a longer time to be implemented, particularly reclassification. Manufacturers will need to support new classifications with clinical evidence, which is obtained from studies that often take years to be completed. This is a major concern especially when these new studies need rare samples and cases to assess how a diagnostic test performs. Additionally, the regulatory burden of re-classification should not be underestimated. The Australian Therapeutic Drugs Authority (TGA), currently further in the process of implementing a similar system, has had to add an additional year to its implementation schedule, bringing it to a total of five years to transition to the internationally recognised GHTF classification model.

It is in the public interest to ensure that in vitro diagnostic devices are safe, effective and widely available. The approach proposed in the ENVI Committee of parliament by rapporteur Dr. Peter Liese is likely to be successful, as it ensures a rapid adoption of critical safety measures. However, a five year transition period is necessary in order to ensure that the revision is implemented adequately and effectively.

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