ABSTRACT FORM ECAT SYMPOSIUM 15 – 16 SEPTEMBER 2022

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Title:

What are the implications of the new IVDR for the daily laboratory practice?

Abstract:

With the implementation of Regulation (European Union [EU]) 2017/746 on in vitro diagnostic medical devices (IVDR) since May 26, 2022 the development and use of diagnostic tests is governed by a vastly expanded and upgraded EU regulatory framework. Currently, a phased roll out, based on amended transition timelines, is taking place.

The IVDR aims to protect EU-citizens by restricting EU-market access to safe and effective medical tests. To accomplish this, key changes for bringing medical tests to the market are: a risk based test classification; the requirement of clinical evidence (encompassing scientific validity, analytical and clinical performance data); third party evaluation by independent notified bodies (replacing self-declaration) and post-market follow-up surveillance during the entire life cycle of tests. In addition, EU reference laboratories and advisory expert panels are installed for evaluating IVDR compliance of the highest risk class tests. Other notable changes are the setup of a track and trace system using a unique device identification code (UDI) and the EUDAMED database. The IVDR mainly regulates market access of commercial medical tests, the so-called CE-IVDs. In-house developed tests (IH-IVDs) are exempted from the IVDR but have to fulfill Art 5.5 and Annex I. IH-IVDs serve specific clinical needs across medical lab disciplines, often for low volume niche applications, or correspond to the translational phase of new tests and treatments, often extremely relevant for patient care. Illustrative is the increasingly important role of laboratory medicine in medical decision-making at diagnosis, follow-up and evolution towards “Personalized” or “Precision” medicine in e.g. Oncology, Hematology and other disciplines.

The impact of the IVDR roll out on (dis)continuation of CE-IVD portfolios and total cost of ownership for end-users in medical laboratories is not yet clear as only scarce information has been presented by IVD-manufacturers so far. Especially small and medium enterprises (SMEs) struggle with the limited number of notified bodies which prevent them from being contracted timely. This situation hinders the SMEs in adequate planning and pro-active communication with medical laboratories. Nevertheless, manufacturers should realize themselves that even incomplete communication is worthwhile to share with medical labs. After all, if commercial tests disappear with the IVDR roll out, that situation may require urgent IH-IVD replacement. The workload for medical laboratories will also depend on which modifications to commercial tests turn them into an IH-IVD, and on how national legislators and competent authorities will handle new competences and responsibilities.

Two key challenges are faced by the academic diagnostic sector for innovative IH-IVDs: (1) the stipulation on equivalence of tests (article 5.5d), which poses a new condition for the use of IH-IVDs and (2) the gray area between CE marked in vitro diagnostics (CE-IVDs), modified CE-IVDs, Research Use Only (RUO) tests, and IH-IVDs. Concerted action by clinical and laboratory disciplines, regulators, industry, and patient organizations is needed to support the efficient and effective implementation of the IVDR in a way that preserves innovation and safeguards the quality, safety, and accessibility of innovative diagnostics.

In summary, although it is recognized that the IVDR promotes positive goals such as increased clinical evidence, surveillance, and transparency, we need to ensure that the capabilities of the diagnostic sector are not damaged by infrastructural unpreparedness, while at the same time being forced to submit to a growing bureaucratic and unsupportive structure that will not support its “droit d’exister”. Therefore, ongoing dialogue between the European Commission and the EFLM Task Force on European Regulatory Affairs respectively the IVD Task Force of the BioMed Alliance, remains essential.