Biomedical Alliance in Europe

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Urgent action needed to ensure optimal implementation of the EU In Vitro Diagnostics regulation

With less than two years left until the application date of the In Vitro Diagnostics Regulation (IVDR), the clock is ticking for its implementation and there are still numerous important issues to be addressed.

Members of the Biomedical Alliance in Europe (BioMed Alliance) involved in the diagnostic field are concerned about various delays related to implementation of the IVDR (EU 2017/746). They call on the European Commission to address these issues rapidly and to assess if the transition timeline needs to be adapted. If the European Commission has insufficient capacity to meet the concerns of the diagnostic health sector, then the date of application of the IVDR should be postponed.

Preparations for the new regulation should advance more rapidly

The IVDR imposes more stringent and wider requirements for conformity assessment procedures of IVDs by Notified Bodies. Whereas self-certification by manufacturers is possible for a majority of tests under the current directive (IVDD), over 85% (all but non-sterile low risk class A devices) of the approximately 40,000 CE-IVDs that are currently on the market will require certification by Notified Bodies after the application date of the IVDR. With only 4 Notified Bodies designated under the IVDR so far, it is essential that more be designated as soon as possible.

The IVDR also introduces stricter requirements for clinical evidence of performance, in addition to analytical precision. The recent appointment of the EU-nominated Expert Panel on IVD is welcome. In addition to their role in reviewing technical documentation of high-risk tests, contributing to dissemination of the impact of the IVDR throughout the diagnostic sector will be crucial. European Reference Laboratories (EURL) will also play an essential role and should be set up as soon as possible.

The postponement of the essential supporting EUDAMED portal and the decision to delay the application of the accompanying Medical Devices Regulation (MDR) by one year, to 26/5/2021, may lead to the MDR implementation being prioritised at the expense of IVDR implementation**.** Current diversion of manpower to COVID-19 management at national and EU levels has slowed down progress. **All these issues make us question if the new IVDR regulatory system will be ready on time to ensure continuity and optimal quality of in vitro diagnostic tests.**

Diagnostic testing in crises requires EU-wide derogation

While EU-wide derogations for crisis management exist within the IVDR and were indeed applied to Medical Devices (governed by the MDR EU 2017/745) during the COVID-19 outbreak, it was not

possible to apply such measures to diagnostic testing, largely due to national fragmentation. Rapid implementation of the IVDR is a fundamental requirement for rapid European reactivity.

Appropriate implementation for Laboratory Developed Tests is vital

BioMed Alliance members have been in the frontline to develop the best diagnostic solutions to fight the COVID-19 outbreak, demonstrating the crucial role of diagnostic Laboratory Developed Tests (LDTs) in cases where suitable alternatives are not yet available on the market. Within one week after the release of the genomic sequence of SARS-CoV-2, LDTs were implemented in several laboratories across Europe, with variable strategies for dissemination. This situation confirmed that it is essential that the IVDR optimally supports, and does not hinder, health institutions in developing and implementing diagnostic solutions.

The IVDR allows for LDT use under strictly controlled conditions. Unfortunately, their proposed regulatory implementation is to be developed with the involvement of health institutions only at a late, advisory, stakeholder stage.

A regulatory evaluation of the use of LDTs under the IVDR, fundamental to optimal availability of high-quality health care and European academic diagnostic competitivity, has not even started. A special position should be retained for European multi-centre LDTs that are: novel (up-to-date); meet an unmet need; standardised and easy to implement by other laboratories in Europe and beyond. Many of these initiatives are born of EU-funded concerted actions. Now is the time to consolidate our own developments by their appropriate integration in the new IVDR regulatory system.

Action should be taken to ensure an optimal regulatory system

We think it is crucial that all new elements (EURL, Expert Panels, EUDAMED) required by the IVDR should be activated as soon as possible. In addition, essential guidance documents preparing appropriate interaction between Notified Bodies and the diagnostic sector are required. The much-needed taskforce on LDTs, with appropriate, early stage, involvement of diagnostic health sector representatives, should be activated to ensure and support health institutions to design and implement diagnostics solutions.

Therefore, the BioMed Alliance calls for specific actions:

- ✓ **The European Commission should speed up work with member states to ensure all elements of the IVDR are implemented in time for the application date.**
- ✓ **Essential, clear, guidance documents should be drafted to guide IVDR implementation in the diagnostic sector, while minimising complex bureaucracy.**
- ✓ **The activation of the LDT Taskforce under the MDCG IVD WG should be accelerated with early involvement of health institution representatives such as Biomed Alliance.**
- ✓ **The European Commission should establish a derogation system for EU-wide application of urgently required new IVD tests (such as for Sars-CoV-2).**

- ✓ **Alternative measures or exemptions should be accompanied by clear guidance (e.g. IVDR article 54).**
- ✓ **Designation of a sufficient number of Notified Bodies accompanied by a regulatory framework ensuring optimal transparency with the IVDR Expert Panel and the diagnostic sector.**

We trust that the European Commission will consider these calls from the BioMed Alliance for accelerated action, and that it will continue to be transparent about the state of concrete progress of the IVDR implementation. An open dialogue with all stakeholders (health professionals, manufacturers, Notified Bodies, the diagnostic health sector, patients) will facilitate the transition during this difficult period and help to adjust and prepare for the IVDR regulatory system.

Diagnostic healthcare professionals need to be educated and kept up to date with all developments in diagnostic practice. The European Commission can benefit from the platforms of communication and education available within the BioMed Alliance.

About the Biomedical Alliance in Europe:

The Biomedical Alliance in Europe is a unique initiative between 33 leading European medical societies that together include more than 400,000 researchers and health professionals. It is a not-for-profit organisation committed to promoting excellence and innovation in the European healthcare field with the goal of improving the health and well-being of all European citizens.