HOT TOPIC IN LABORATORY MEDICINE

Safeguarding innovation in precision laboratory diagnostics: a call to amend IVDR Article 5(5)

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As the European Commission undertakes a formal evaluation of the in-vitro Diagnostic Regulation (IVDR) EU 2017/746, it is imperative to reflect on some of its parts that are being perceived as problematic by a large majority of laboratory diagnosticians of various professional backgrounds.

The central objective of the regulation EU 2017/746 (IVDR) is to achieve and secure optimal medical benefit and safety for the patient regarding the diagnostic process and its analytical results. So far, the IVDR has accomplished to bringing all stakeholders in in-vitro diagnostics to the table for a continued and structured effort to fulfil with these objectives. Considering the original intentions of the IVDR, several important specifics of in-vitro diagnostics are not accounted for and do not meet the objectives, leading to unintended consequences, additional administrative burden and patient harm or disservice. Particularly, Article 5(5) regulating development, use and making-available of so-called "in-house in vitro diagnostics" (IH-IVDs) is not fit for purpose, but possesses severe damaging potential for the patient and will likely impede diagnostic innovation in Europe.

IH-IVDs play a crucial role in all specialty diagnostic testing often covering half of the laboratories´ low volume i.e. niche biomarker portfolio (1), e.g. covering uncommon somatic mutations (in tumours) or rare germline variations (in rare inherited conditions). IH-IVDs represent biomarkers not having attracted diagnostic manufacturers´ interests in their development and clinical validation with the consequence that they are not commercially available in medical laboratory diagnostics. Scientifically established IH-IVD biomarkers are reliably measured in specialty labs, are used successfully for years as customized diagnostics, are subjected to the same quality assurance schemes as CE-marked tests and often draw on a substantial body of research and validation data. Considering IH-IVD as "garage-developed tests" is a grave misconception of the concept of non-commercial specialty testing.

However, IVDR Article 5(5) imposes a series of disproportionate regulatory conditions - most notably in its subclauses (a) and (d) through (i) - that threaten the sustainability, accessibility, and innovation of such diagnostics within healthcare institutions within the EU. More specifically, Article 5(5)d places the burden of proof of equality and necessity of a given IH-IVDs against a new commercial test squarely on the IH-IVD-providing laboratory, thereby generating a disadvantageous additional administrative strain for the lab. Similarly, the Article 5(5)a prohibits any – even non-commercial - distribution of IH-IVDs, thus requiring EU-wide specimen trafficking to IH-IVD-providing laboratories with all consequences of additional costs, time delays to diagnostics, biological and data safety issues and preanalytical imponderability's of generating analytically false results.

EFLM Launches Joint Action with National Societies on IVDR Revision

In light of the upcoming targeted revision of the In Vitro Diagnostic Regulation (IVDR) by the European Commission, EFLM has reached out to all its National Society Members to coordinate a joint and unified response.
The European Commission has invited national standardization bodies to collect and submit feedback on the IVDR. To ensure the voice of laboratory medicine is clearly and effectively heard, the EFLM Commission on European Regulatory Affairs (C-ERA) has prepared an official position paper (see reference below), strongly supported by the Division for Quality, Standards and Regulations (D-QSR) and its Committee on Accreditation and ISO/CEN Standards.

EFLM has formally invited all National Societies to submit this shared position to their national standardization committees via the official EU consultation platform (Deadline: 6 October 2025).

A harmonized response, using the same EFLM expert-backed message across countries, will significantly increase the visibility and impact of our position. Fragmented or conflicting messages risk weakening our voice at this critical moment.
This joint initiative is a strategic move to defend the interests of laboratory medicine and promote an IVDR framework that is both applicable in real-world settings and aligned with the needs of precision and personalized diagnostics.

I wish to thank all EFLM National Societies for their support and active collaboration in this vital action.

Mario Plebani,
EFLM President

Taken together, overregulation not only increases costs and delays in diagnostics but also risks harming patients by reducing access to essential and niche tests or to tailored precision diagnostic tests, i.e. tests often developed and maintained by science-driven, ISO 15189:2022-accredited laboratories.

In our very recent position paper (2), which is one of a series of notes on issues in IVDR (3-5), we have urged the European Commission to contextualize Article 5(5) and propose to remove said subclauses while retaining the conditions (b) and (c), which ensure traceability and quality without hampering innovation or clinical autonomy. We advocate for a smarter, quality-driven approach that will leverage existing professional infrastructure and Quality Management Systems in European medical laboratories. Requiring parallel compliance checks by both national authorities and accreditation bodies only leads to confusing redundancies, administrative overload and potential conflict between regulatory interpretations while not adding substantial benefits to the diagnostic process or its results.

The Commission should work closely with the European Cooperation for Accreditation (EA) to ensure harmonized audits and mutual recognition of ISO 15189 as proof of compliance for IH-IVDs. Furthermore, creating a European register for niche IH-IVDs (we consider the term "orphan" not generally applicable in this context) would help coordinate care across borders, enabling access to essential diagnostics on a non-commercial basis.

In-house IVDs, in the hands of registered and qualified specialists operating under appropriate certifications should be regulated based on their intended use(s), risk classification, and patient impact and only thereafter on EU single market interests. We strongly believe that differentiated rules and professional monitoring will help improve diagnostic quality on behalf of the patients with special diagnostic needs.

References

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