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Association for Molecular Pathology Releases Survey Findings and Recommendations to Improve Implementation of European Union's In Vitro Diagnostic Regulation

Clinical laboratories require additional resources to understand complex compliance requirements, reduce workforce burdens, and ensure patient access to vital diagnostic testing procedures

ROCKVILLE, Md. – Feb. 20, 2024 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today released the results of its Impacts of the European Union (EU) In Vitro Diagnostic Regulation (IVDR) Survey. The anonymous survey was created and administered to molecular diagnostics professionals around the world to determine current levels of understanding, assess broad implications, and identify future trends related to the new regulation. The survey results are being used to help inform AMP's clinical practice and advocacy programs with the shifting regulatory landscape worldwide.

AMP's 35-question survey evaluated many important aspects of the IVDR, including laboratory demographics, day-to-day operations, implementation readiness, the Conformité Européene (CE) certification process, financial repercussions, and patient access. Feedback was collected from both AMP members and non-members from March 30, 2023 – April 28, 2023. Priority was given to laboratories directly impacted by the new IVDR and located within the European Union and the United Kingdom, but the survey was made available globally. Overall, the results showed a general sense of frustration and concern about the IVDR implementation process with the majority of laboratories seeking further instruction and education from the European Commission and their respective notified bodies, along with additional funding from payors dedicated to properly reimburse diagnostic testing.

"The IVDR is very complex and the new compliance requirements are placing a significant burden on clinical laboratories around the world. Given the current workforce shortage, laboratories will find it even more challenging to recruit and retain professionals in this specialized area of medicine," said Maria E. Arcila, MD, AMP President and Deputy Chief of the Molecular Diagnostics Service at Memorial Sloan Kettering Cancer Center. "AMP will continue to review and analyze the results of the survey as part of our ongoing commitment to share expertise, assess laboratory needs, engage key stakeholders, and provide recommendations for improving clinical practice and ensuring more patients have access to high-quality testing procedures."

Based on the common themes found in results from the survey, AMP made the following recommendations:

1. **Molecular diagnostic professionals should partner with laboratories and the National Competent Authorities (NCAs) to reduce administrative and other resource burdens while substantially increasing a more thorough understanding of the new IVDR requirements.**

2. **Healthcare system authorities, insurance companies, national health systems, and other payers should allocate additional funding dedicated to properly reimburse diagnostic testing developed to comply with the IVDR.** This recommendation was first made by the European Hematology Association. AMP agrees additional funding will be critical for preserving rare disease diagnostics.

3. **The European Commission, European Medicine Agency, and NCAs should facilitate meetings between the clinical laboratory community and regulatory experts to better ensure that laboratories can meet the standards of the IVDR.**

4. **The European Commission, European Medicine Agency, and NCAs should bolster existing online resources and provide additional educational materials and communications on their webpage to assist with streamlining the regulatory process.**

AMP plans to conduct a follow-up survey in 2025 and again in 2028 after the IVDR has been fully implemented for three years to track laboratory progression throughout the IVDR process.

The February 2024 report on the Impacts of the European Union In Vitro Diagnostic Regulation Survey was sponsored by Loxo@Lilly. To view the full report, please click here.

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,900+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest-growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high-quality, appropriate testing. For more information, visit www.amp.org and follow AMP on X: @AMPath.

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