PRESS RELEASE

From IVD Directive to Regulation: Gathering Scientific Data takes Time

European in vitro diagnostic industry believes the proposed transition period of 3 years is insufficient

Brussels, 25 September 2013 –The European in vitro diagnostic industry appreciates the outcome of the vote in the European Parliament's Committee for Environment, Public Health and Food Safety (ENVI) but takes note of the Committee's decision to provide a transition period of only three years. The change to the new classification and the implementation of clinical evidence will potentially require manufacturers to go back to gather data on new studies. EDMA, the European in vitro diagnostic industry association, believes that the optimal transition period for the new IVD regulation is five years as gathering scientific data takes longer than the proposed period.

In order to implement this revision, manufacturers will need to produce and provide significant amounts of scientific evidence to support the efficacy of IVDs — about 90% of IVDs currently in the market will be affected. The process of conducting and analysing clinical trials is complex and time-consuming requiring significant resources. For IVD manufacturers, it is essential to ensure both the integrity and the efficiency of the implementation process for the directive.

The vote presents a series of key aspects in the way in vitro diagnostics are regulated. Key decisions on how companion diagnostics are to be assessed in order to reach patients, new safety measures for when laboratories develop their own in house tests, how to combat fraud and counterfeiting and how to ensure liability for defective devices have all been voted on today. The on-going revision of the IVD directive is a promising overhaul of IVD regulations in the European Union that has the potential to improve the safety and quality of healthcare across Europe. The most prominent of the IVD directive revisions is that IVD manufacturers, in addition to having to meet the current requirements for evidence that their products can effectively measure specific properties of a sample, also need to demonstrate that the measurement of those properties is linked to diagnosing specific conditions.

The present directive places the responsibility of establishing a connection between the information collected in a test and clinical conditions on clinicians. While it is currently expected of the physician, for instance, to know that high cholesterol levels are connected to heart disease, the revision will now place the responsibility to produce evidence of the connection between a diagnostic and health on manufacturers.

"Despite the requirements currently proposed in the revised regulation, the IVD industry maintains that a staggered approach that upholds safety, while ensuring the proper management of available resources is the most responsible approach to take. It is in the interest of all to find value in time in order to maintain the integrity of the new regulation", says Serge Bernasconi, Chief Executive Officer of EDMA.

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About EDMA

European Diagnostic Manufacturers Association (EDMA) is an international, non-profit organisation representing the interests of the medical in vitro diagnostics (IVD) industry in Europe. Its mission is to promote the value of IVDs in delivering sustainable and effective public health systems, and provide technical, regulatory and market research information to its members. The European IVD industry is a market worth around €11 billion. Driven by research and development, 95% of the industry is comprised of small and medium size enterprises and approximately 1 billion euros per year is reinvested in R&D. EDMA is a member of MedTech Europe, an alliance of European medical technology industry associations. For more information, visit www.edma-ivd.eu.

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