



Regulatory Preparedness

Proposal for a Viable Regulatory Framework for In Vitro Diagnostic Medical Devices in the Event of an Arboviral Outbreak in Europe

Master Thesis

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Abstract

The recent COVID-19 pandemic has triggered numerous activities within the European Union regarding the adoption of new regulations as part of preparedness strategies for future similar events. Predictions have been made by the World Health Organization (WHO) regarding expected regional and cross-border outbreaks, focusing mainly on the group of arboviruses. Driven by ongoing climate change, the vectors of this very heterogeneous group of viruses, such as mosquitoes and ticks, are spreading worldwide, so that the risk of outbreaks is also continuously increasing in Europe. In the event of an outbreak, safe and effective *in vitro* diagnostic medical devices (IVD) are essential in addition to vaccines and drugs. The legal framework for placing IVD into the market is provided by Regulation (EU) 2017/746. This thesis addresses the question of how a regulatory preparedness strategy adapted to arboviral outbreaks can be implemented, enabling the rapid market entry of a comprehensive IVD toolbox. Currently, a conformity assessment procedure takes an average of 13-18 months - a period that is unacceptable within the scope of preparedness. Therefore, the existing legislation was analyzed for its potential to make the conformity assessment strategies for high-risk products significantly more effective. For this reason, an assessment was conducted to determine which procedures are currently in place, who are the relevant participants, their roles, and skills, and how they interact. As a key element to show compliance with IVDR requirements, existing Common Specifications (CS) were discussed, and new CS were proposed also reflecting on existing international guidance on arboviral diagnostics and related International Standard preparations that serve for harmonization of device performance. It is demonstrated that through the consistent utilization of available resources, improved communication of stakeholders and some measures as adopting new CS and optimized digitalization strategies, a significant acceleration of existing processes could be possible. Within the following step, a completely new regulatory path was developed, adapted to an emergency use scenario, and tailored to the current conditions in the European Union. In the event of an acute outbreak, such a process must be carried out as quickly as possible, with a duration of 30 days considered reasonable. The proposal includes the involvement of all relevant groups, the utilization of their existing scientific and regulatory expertise, and an optimized communication strategy. As a result, an Emergency Use Conformity Assessment Pathway (EUCAP) deemed to be possible, that appropriately considers the EU principles of the New Legislative Framework and allows strict reduction of the overall timeframe. A brief outlook on how to reduce bureaucratic burdens in general and on international regulatory harmonization efforts concludes the thesis.