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Submission to the European Commission Consultation on Medical Devices and In Vitro Diagnostics Regulations

The current Medical Device Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR) frameworks create significant barriers to implementing personalised medicine approaches in clinical practice, despite being formally prioritised by the European Council since 2015.

The EU Innovative Health Initiative project 'iCARE4CVD' is developing personalised medicine approaches for improved risk stratification, diagnosis, and treatment response in cardiovascular diseases (CVD) that hold the potential to close the unacceptable care gap in CVD, Europe's number one killer.

However, as the iCARE4CVD Consortium, we are concerned that there are gaps and uncertainties within the MDR and IVDR that are impeding innovation in personalised medicine, denying patients access to tailored, more effective care:

- **The MDR and IVDR guidance does not sufficiently cover personalised medicine solutions, such as decision support systems.** Clinical decision support systems (CDSS) and drug companion applications currently fall under the broad Medical Device Software qualification, which can create uncertainty in how to classify and regulate such solutions, including novel drug-software combinations.

- **Integration of the MDR and IVDR with horizontal regulations lacks clarity.** Such regulations include, for example, the AI Act, the General Data Protection Regulation, the European Health Data Space, and the Cyber Resilience Act. This can create substantial challenges during product development and approval and result in insufficient legal certainty for innovators.

- **Regulatory pathways and designation of national versus EU competences for certain personalised medicine devices remain unclear.** While interaction between the EMA and Notified Bodies exists for companion diagnostics, there is no defined process for complex drug companion applications that influence therapeutic decisions and impact drug safety or efficacy. A split in responsibilities between multiple authorities may introduce complexity and challenges in navigating regulatory approval.

We urge the European Commission to clarify definitions and regulatory pathways for CDSS and other personalised medicine solutions within the MDR and IVDR and to ensure harmonisation across regulations. This is a crucial step towards more personalised care in CVD.

The iCARE4CVD Consortium

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