COCIR feedback on Civil Liability – adapting liability rules to the digital age and artificial intelligence (Inception Impact Assessment) [1]

COCIR welcomes the opportunity to provide feedback to the European Commission's inception impact assessment on adapting liability rules to the digital age and artificial intelligence.

Digital transformation and increased connectivity have drastically changed how we have come to interact with products and technology. It makes therefore perfect sense to evaluate whether existing rules keep up with current and future developments, in particular when it comes to critical aspects such as safety and liability.

Member organisations of COCIR have been at the forefront of bringing innovative health technologies, including Artificial Intelligence applications, to the market and to the patient. The Medical Device Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR) establish a unique framework that takes a risk-based and lifecycle approach to the safety and performance of both medical hardware and software, even considering software in its own right.

COCIR would like to refer to the recent study *"Safety and Liability Related Aspects of Software"* [2] published by the European Commission which acknowledges the **MDR/IVDR as one of the legal frameworks that is best suited to deal with software-related aspects.** Moreover, this study clearly underlines that there are already regulatory frameworks in place that address particular challenges identified by the European Commission under the current initiative.

COCIR would like to stress that the introduction of any **new rules would compound the already existing complex and fragmented legal landscape**. On the one hand the growing field of digital rules at EU level creates tension and confusion between horizontal and vertical (sector-specific) frameworks, on the other hand the implementation at national level leads to further divergence and inconsistencies.

In the case of cybersecurity for instance, health technology manufacturers are already subject to provisions under the Medical Device Regulation, the General Data Protection Regulation and – depending on the national implementation – the Network and Information Security Directive (NIS Directive).

In the case of artificial intelligence, health technology manufacturers are already subject to provisions under the Medical Device Regulation,[3] the In-vitro Diagnostics Regulation, the General Data Protection Regulation and poentially might also have to face additional burden under the proposed Artificial Intelligence Act.[4]

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[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence_en

[2] https://ec.europa.eu/newsroom/dae/redirection/document/77327

[3] *COCIR analysis on AI in Medical Device Legislation* - https://www.cocir.org/fileadmin/Publications_2021/COCIR_Analysis_on_AI_in_medical_Device_Legislation_-_May_2021.pdf

[4] *COCIR feedback to the proposal for a European Artificial Intelligence Act* - https://www.cocir.org/fileadmin/Position_Papers_2021/COCIR_Feedback_AI_Regulation_-_1_July_2021.pdf

The introduction of new liability rules – or possible extension of damages, statute of limitations or reversal of the burden of proof - would also disregard and undermine both the legal and practical reality of responsibility and accountability at sector-specific level. Within healthcare, in particular when it comes to cybersecurity and the use of AI-based systems, there is a shared responsibility between different actors. The Medical Device Regulation also defines rules for distance sales that include online marketplaces. Next to that, the MDR specifies how refurbishing affects liability. The MDR/IVDR already explicitly identify the responsible persons among various stakeholders.[5]

Introducing critical and lifesaving technology to the market COCIR fully embraces the principles – which are at the core of the healthcare sector - of safety, health and wellbeing for its users and patients.

COCIR stands ready to work with the European Institutions, the Member States and relevant stakeholders and provide its longstanding expertise in the health technology space to ensuring liability rules are fit for the digital age.

About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. www.cocir.org

[5] https://ec.europa.eu/newsroom/dae/redirection/document/77327