COCIR response to the consultation on the WHITE PAPER ON ARTIFICIAL INTELLIGENCE [1]

COCIR welcomes the opportunity to provide feedback to the European Commission's White Paper on Artificial Intelligence [2] as presented on 19 February 2020.

Representing the medical imaging, radiotherapy, electromedical and health IT industries COCIR is well-placed to inform the European Commission on Artificial Intelligence as these sectors have been at the forefront of developing AI applications for the healthcare setting.

Already today clinicians are making use of AI applications as part of their workflows and decision-making processes. There are many examples[3] of how AI has been contributing to better patient outcomes. Even more, in light of the COVID-19 pandemic AI technology has been proven a very valuable tool in tackling some of the most critical challenges, as recognised by the Commission[4].

- **An ecosystem of excellence to support the development and uptake of AI**

COCIR supports the actions identified by the Commission to build an ecosystem of excellence to support the development and uptake of Artificial Intelligence.

More concerted efforts are however necessary to scale up the use of AI-based technologies.

- There is a clear need for **high-quality data** sets for the purpose of research and development as well as for training and validation of AI systems. Efforts should continue and be accelerated on drastically improving **interoperability**.

- **Access to and use of health data** should be better accommodated by creating a trusted governance framework and clarifying the rules within the context of the General Data Protection Regulation. **Regulatory sandboxes** may be useful in bringing innovative solutions to the market.

- Resources should be made available to invest in and provide access to infrastructure, **computing technology** and **testing and experimentation facilities**.

- **International cooperation** should be fostered and aimed at regulatory convergence, while cross-border exchange should not be obstructed by data localisation measures.

In order to facilitate the above, COCIR calls upon the Commission to fully commit to the actions and resources specified in the

- **European Digital Strategy** [5]
- **European Data Strategy** [6], and in particular on the **European Health Data Space**
- **Digital Europe Programme** [7] and **Connecting Europe Facility** [8] Programme to invest in digital technologies, skills and infrastructure

[1] https://ec.europa.eu/eusurvey/runner/AIConsult2020?surveylanguage=EN
[2] https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en
[3] *COCIR is periodically publishing AI use cases of its membership on the COCIR website.*
[4] Digital technologies – actions in response to coronavirus pandemic: Data, artificial intelligence and supercomputers
[5] https://ec.europa.eu/digital-single-market/en/content/european-digital-strategy
[6] https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy
[7] https://ec.europa.eu/digital-single-market/en/europe-investing-digital-digital-europe-programme
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1528878837354&uri=CELEX:52018PC0438

- **Horizon Europe** [9] and the opportunity for establishing a **European Partnership for Health Innovation** [10]

- **An ecosystem of trust for the development and uptake of to AI**

While COCIR is convinced that AI can bring meaningful benefits to patients and health systems, it is not uncommon that the use of new technologies raises questions. COCIR shares the opinion that concerns should be properly assessed to ensure a safe and reliable use of technology and to build trust with all stakeholders.

COCIR appreciates that the Commission is considering moving cautiously and to assess what is already existing today. Any measures to address identified gaps should come with a thorough assessment process that fully takes into consideration sector-specific regulatory frameworks and that avoids incoherence or inconsistencies at all cost.

COCIR is confident that the new **Medical Devices Regulation** (MDR) provides sufficiently strong safeguards, ex-ante as well as ex-post, to ensure the safety and performance (including reliability) of AI applications in the healthcare sector that qualify as medical devices. Next to that, the **General Data Protection Regulation** also includes specific provisions related to automated decision-making.

COCIR is in full support of a **risk-based approach** considering the MDR also applies a risk classification model for medical devices, including software. However, the current Commission proposal may not be well adjusted to correctly delineate different levels of risk.

The current definition of **high-risk** does not take into consideration the probability and severity of possible injury or damage, nor the scale of number of people that may be affected. Furthermore, it does not balance the risk of using an AI application compared to not using an AI application, or the inherent high-risk environment in which the application may be used.

Within healthcare, situations of life and death have existed for ages, far pre-dating the use of any technology. At the same time there are also many low-risk applications that are being used in daily practice.

A **labelling** system should at all times remain voluntary as other means of communication may be more effective, particularly in B2B settings or in conversations with trained professionals. In case of labelling, this can only have value as a European system that is built upon industry standards. The success of such a scheme will however be highly dependent on the qualifying criteria, the costs and mechanisms for validation and oversight, as well as general acceptance by the public and private sector.

- **Safety and liability implications**

COCIR appreciates the Commission's acknowledgement that the regulatory requirements for medical devices already explicitly cover aspects related to new technologies. Artificial Intelligence does indeed not operate within a vacuum.

COCIR believes that safety and liability aspects as identified in the Commission's report on safety and liability implications of AI, IoT and robotics [11] are adequately covered by the **Medical Devices Regulation** and the **Product Liability Directive**.

Any assessment from the Commission's side should therefore take into account all existing (sector-specific) frameworks to ensure no unnecessary or incoherent measures are taken.

[9] *https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme_en*
[10] *https://www.euhealthppp.org/*
[11] *https://ec.europa.eu/info/files/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics_en*

COCIR furthermore believes that **national liability regimes** should be harmonised as much as possible to provide equal protection for all EU citizens and to ensure legal certainty for both developers and deployers/users of AI applications.

COCIR also shares the view that AI applications should **not be given legal personality**.

- **Conclusion**

COCIR welcomes the actions identified by the Commission to create an ecosystem of excellence. Nevertheless, more is needed to ensure access to data, technology and infrastructure through strategic investments and actions. This not only requires a coordinated approach but also full commitment to the Commission's Digital Strategy and Data Strategy and proper funding through the EU's future financial programmes.

COCIR agrees an ecosystem of trust is essential for the development and uptake of AI. COCIR considers that the Medical Devices Regulation provides an adequate framework to ensure safe and reliable AI applications in the healthcare sector. Any other measures should only be considered after a thorough assessment process and be in coherence and consistency with already existing measures.

COCIR shares the Commission's view that the Medical Devices Regulation is well adapted to cover the safety and liability implications of the use of AI in the healthcare sector. Any further assessment should take the sector-specific context in account and avoid any unnecessary or incoherent measures.

COCIR References
Artificial Intelligence – COCIR AI use cases
The vital role of Artificial Intelligence in a time of COVID-19
European Health Data Space – Towards a better patient outcome
Artificial Intelligence in Healthcare

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