COCIR response to the consultation on Artificial Intelligence – ethical and legal requirements [1]

(inception impact assessment)

COCIR welcomes the inception impact assessment by the European Commission on ethical and legal requirements for Artificial Intelligence (AI) and the opportunity to provide feedback.

Continuing our engagement in this area, and following the earlier consultation on the AI White Paper[2], COCIR is pleased to share its experience and expertise on the use of AI within healthcare.

Artificial Intelligence is increasingly being used in healthcare[3]: improving patient outcomes and health systems, supporting researchers, healthcare professionals and providers in making the right decisions. AI applications have also made a reliable and valuable contribution in the global fight against COVID-19.

It is therefore important to frame the discussions in a proper way. A lot of good things can come from AI applications. And especially within healthcare, AI applications are there mainly to support, rather than replace the human; this is something we don't expect to see changing quickly in the foreseeable future.

Europe has made the right decision to pursue trustworthy AI. It is essential to have safeguards in place that protect fundamental rights and physical and mental integrity. A comprehensive assessment of existing frameworks should clearly identify any existing gaps and address these in a coherent and consistent way in order to provide legal clarity and certainty, creating a level playing field.

COCIR appreciates that the European Commission is treading carefully into this space, approaching the matter with an open view that allows for flexibility, trying to find the right level of regulating where necessary.

COCR analysis of AI in Medical Device Legislation

COCIR and its members have recently published a comprehensive in-depth analysis of Artificial Intelligence in Medical Device Legislation. The document provides a thorough analysis of the legal requirements applicable to AI-based medical devices.

COCIR sees no need for novel regulatory frameworks for AI-based medical devices, because the requirements of the EU Medical Device Regulation[4] (MDR) in combination with provisions of the General Data Protection Regulation (GDPR) are adequate to ensure excellence and trust in AI in line with European values.

Within the context of our analysis we do however put forward a set of recommendations, including the adoption of practical guidance, supported by the development of international standards.

COCIR feedback to the proposed policy options

Based on our analysis and in response to the outlined options in the inception impact assessment COCIR would like to add following comments:

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[1] *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements*

[2] *COCIR response to the White Paper on Artificial Intelligence - https://www.cocir.org/fileadmin/Position_Papers_2020/COCIR_response_AI_White_Paper__final_.pdf*

[3] *COCIR has been periodically publishing AI use cases from its membership: https://www.cocir.org/activities/digital-health/artificial-intelligence-1.html*

[4] *Within the context of this response, references to the EU Medical Device Regulation (Regulation (EU) 2017/745) are equally valid for the EU In vitro Diagnostic Regulation (Regulation (EU) 2017/746)*

- Option 0 (Baseline)
  Based on our in-depth analysis of the regulatory requirements applicable to AI in medical device legislation we found that the Medical Device Regulation in combination with the General Data Protection Regulation already contain requirements for AI in healthcare to be safe and performant throughout the entire lifecycle, including the management of changes in software.

  In order to facilitate the practical implementation of the existing legal requirements, there could be the adoption of practical guidance, preferably accompanied by the development of international standards.

- Option 1 (soft law)
  Expectations on the ethical use of AI or on the use of ethical AI may exceed the level of lawful AI, considering some actions/decisions may be lawful but are not necessarily considered ethical. These expectations can vary strongly, based for example on the sector, the type of application or even the specific user and these expectations can also vary over time.

  In order to build trust organisations should have the flexibility to make use of ethical guidelines, ethical initiatives or self-regulating codes of conduct where appropriate, and this on a voluntary basis.

- Option 2 (voluntary labelling)
  For the successful uptake and acceptance of a voluntary labelling scheme, it is necessary

  - to assess which specific use cases could benefit from such approach as there are clearly cases where other means of communication may be more effective, particularly in a B2B setting or in cases where AI applications are being used by trained professionals

  - to have a pan-European approach whereby the labelling scheme includes an appropriate, fair and efficient standard setting process and enforcement infrastructure

  - to develop an approach that is workable and attractive for SMEs, as well as for larger organisations, and whereby the costs and mechanisms for validation and oversight are fairly balanced compared to the demands and rewards from the market

  The rules and requirements of any such labelling scheme should not overlap with or duplicate already existing mandatory requirements, and such labels should be used as an additional sign indicating compliance with additional requirements.

- Option 3 (mandatory requirements)

  The variety and complexity of AI applications can not be addressed by a one-size-fits-all approach as proposed by ***sub-option c***. Instead a more targeted, sector-specific and risk-based approach should be taken. AI applications do not operate within a vacuum. The European Commission should perform a comprehensive assessment of existing (sector-specific) frameworks to ensure no unnecessary or incoherent measures are being taken.

  Where required, any introduction of new measures should not create conflicts or duplications between the various regulations or not create new barriers for the development of in particular AI-based medical devices. Based on our analysis the MDR is fit for purpose covering AI-based medical devices.

  Should any remaining gaps be identified after careful assessment, measures should to the fullest extent possible employ existing regulatory frameworks in terms of requirements, conformity assessment, technical assistance and enforcement in order to ensure legal clarity and certainty.

The existence of a regulatory framework should however not lead to an unlevel playing field whereby similar applications that are excluded or exempted from its scope would be subject to less stringent requirements for trustworthy AI.

Mandatory requirements that would apply to AI applications that do not pose significant risks may be overly burdensome or costly, stifling innovation and undermining the potential of the European and digital economy. Therefore, ***sub-option b*** would be better adjusted to balance the risks and benefits of AI applications.

If the notion of "high-risk" would be applied in line with the Commission's AI White Paper such criteria should be further refined. It should, in particular be clarified, if and how this would align to the classification of medical software as defined by the MDR. A medical device, classified as an AI application as proposed in the Commission's AI White Paper, currently may possibly fall into the MDR class 1, 2a or 2b. None of these classes shall qualify the medical device as a 'high-risk AI application', but the manufacturer should have the possibility to clarify as to whether such system is to be regarded as a high-risk AI application or not.

When distinguishing different levels of risk, there may also be a need to consider the likelihood of a particular risk, the presence of mitigating or preventive actions, or the risks associated with the non-use of the AI application. It is important to acknowledge that not every use of AI in healthcare necessarily involves significant risks.

With regard to ***sub-option a,*** that considers a legislative instrument limited to a specific category of AI applications only, this would both require a well-defined group of applications as well as a clear definition on the covered or allowed purposes. The use of biometric information or identification within a healthcare setting will likely serve different purposes than similar AI applications in a surveillance or security setting, and might by consequence impact fundamental rights or safety in a totally different way.

- Option 4 (combination of measures)

To ensure a targeted and effective approach addressing the risks that may arise from the use of AI applications a combination of measures as outlined above may be most appropriate.

COCIR would like to reiterate however that the baseline scenario (option 0) should not be ruled out *a priori* and that a comprehensive assessment of existing regulatory frameworks such as the MDR and GDPR should give direction to any other potential measures.

In the first place, this should be further developed through practical guidance, international standards and soft law, including self-regulating sectoral codes (option 1).

Where other measures are required different policy options may be considered, focusing on those AI applications that carry significant risks (option 3b), and where further distinctions may be considered, for instance:

- *On the basis of the regulatory framework*: for example whether it concerns AI-based medical devices (covered by MDR) or other health related AI applications (not covered by MDR)
- *On the basis of the change dynamics of the AI applications*: whether it concerns "locked AI" or AI that changes during runtime, and if so whether this happens within or outside pre-defined boundaries
- *On the basis of a risk impact assessment* which takes into consideration the likelihood of risk as well as the risk associated to non-use of the AI application

Furthermore, any potential requirements should also take into consideration

- *The targeted environment of the AI application*: does it concern an AI application that functions within a B2B or B2C context
- *The user of the AI application*: to what extent is the user knowledgeable or trained
- *The effect of the AI application*: to what extent does it affect a third party or a larger group of individuals

Ethics within a legal framework

Ethics means different things to different people. It is therefore elemental that where ethical principles are defined into a legal framework there is a common understanding on the expectations.

An ethical framework should have following characteristics:

- Address those that can influence the ethical aspects, including:
  - Those organizations that control the data pipelines for training the AI
  - Those that implement/operate the AI
- A process of continual deliberation, critique, and inquiry
- A mechanism in place to deal with conflicts between ethical principles and their changing nature; capable of being used within agile software development processes[5]
- Ethics frameworks for AI should not apply metrics

Ideally, to limit the administrative burden, an ethics framework is integrated in existing sector-specific frameworks, either through its regulations or through its standards.

An agile approach to legislating AI ethics is needed, rather than a big-bang approach. Therefore it would be recommended to start small (e.g. on transparency), refine and increment as we learn.

International dimension

The International Medical Device Regulators Forum (IMDRF) has started a working item on AI in medical devices with the intention to create convergence at the international level.

Next to that there are several other international initiatives aiming to address legal and ethical aspects of AI, albeit mostly on a horizontal level, such as the Global Partnership on Artificial Intelligence (GPAI), the OECD AI Principles or the Council of Europe's Ad hoc Committee on Artificial Intelligence (CAHAI).

It is essential that the European Commission acts with confidence on the global stage, defending European values and defining the path towards trustworthy AI while fully respecting and favouring international cooperation.

Conclusion

COCIR supports a targeted, sector-specific and risk-based approach that takes full account of the existing regulatory frameworks. A comprehensive assessment should be done prior to the consideration of new measures, and where required, they should be defined in coherence and consistency with what is already in place today.

COCIR looks forward to working with the EU institutions and relevant stakeholders to create the right environment for further uptake and deployment of AI in healthcare for the benefit of the patients and society, while safeguarding fundamental rights and providing the best possible care and protection.

[5] *Artificial intelligence: From ethics to policy, European Parliament Panel for the Future Science and Technology (STOA), (June 2020): https://www.europarl.europa.eu/stoa/en/document/EPRS_STU(2020)641507*

COCIR References
COCIR Analysis of Artificial Intelligence in Medical Device Legislation (September 2020)
COCIR response to the White Paper on Artificial Intelligence (June 2020)
COCIR AI Use Cases: June 2020 | January 2020
COCIR White Paper: Artificial Intelligence in Healthcare (April 2019)

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