PROPOSAL FOR A REGULATION LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE – IMPACT ON THE HEALTHCARE SECTOR AND THE MEDICAL DEVICE INDUSTRY

On 21 April 2021, the European Commission published a proposal for the world's first legal framework on Artificial Intelligence ("**AI Proposal**"). The AI Proposal is intended to strengthen and secure Europe's position in the development of a human-centric, sustainable, secure, inclusive and trustworthy AI. The proposal follows a risk-based regulatory approach, laying down a methodology to define "high-risk" AI systems that pose significant risk to the health and safety of natural persons. High-risk AI systems shall be subject to a strict regulatory framework, and the AI Proposal provides for strict obligations for AI system providers.

Supplementing Clifford Chance's briefing on the AI Proposal "The Future of AI Regulation and its Global Impact" this briefing draws special attention to the impact of the AI Proposal on the healthcare sector.

Among others, the AI Proposal focuses on manufacturers of medical devices and *in vitro* diagnostics which use AI systems. And as AI will increasingly be used in the healthcare sector, it is not unlikely that further areas will still be included in the scope of application of the planned Regulation in the further legislative proceedings.

Key issues

- The AI Proposal applies to so-called high-risk AI systems.
- AI applications used in medical devices and *in vitro* diagnostic medical devices are considered high-risk AI systems if the respective device is subject to a third-party conformity assessment under the sectoral regulations.
- In the event self-learning abilities of high-risk AI system lead to "substantial modifications", a new conformity assessment will be required.

INTRODUCTION

The rise of AI has been apparent for quite some time already. The publication of an EU White Paper on AI and the related public consultation has, at the latest, revealed the potential and the need for regulation which the European Commission sees in AI. The particular relevance of AI has now finally been confirmed by the proposal of a Regulation which will be, once approved,

directly applicable in all EU Member States. This shall reduce legal fragmentation and facilitate the development of a single market for lawful, safe and trustworthy AI systems.

DEFINITION OF AI SYSTEMS

The AI Proposal provides for a legal definition of AI systems which aims to cover a wide array of AI software and to meet the requirements of the fast-evolving AI market. The AI Proposal defines 'artificial intelligence system' as "*software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with*"[1] ("**AI system**"). Annex I refers to machine learning, logic- and knowledge-based and statistical approaches. This broad definition reflects the rather complex (and highly controversial) technical definitions of AI and is intended to cover as many software solutions as possible while granting the necessary legal certainty.

SCOPE OF APPLICATION

AI systems

Generally, the factual scope includes all AI systems covered by the definition. There are a few exceptions in place such as, for example, for AI systems developed or used exclusively for military purposes and third country public authorities, or international organisations using AI in the framework of international agreements for law enforcement and judicial co-operation.

Geographical reach

In addition to the broad definition of AI systems, the AI proposal also covers a wide geographical scope. The AI proposal shall apply to

(i) providers placing on the market or putting into service AI systems in the European Union, irrespective of whether those providers are established within the EU or in a third country;

(ii) (professional) users of AI systems located within the EU; or

(iii) providers and (professional) users of AI systems that are located in a third country, where the output produced by the system is used in the EU[2].

While the focus is on providers and users, some obligations also apply to other parties across the entire AI value chain like authorised representatives, importers, distributors or relevant third parties, *e.g.* those involved in sale and supply or network service providers.

PROHIBITED AI

Also, the AI Proposal contains a list of prohibited AI which is considered unacceptable and contravening European values (such as, for instance, fundamental rights). Any non-compliance shall be subject to sensitive fines (see below).

[1] Art. 3 para. 1 AI Proposal.
[2] Art. 2 para. 1 AI Proposal.

HIGH-RISK AI SYSTEMS

Medical devices and *in vitro* medical devices

The AI Proposal lays down a methodology to define high-risk AI systems. Generally, AI systems are classified as high-risk systems if the two following conditions are fulfilled, cumulatively:

> "*(i) the AI System is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;*
>
> *(ii) the product whose safety component is the AI System, or the AI System itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.*" [3]

Annex II refers to, among others, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("**Medical Device Regulation**") and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices ("***In Vitro* Medical Device Regulation**"). Therefore, all medical devices and *in vitro* diagnostic medical devices required to undergo a third-party conformity assessment under these regulations are considered as high-risk systems under the AI Proposal. Taking into account that most of the medical devices covered by these regulations require the involvement of a notified body for a mandatory conformity assessment, the AI Proposal applies to the majority of AI Systems used in such devices.

Pre-defined areas of usage

In addition, the AI Proposal also defines those AI systems as high-risk systems which are intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services (*e.g.* by firefighters or medical aid) or which may be used as safety components (*e.g*. AI systems for robotic surgery) (cf. Art. 6 para. 2 in connection with Annex III).

According to the AI Proposal, the European Commission shall be entitled to review and update high-risk AI areas (as referred to in Annex III) and might in future add further healthcare-related AI systems to the list of high-risk areas. According to the AI Proposal, AI systems should be classified as high-risk systems and then be subject to the AI Proposal if, in the light of their intended purpose, they pose a high risk of harm to the health and safety or fundamental rights of persons, taking into account both the severity of the possible harm and its probability of occurrence[4].

CONFORMITY ASSESSMENT

Medical devices and *in vitro* diagnostic medical devices

With regard to all high-risk AI systems in medical devices and in *in vitro* diagnostic medical devices, the provider of an AI system is not required to undergo an *additional* conformity assessment defined by the AI Proposal. Rather, the conformity assessment required under the Medical Device Regulation or *In Vitro* Medical Device Regulation will continue to apply also to

[3] Art. 6 para. 1 AI Proposal.
[4] Recital 32 AI Proposal.

high-risk AI systems. However, the scope of the relevant conformity assessments will be broadened up to also include the requirements laid down in the AI Proposal.

Pre-defined areas of usage

AI systems, which fall under the areas of usage (as defined in Annex III)[5] and potential future amendments shall be subject to a conformity assessment procedure based on internal control, which does not require the involvement of a notified body. The assessment is rather based on the provider's own evaluation of its quality management system, the information contained in the technical documentation of the relevant AI system and an assessment of conformity of the design and development process of the AI system with all technical documentation.

Substantial Modifications

With respect to the inherent feature of AI to learn and progress on the basis of new data, the European Commission suggests in its AI Proposal that high-risk AI systems should undergo an entirely new conformity assessment procedure whenever they are substantially modified[6]. However, according to the AI Proposal, for high-risk AI Systems that continue to learn after being placed on the market or put into service, changes to the system or its performance shall not be considered as substantial modifications if such changes have been pre-determined by the provider at the moment of the initial conformity assessment and if the changes are part of the information contained in the technical documentation of the AI system.

By this approach, the European Commission has chosen not to create unnecessary restrictions to innovation, even though it can become challenging to determine whether and to what extent any such changes might have been pre-determined already at an initial conformity assessment.

MANDATORY OBLIGATIONS

The AI Proposal lays down numerous obligations for providers of high-risk AI systems:

Risk management system

Providers of high-risk AI systems have to establish, implement, document and maintain a risk management system. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating.

Data and data governance

[5] Except for the usage of AI Systems in biometric identification and categorisation of natural persons where the provider is generally entitled to choose between self-assessment and third-party assessment.

[6] Art 3 para. 23 AI Proposal defines 'substantial modification' as "*a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed*" ("**Substantial Modification**").

High-risk AI systems which make use of techniques involving the training of data models shall be developed on the basis of training, validation and testing of data sets that meet certain minimum quality criteria.

Technical documentation

The provider of high-risk AI systems shall keep detailed (technical) documentation to demonstrate that the relevant system comply with all applicable requirements, and to provide the national competent authorities and notified bodies with all necessary information to assess the compliance.

Record-keeping

High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events (*i.e.* logs) while the systems are operating. The logging shall ensure an appropriate level of traceability throughout the entire lifecycle of the AI system.

Transparency

High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. This shall include instructions for use specifying, among others, pre-determined changes to the high-risk AI systems.

Human oversight

Also, high-risk AI systems should be designed and developed in such a way that natural persons can oversee the systems' functioning. Where appropriate, such measures should in particular guarantee (i) that the systems are subject to in-built operational constraints that cannot be overridden by the systems themselves and are responsive to the human operator, and (ii) that the natural persons to whom human oversight has been assigned have the necessary competence, training and authority to carry out that role.

Accuracy, robustness and cybersecurity

Eventually, high-risk AI systems shall also be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in all these respects throughout their entire lifecycle.

FURTHER RELEVANT OBLIGATIONS

Post-market surveillance

Providers of high-risk AI systems shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the AI technology and the risks of their relevant systems. The monitoring system shall be based on a post-market monitoring plan as part of the technical documentation of the AI system and shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources.

This system shall help providers of high-risk AI systems to improve the systems and take possible corrective measures in a timely manner.

Quality Management System

A quality management system shall be implemented and documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The system shall *e.g.* include (i) a strategy for regulatory compliance, including compliance with conformity assessment procedures, (ii) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, (iii) systems and procedures for data management, and (iv) the handling of communication with national competent authorities.

NON-HIGH-RISK AI SYSTEMS

The AI Proposal does generally not apply to AI systems which are not classified as high-risk systems. However, the AI Proposal encourages providers of non-high-risk AI systems to voluntarily apply the mandatory requirements for high-risk AI systems. Moreover, transparency obligations shall apply for certain non-high-risk AI Systems which pose specific risks of manipulation (*i.e.* systems that (i) interact with humans, (ii) are used to detect emotions or determine association with (social) categories based on biometric data, or (iii) generate or manipulate content).[7]

MONITORING

According to the AI Proposal, the implementation of the new AI Regulation shall be supervised and accompanied by a European Artificial Intelligence Board, composed of representatives from the Member States and the Commission, which shall assist the national supervisory authorities and the Commission to ensure a consistent application of the new AI Regulation throughout the entire EU.

SANCTIONS

The AI Proposal provides for extraordinarily high sanctions. In the event of the use of AI systems which fall under scope of prohibited AI or high-risk AI systems non-compliant with data and data governance requirements, fines of up to EUR 30 million or, if the offender is a company, up to 6 % of the total worldwide annual turnover for the preceding financial year, whichever is higher, may apply. And in the event of non-compliance with any requirements and obligations set forth for generally permitted AI, administrative fines of up to EUR 20 million or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher, may apply.[8]

NEXT STEPS

The AI Proposal will now go through the ordinary legislative procedure, with numerous amendments and modification proposals still to be discussed. Entry into force is not expected before the second half of 2022. Once finally adopted, the new AI Regulation will be directly applicable in all EU Member States.

[7] Art. 52 AI Proposal.
[8] Art. 71 AI Proposal.

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