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White Paper on Artificial Intelligence & Medical Devices:

A New Regulatory Frontier

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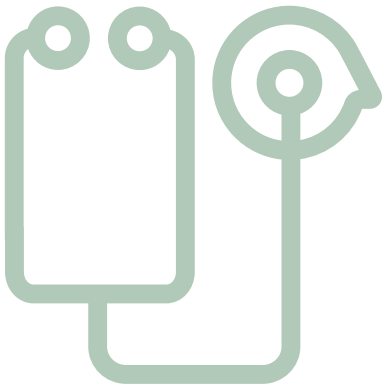
Introduction

The growing use of AI in medical devices is already leading to improvements in patient outcomes on a mass scale, as well as fundamental changes in the way that healthcare is delivered in the 21st century. However, with all the promise that they offer, these powerful new technologies also demand correspondingly bold shifts in thinking by policy makers. As a result, the EU regulatory landscape is evolving to provide regulators with the powers required to keep pace with ever-increasing rates of innovation and disruption brought about by the use of tools such as predictive algorithms and machine learning in medical devices.

This White Paper provides an overview of the key recent developments in this space at European Union ("**EU**") level and highlights some of the most important issues that medical device manufacturers should be aware of.



The Draft EU AI Regulation

In April of this year, the European Commission (the "**EC**") published its eagerly awaited Proposal for a Regulation on Artificial Intelligence[1] (the "**Draft Regulation**"). The Draft Regulation is the culmination of a series of steps, most notably:

- The publication of a White Paper on Artificial Intelligence[2] and the accompanying Report on Liability for AI, IoT and Robotics[3] by the EC in February 2020
- The adoption of a suite of Resolutions by the European Parliament (the "**EP**") in October 2020 covering:
  - A civil liability regime for artificial intelligence[4]
  - A framework for ethical aspects of artificial intelligence, robotics and related technologies[5]
  - Intellectual property rights for the development of artificial intelligence technologies[6]

The Draft Regulation has as its aim, the provision of a comprehensive regulatory framework for AI, with the stated goal of making *"Europe fit for the digital age and turning the next ten years into the Digital Decade"*. The EC has sought to do this by firstly developing a software-based definition of AI that is designed to be as future-proof as possible:

"'artificial intelligence system' (AI system) means 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."[7,8]

1. *European Commission, Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts, COM/2021/206 final*
2. *White Paper: On Artificial Intelligence – A European approach to excellence and trust, Brussels, 19.2.2020 COM (2020) 65 final*
3. *Report on safety and liability implications of AI, the Internet of Things and Robotics, COM (2020) 64 final*
4. *European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL))*
5. *European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL))*
6. *European Parliament, Resolution on intellectual property rights for the development of artificial intelligence technologies, 2020/2015(INI)*
7. *Article 3(1)*

The scope of the Draft Regulation is also very broadly cast, with the proposed new rules applying to:

- Providers (defined broadly as a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge [9]) irrespective of whether those providers are established within the EU or in a third country
- Users (defined as any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity [10]) of AI systems located in the EU
- Providers and users located in third countries *"where the output produced by the system is used in the EU"*. [11]

The focus will therefore be on whether the impact of the AI system occurs in the EU, regardless of the location of the provider or the user, meaning the effect of the Draft Regulation has the potential to be felt far beyond the physical borders of the EU.

Another important feature of the Draft Regulation is the focus that is placed on the intended purpose of the AI systems to be regulated i.e. the provider's intended use for the system. The Draft Regulation defines this further with reference to the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation for the system.[12]

Risk-based Approach

The EC has also provided for a graded risk-based system in the Draft Regulation as a means of grouping AI systems into a set of discrete categories: unacceptable risk (prohibited AI), high-risk, limited risk and minimal risk systems.

Prohibited AI Systems

The prohibited category comprises those applications of AI whose use is viewed as a contravention of EU values, by violating fundamental rights for instance. Examples of this include systems that would facilitate or enable 'social scoring' by governments, or which utilise subliminal techniques to exploit vulnerabilities of a specific group of persons in a manner designed to materially distort the behaviour of a person belonging to the group causing physical or psychological harm.

High-risk AI Systems

The focus of the Draft Regulation is undoubtedly on those AI systems which are 'high-risk'. This is a feature of the risk-based approach that is particularly significant for medical device manufacturers because the high-risk category will include AI systems that are products (or are intended for use as safety components of products) covered by legislation listed in Annex II to the Draft Regulation.[13] This list includes the Medical Devices Regulation (EU) 2017/745 (the "**MDR**"). Annex III to the Draft Regulation also lists a number of other settings in which AI systems will be considered to be high-risk, such as:

8. *Annex I to the Draft Regulation currently lists three techniques and approaches:*
   a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
   b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; and
   c) Statistical approaches, Bayesian estimation, search and optimization methods.
9. *Article 3(2)*
10. *Article 3(4)*
11. *Article 2(1)(c)*
12. *Article 3(12)*
13. *Article 6*

- Critical infrastructure
- Biometric identification and categorisation of natural persons
- Educational and vocational training
- Employment, workers management and access to self-employment
- Access to essential private and public services
- Law enforcement
- Migration, asylum and border control management
- Administration of justice and democratic processes
- Law enforcement, border control management

These systems will be subject to strict obligations before they may be placed on the market and Title III, Chapter 2 of the Draft Regulation makes provision for detailed requirements relating to the following:

- Risk management systems
- Data and data governance
- Technical documentation
- Record-keeping
- Transparency and provision of information to users
- Human oversight
- Accuracy, robustness and cybersecurity

Article 16 of the Draft Regulation provides that providers of high-risk AI systems must ensure that their systems comply with all of these requirements (and that they can demonstrate this to a national competent authority on request), as well as:

- Having a compliant quality management system in place
- Drawing up the technical documentation for the system and affixing a CE marking
- Keeping the logs automatically generated by AI systems under their control
- Ensuring that the AI system undergoes the relevant conformity assessment procedure prior to its placing on the market or putting into service
- Complying with the necessary registration obligations provided for under the Draft Regulation
- Taking any necessary corrective actions and informing national competent authorities in relation to same

Limited/Low Risk AI

Limited risk systems such as chatbots will be subject to specific transparency obligations that will allow users to know when they are interacting with a machine and make an informed decision as to whether or not they wish to maintain that interaction.

In recognition of the very low risk they pose to citizens, minimal risk systems, which are viewed by the EC as by far the largest category of AI system (comprising of applications such as spam filters and AI features in video games) will not be subject to further rules under the Draft Regulation.

Enforcement and Penalties

The EC has proposed that primary supervision and surveillance responsibilities will fall to national competent authorities, however a planned European Artificial Intelligence Board will facilitate the implementation of AI rules at EU level through the development of standards, for instance.

Although the EC has stressed that the levying of significant fines will only be deployed as a last resort, Article 71 of the Draft Regulation does provide for penalties arising from non-compliance with the prohibition of certain artificial intelligence practices or non-compliance of the AI system with data and data governance requirements, which can reach up to €30M or 6% of total worldwide annual turnover for the preceding financial year (if the offender is a company), whichever is higher. Smaller fines are also proposed in respect of lesser infringements.

Key Issues and Challenges

Given the classification of AI used in medical devices as high-risk, manufacturers of medical devices incorporating AI need to be aware of several unique features of AI as a technology, reflected in the requirements under the Draft Regulation, that will need to be carefully scoped and navigated:

- Manufacturers will be challenged to demonstrate conformity with the requirements of the Draft Regulation, as well as general safety and performance requirements provided for in Annex I of the MDR, which lays out general requirements related to software medical devices but remains silent on AI specifically. Given a current dearth of harmonised standards or guidance documents on either AI or software medical devices, successfully demonstrating conformity under both frameworks will require a very careful consideration, in conjunction with notified bodies, of "state of the art" for medical devices incorporating AI and how these devices are to achieve the high levels of safety required under both frameworks. A unique example of these types of challenges relates to the 'black box' nature of AI tools such as machine learning algorithms and deep neural networks which make it very difficult to trace the roots of errors and malfunctions that would be more readily identifiable in software that is programmed 'line by line'.
- Manufacturers will also need to pivot their existing competencies in preparing and maintaining technical documentation for medical devices towards also meeting the new technical documentation requirements applicable to AI under the Draft Regulation. For example, careful consideration will need to be given to the description and presentation of the intended purpose of the AI system, the methods and steps performed for the development of the AI system, data requirements in terms of description of training methodologies and techniques, as well as information about the provenance of those data sets, their scope and main characteristics.
- Specific requirements for high-risk AI systems in the Draft Regulation relating to record-keeping,[14] transparency, the provision of information for users[15] and human oversight[16] will also need to form part of manufacturers' approach to design and development of medical devices incorporating AI systems. Manufacturers will therefore be challenged to design systems and features that can ensure that devices incorporating AI can automatically record relevant events (logging), provide for a sufficient degree of human oversight and also operate in a manner that allows users to interpret a system's output and use it appropriately.
- Manufacturers also need to account for the need for AI systems deployed in a healthcare context to comply with the General Data Protection Regulation (EU) 2016/679 (the "**GDPR**"). For example, Article 25 of the GDPR imposes a "data protection by design" requirement and Recital 78 states that manufacturers should be *"encouraged to take into account the right to data protection when developing and designing such products, services and applications and, with due regard to the state of the art, to make sure that controllers and processors are able to fulfil their data protection obligations."* Notwithstanding this overlap with data protection legislation, a June 2021 joint opinion[17] published by the European Data Protection Board (the "**EDPB**") and the European Data Protection Supervisor (the "**EDPS**") has highlighted concerns over a need for a harmonised and consistent approach regarding the provisions of the Draft Regulation and European data protection laws, particularly the GDPR. To achieve this, the EDPB and EDPS suggest that current data protection

14. *Article 12*
15. *Article 13*
16. *Article 14*
17. *EDPB-EDPS Joint Opinion 5/2021 on the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)*

authorities should also be designated as the national supervisory authorities under the Draft Regulation and call for further prohibitions on certain types of AI systems such as systems for automated recognition and categorisation using sensitive biometric data, systems for inferring emotions and any type of social scoring.

- AI also brings its own unique challenges when it comes to cybersecurity, accuracy and the robustness of medical devices that it forms part of. Related again to the 'black box' issue whereby there is a lack of clarity as to exactly how some AI systems calculate outcomes, manufacturers need to pay close attention to the risk of inadvertent as well as deliberately triggered malfunctions stemming from the 'brittleness' or 'instability' of AI models. This issue is particularly prominent in the field of visual AI and although there have been advances in the development of 'adversarial training techniques' and 'human-in-the-loop' mechanisms designed to mitigate these risks, this remains a challenge of particular concern when one looks to the growing importance of AI systems as part of software-based visual diagnostic screening devices.
- Many AI systems, especially those utilising machine learning methods, are trained using very high volumes of data that are divided out into training and testing sets. Manufacturers of medical devices need to carefully manage the process of acquiring and using this data in a manner that ensures that it provides an accurate representation of the environment that the AI system will operate in. If the data used to train and test AI systems is not sufficiently representative, biased outcomes can lead to not only moral and ethical issues, but also more fundamental safety and performance challenges. Article 10 of the Draft Regulation makes specific provision for this unique feature of AI as a technology.
- Whereas the MDR has been in effect since 26 May 2021, the EC has proposed a 24-month timeline for application of the Draft Regulation once enacted. However, given the breadth of new and enhanced requirements that it provides for, this timeline may prove to be quite pressured for manufacturers and other stakeholders. As has been demonstrated during the transition to the MDR (as well as the In-Vitro Diagnostic Regulation (EU) 2017/746) for instance, the role of notified bodies in the conformity assessment process may develop as a regulatory 'pinch point' for medical devices incorporating AI. Even if detailed guidance and standards were to be published, manufacturers and their notified bodies can still expect to have to undergo quite an involved bedding in process where solutions to the nuances and challenges brought about by the overlap of two sophisticated frameworks are worked through.

AI Liability

A further dimension to the use of AI in medical devices warranting further treatment relates to liability for AI systems amongst those who operate and/or manufacture them. Firstly, the EP Resolution on 'civil liability for AI' (the "**Resolution**") referred to above focused on the types of AI systems in use and recommends a strict liability regime for operators of 'high-risk' AI systems, and a fault-based liability regime for 'non-high-risk' systems. In respect of operators of AI systems, the Resolution states that liability rules should cover all operations of AI systems, *"irrespective of where the operation takes place and whether it happens physically or virtually"*. It also states that liability insurance is necessary for functioning of new technologies.

Secondly, additional developments in the liability space are expected to be brought about by the publication of proposals aimed at revising the EU Product Liability Directive 85/374/EEC (the "**PLD**"), which was first published in 1985. The proposal to revise the PLD is expected to address liability issues arising from digital health technologies and AI and is due to be published in the fourth quarter of 2021. An Inception Impact Assessment taking place throughout July 2021 elicited feedback from a variety of stakeholders, and further feedback from a public consultation on this legislative proposal should also be published shortly. Manufacturers of AI-enabled medical devices and other interested stakeholders should carefully track the debates and discussions arising from this feedback as draft legislation continues to take shape.

Regulatory Divergence

It will also be interesting to see if and how a UK AI regulatory regime will reflect or perhaps diverge from the regime provided for in the Draft Regulation. In September 2021, the UK's Medicines and Healthcare Products Regulatory Agency (the "**MHRA**") launched a series of work packages entitled, *"Software and AI as a Medical Device Change Programme"* as part of a wider consultation on the future regulation of medical devices and in vitro diagnostic devices. The work packages include broad suggestions for the use of AI in medical devices with a focus on concepts such as 'AI Rigour', 'AI Interpretability' and 'AI Adaptivity'. The MHRA's stated objectives for the wider consultation include improved patient and public safety, closer alignment with international best practice, and a more flexible, responsive and proportionate regulation of medical devices.

Different Perspectives

In terms of guidance, the EU Medical Device Coordination Group (the "**MDCG**") has not yet published anything specifically addressed to the use of AI in medical devices, however this does form part of the MDCG's work schedule. Meanwhile however, regulators and international organisations around the world have been publishing documents designed to provide guidance to stakeholders. For example:

- In June 2021, the World Health Organization published a document titled *"Ethics & Governance of Artificial Intelligence for Health"* which sets out six principles for the appropriate use of AI for health
- The US Food and Drug Administration (FDA) published a discussion paper in 2019 entitled *"Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device"* and more recently published its action plan on furthering AI in medical devices in January 2021
- The South Korean Ministry of Food and Drug Safety (MFDS) has released multiple guidance documents related to software using AI, Big Data and Machine Learning
- In September 2021, the International Medical Device Regulators Forum (the "**IMDRF**") published a proposed document entitled *"Machine Learning-enabled Medical Devices—A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions"*

Outside of the EU, manufacturers and stakeholders should continue to monitor the publication of these and other future regulatory documents as a means of placing the EU regime within its global context.

Conclusion

The combination of AI applications as part of medical devices gives rise to some of the most exciting possible applications for AI systems. However, this marriage also highlights the issues and challenges faced by both industry and governments in designing and working within and across separate complex regulatory frameworks, all in a way that ensures safety in the present while also allowing for innovation in the future.

As manufacturers continue to adapt to the MDR and the Draft Regulation continues on the path to enactment, stakeholders must also monitor an evolving liability landscape as well as the potential for regulatory divergence outside of the EU. While these and other currently unknown challenges have the potential to slow rates of innovation and technological progress, the EU is still fast becoming a bold new regulatory frontier in this highly complex but exciting area.

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