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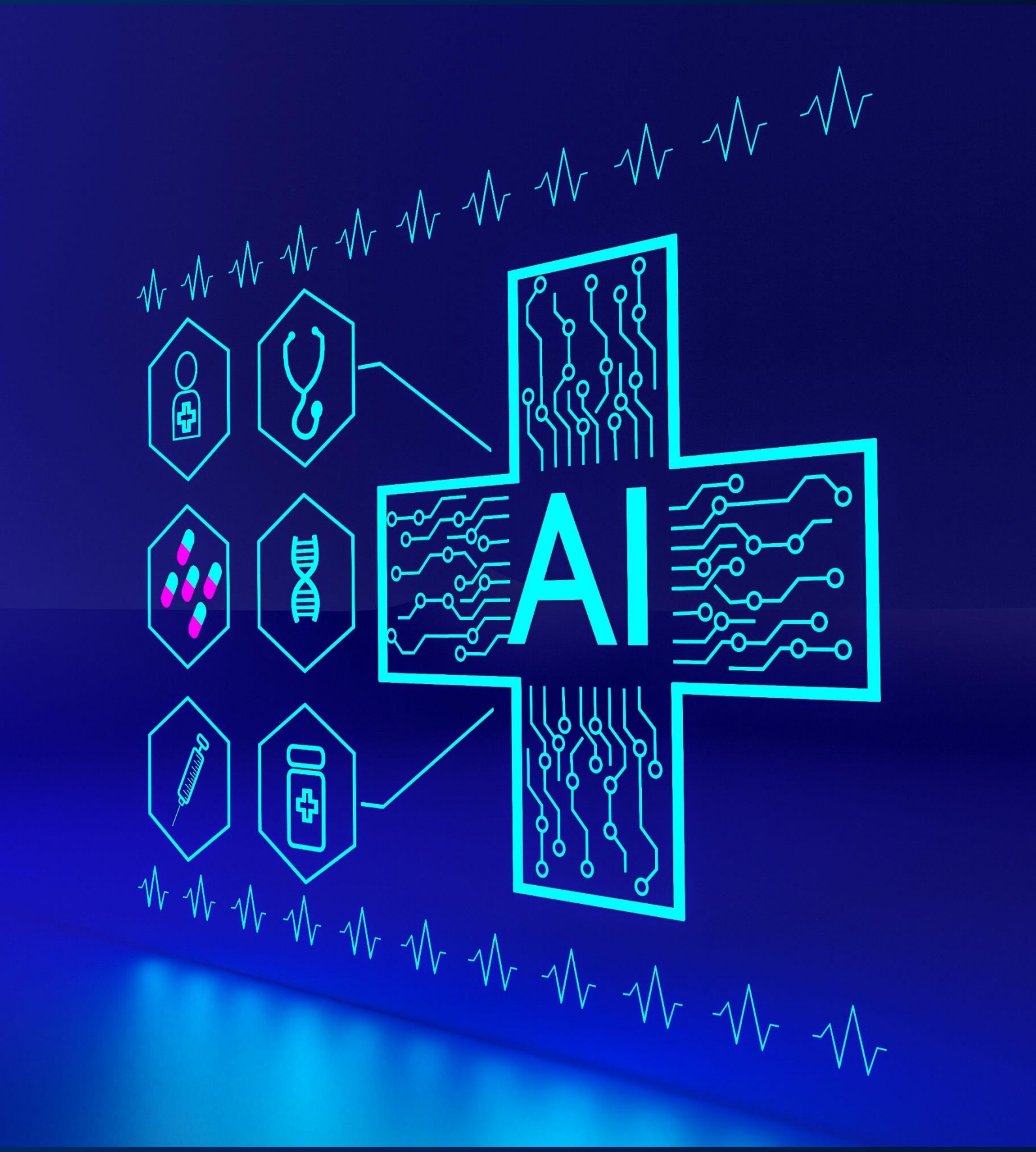

LIFE SCIENCES & HEALTHCARE

Artificial Intelligence (AI) and the Healthcare Industry

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BY IRENE KYRIAKIDES, VICTORIA MERTIKOPOULOU, AITHRA VALENTINA ANTONIADOU, ANASTASIA ILIOPOULOU

Background

Research on the "CORDIS" platform, part of the European Commission's Research and Innovation Community platform, has identified more than 4,000 Artificial Intelligence ("AI") Research & Development projects related to the healthcare sector.

On March 13, 2024, MedTech Europe published the medical technology industry's perspective on the final agreed text of the Artificial Intelligence Act ("AI Act" or "Act"), concluding that implementation guidance is needed, particularly regarding the alignment requirements and standards for high-risk AI systems from the MDR/IVDR and the AI Act, the conformity of AI-enabled medical technologies, and the clinical investigations and performance studies required by the MDR/IVDR.

On March 28, 2024, the Greek Commission for Bioethics & Technoethics published on its website an opinion and an accompanying report on "*The applications of Artificial Intelligence in Health in Greece*", which is the first official Greek document addressing the implications of the development and use of AI applications in health.

In light of the above, it is clear that the Regulation (EU) 2024/1689 laying down harmonized rules on AI ("AI Act" or "Act"), provides for a legal framework that has been much needed and anticipated by the healthcare industry.

Key Provisions

The AI Act, the first comprehensive regulatory framework for AI, includes the following key provisions:

- Introduction of a **risk-based classification system** of the AI systems, with four categories (unacceptable risk, high risk, limited risk, and minimal risk) and **implementation of different regulatory requirements** for each category.

- **Strict requirements** regarding data quality, transparency, human oversight, and robustness **for high-risk AI systems** that include those used in healthcare.

- **Transparency requirements** for AI systems that interact with humans, generate content, or are used for surveillance.

- **Data governance practices for high-risk AI systems** to ensure the quality and integrity of data processing.

- **Conformity assessments** to meet the requirements of the Act and **obtain certification** prior to deployment.

- **Post-market monitoring** of AI systems and **mandatory reporting** of incidents and malfunctions.

- **Sanctions and penalties** for non-compliance.

Impact on the Pharmaceutical Sector

The enactment of the Act, will have a significant impact on the pharmaceutical sector, particularly in the following areas:

- **Drug development and clinical trials**: AI systems used for drug development and clinical trials are likely to be classified as high-risk due to their direct impact on human health and will be required to adhere to strict data quality and governance standards to ensure that AI models are trained on diverse and accurate datasets.

- **Personalized medicine**: AI's role in personalized medicine, such as tailoring treatments to individual patients, will be subject to intense regulatory scrutiny. Compliance with the Act will ensure that the algorithms used to recommend treatments are safe, effective, and free of bias.

- **Pharmacovigilance**: AI systems used to monitor the safety of drugs post-market will benefit from the post-market surveillance provisions of the Act. The mandatory reporting of adverse events will improve the detection of adverse drug reactions and enhance patient safety. However, pharmaceutical companies will need to invest in a robust monitoring infrastructure to meet these requirements.

- **Supply chain and manufacturing**: AI applications in pharmaceutical manufacturing and supply chain management will also be subject to the Act. Ensuring that AI systems used in these areas are reliable and secure can optimize production processes and reduce costs.

Impact on the Medical Devices Sector

The adoption of the Act will also have a significant impact on the medical devices sector as well, particularly in the following areas:

- **Classification of devices**: Medical devices companies will need to classify their products incorporating AI technology under both the MDR/IVDR and the Act and assess whether such products fall within the definition of high-risk AI systems or under the definition of prohibited AI systems.

- **Compliance with new requirements and obligations:** Medical devices manufacturers should comply with additional requirements and obligations based on the new Act, such as data governance and human oversight.

- **Conformity assessments:** Both the MDR/IVDR and the Act are risk-based frameworks, and therefore require conformity assessments by independent notified bodies. However, the Act does not provide sufficient clarity on conformity assessment procedures compared to MDR/IVDR and, at least currently, notified bodies do not have the appropriate expertise or guidance.

Changes for Pharmaceutical and Medical Devices Companies

Because high-risk AI systems must meet strict regulatory requirements for data quality, transparency, human oversight, and robustness, pharmaceutical and medical devices companies will need to **increase operational costs** to comply with the provisions of the Act and the demanding new standards. Pharmaceutical and medical devices companies will need to **invest in new technologies, staff training, and possibly redesigning existing AI systems**, as well as **allocate sufficient resources to meet compliance requirements**.

In addition, under the new framework, AI systems will need to **be transparent and explainable** to users, regulators, and stakeholders. As a result, pharmaceutical and medical devices companies will be required to develop **mechanisms to clearly document and explain AI decision-making processes**.

For medical devices companies in particular, alignment, clarity and certainty between the requirements and the harmonized standards of the Act and the MDR/IVDR is of paramount importance to avoid delays in the delivery of medical technologies to patients and healthcare systems. Therefore, European Commission guidelines and MDCG guidance are needed to provide clarifications on the newly applicable framework.

While these requirements may initially strain resources, in the long run they could lead to improved patient safety, increased innovation, and safer and more reliable AI applications in the industry.

Next Steps

Following a series of arduous consultations, the AI Act will enter into application on August 2nd, 2026, with a phased approach to its implementation and enforcement.

It remains to be seen how European regulations, such as the AI Liability Directive, guidelines and directives as well as national policies and complementary legislation, will implement the newly introduced AI legal framework and how this framework will actually affect and influence industries in the process of placing new products on the market.

Contact Us

Irene Kyriakides
PARTNER
i.kyriakides@kglawfirm.gr

Victoria Mertikopoulou
PARTNER
v.mertikopoulou@kglawfirm.gr

Follow Us

ATHENS OFFICE

28, Dimitriou Soutsou Str.,
115 21 Athens

T +30 210 817 1500
F +30 210 685 6657-8
E kg.law@kglawfirm.gr

THESSALONIKI OFFICE

31, Politechniou Str.,
551 34 Thessaloniki

T +30 2310 441 552
E kg.law@kglawfirm.gr

www.kglawfirm.gr