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EU AI Act: Key Considerations for the Life Sciences Sector

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In this article, the authors introduce the overall legislative framework set forth under the EU Artificial Intelligence Act, focusing on the aspects of the law that will likely apply to artificial intelligence (AI) systems used in the life sciences sector. They then proceed to discuss at a high-level how the EU AI Act will apply to the following use cases in the life sciences sector: (1) AI incorporated into medical devices and in vitro diagnostic medical devices, (2) AI systems that triage patients for emergency care, (3) chatbots used in digital health applications, and (4) AI employed in drug discovery. The authors conclude by pointing out the aspects of the EU AI Act that will likely create practical challenges for entities operating in the life sciences sector, and where further regulatory guidance and clarification will likely be needed.

The EU Artificial Intelligence Act[1] is a landmark piece of legislation that the European Union adopted to regulate AI systems and models. It is a "horizontal" law, meaning that it will regulate multiple industry sectors at once. It is also a "Regulation," which means that it has binding force and will be directly applicable across all 27 EU member states, without the need for transposition into national law.[2] During the early stages of the EU AI Act legislative process, there were heated debates as to whether the European Union should take a sector-specific approach to AI regulation, and whether the European Union should take a proscriptive or non-proscriptive approach to AI regulation. Ultimately, the EU lawmakers adopted the more ambitious approach: a horizontal and proscriptive approach to AI regulation.

This article introduces the overall legislative framework set forth under the EU AI Act, focusing on the aspects of the EU AI Act that will likely apply to AI systems used in the life sciences sector. It then proceeds to discuss at a high level how the EU AI Act will apply to the following use cases in the life sciences sector:

1. AI incorporated into medical devices and in vitro diagnostic medical devices;
2. AI systems that triage patients for emergency care;

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3. Chatbots used in digital health applications; and
4. AI employed in drug discovery.

This article concludes by pointing out the aspects of the EU AI Act that will likely create practical challenges for entities operating in the life sciences sector, and where further regulatory guidance and clarification will likely be needed.

Background

The EU AI Act entered into force on August 1, 2024. There is a transition period of two years (concluding August 2, 2026) for most provisions, with the following exceptions:

- The provisions relating to prohibited AI practices and AI literacy applied as of February 2, 2025;
- The provisions relating to general purpose AI models and the EU AI Act's governance framework apply after one year (by August 2, 2025); and
- The provisions relating to high-risk AI systems that are used as safety components of products or are themselves products regulated by certain EU harmonization legislation (e.g., toys, medical devices) apply after three years (by August 2, 2027).

The EU AI Act expressly states that the EU AI Act will not apply to high-risk AI systems placed on the market or put into service before August 2, 2026,[3] but this exclusion does not apply if the AI systems are subject to "significant changes"[4] after that date.

The Overall Legislative Framework Under the EU AI Act

The aim of the EU AI Act is to establish harmonized rules for the development, use, and deployment of AI in the European Union, in a way that mitigates the risk that AI may pose to human health, safety, and the protection of fundamental human rights.

The EU AI Act applies to "AI systems," which are defined as:

> a machine-based system designed to operate with varying levels of autonomy, that may exhibit adaptiveness after

> deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations or decisions that can influence physical or virtual environments.[5]

This definition of "AI systems" is similar to the Organisation for Economic Co-operation and Development's (OECD) definition of AI,[6] which underpins other regulatory frameworks emerging around the world. This definition of AI is purposefully broad, and captures a number of approaches and techniques in computer-based systems, including, among others, machine learning, deep learning, reinforcement learning, machine reasoning, and automated robotics.[7]

The EU AI Act imposes different sets of obligations on different actors in the AI supply chain, including providers (i.e., developers), deployers, importers, distributors, product manufacturers, and authorized representatives of providers. This article focuses on the obligations that apply to providers and deployers of AI systems. Similar to other EU regulations, such as the EU General Data Protection Regulation (GDPR),[8] the EU AI Act has extraterritorial scope. It applies to:

- Providers placing AI systems on the EU market or putting them into service in the European Union, irrespective of where providers are established;
- Deployers of AI systems that are established in the European Union; and
- Providers and deployers of AI systems where the output produced by the AI system is used in the European Union.

The overall structure of the EU AI Act is as follows:

- Establishing a list of prohibited AI practices;[9]
- Classifying certain AI systems as "high risk" and imposing a set of enhanced obligations on providers and deployers of such systems;[10]
- Imposing transparency obligations on providers and deployers of certain "limited-risk" AI systems, such as those that interact directly with individuals or are capable of generating realistic content (also called "deepfakes");[11]
- Setting out obligations that apply to providers of "general-purpose AI models";[12]
- Introducing measures to support innovation through regulatory sandboxes;[13] and

- Setting up governance systems at both the EU and member state level, encompassing market monitoring, surveillance, enforcement, and codes of conduct.[14]

The EU AI Act requires member states to designate "at least one notifying authority and least one market surveillance authority" as "national competent authorities" for that member state.[15] The EU AI Act grants extensive powers to these regulatory bodies. For instance, market surveillance authorities have the power to request and obtain access to the documentation, training, validation, and testing data relating to an AI system from the provider.[16] In addition, when requested, providers must grant market surveillance authorities access to the AI system's source code where (1) such access is necessary to assess the conformity of high-risk AI system requirements, and (2) testing, auditing, and verifications proved insufficient.[17]

Noncompliance with the EU AI Act could lead to fines of up to:

- €35 million or 7 percent of an organization's total worldwide annual turnover, whichever is higher, for violations of banned AI practices;
- €15 million or 3 percent of an organization's total worldwide annual turnover for violations of other obligations; and
- €7.5 million or 1 percent of an organization's total worldwide annual turnover for supplying incorrect information to notified bodies and national competent authorities.[18]

Member states may also lay down additional penalties, including warnings and non-monetary measures. Any natural or legal person may lodge a complaint with the relevant market surveillance authority if there are grounds that a company has infringed the EU AI Act.[19]

Application of the EU AI Act to Life Sciences Use Cases

AI in Medical Devices and In Vitro Diagnostic Medical Devices

In the European Union, the Medical Devices Regulation (MDR)[20] and the In Vitro Diagnostic Medical Devices Regulation (IVDR)[21] regulate medical devices and in vitro diagnostic medical devices (IVDs), respectively, which include standalone AI devices

and medical devices that may contain AI elements. The EU AI Act supplements the MDR and IVDR to introduce additional obligations on AI systems that are medical devices or safety components of medical devices regulated under the MDR/IVDR. The EU AI Act provisions that are relevant to medical devices (namely, those on "high-risk" AI systems) will start to apply three years from the entry into force of the EU AI Act—from August 2027.

The EU AI Act enumerates exhaustively in Annexes I and III the AI systems considered to be "high risk."[22] These include AI systems that are, or are safety components of, products already subject to EU harmonized safety regimes listed on Annex I of the EU AI Act, where such products are "required to undergo a third-party conformity assessment" before being placed on the market under the existing harmonized regimes.[23] The MDR and IVDR are listed under Annex I to the EU AI Act. This means that medical devices and IVDs that are required to go through a third-party conformity assessment under the MDR (i.e., Class IIa, IIb, and III devices) or IVDR (i.e., Class B, C, or D devices) and that incorporate AI systems or are themselves an AI system are considered "high risk" under the EU AI Act—are subject to enhanced obligations.

Many of the procedural obligations for providers under the EU AI Act overlap with those that the device manufacturer would be subject to under the MDR/IVDR—and the EU AI Act recognizes this. For instance, for AI medical devices, the third-party conformity assessment required for compliance with the EU AI Act will be combined with the conformity assessment required under the MDR/IVDR, and compliance with the substantive obligations under the EU AI Act will be part of that assessment.[24] In addition, the risk management system and quality management system required by the EU AI Act can be part of or combined with the risk management system and quality management systems required under the MDR/IVDR.[25] Moreover, the provider/manufacturer of the device is required to draw up a single set of technical documentation for the purposes of both the MDR/IVDR and the EU AI Act.[26] The resulting CE marking, which is a mark of compliance with harmonized standards, must indicate compliance with both the EU AI Act and the MDR/IVDR. Providers of high-risk AI systems covered by the device rules also have the choice to integrate the post-market monitoring system required by the EU AI Act with the post-market monitoring system established by the MDR/IVDR.[27]

Although AI medical device manufacturers will be able to build on existing procedural elements from the MDR/IVDR, they will

need to comply with the substantive obligations set out in Chapter III, Section 2 of the EU AI Act. At a high level, these substantive obligations require the following:

- *Data and Data Governance—Article 10*. Ensuring that the data used for the training meets specific criteria, such as appropriate data governance and management practices, and bias detection and correction;
- *Recordkeeping—Article 12*. Ensuring that the high-risk AI system has the technical capability to record logs during the system's entire lifetime automatically. The technical logs must record events relevant to: (1) identifying risks or substantial modifications, (2) facilitating post-market monitoring, and (3) allowing deployers to monitor the operation of the AI system;
- *Transparency—Article 13*. Ensuring that the AI systems' operations are transparent enough to enable providers and deployers to comply with their obligations and enable deployers to interpret the system's output. Providers must also accompany the AI system with concise, complete, correct, and clear instructions for use containing certain minimum information;[28]
- *Human Oversight—Article 14*. Ensuring that the high-risk AI system is built in a way that enables human oversight during its use; and
- *Accuracy, Robustness, and Cybersecurity—Article 15*. Ensuring that the high-risk AI system achieves "an appropriate level of accuracy, robustness, and cybersecurity" throughout its life cycle.

Some of these obligations, such as recordkeeping, transparency, robustness, and cybersecurity, overlap in some respects with obligations that already apply under the MDR/IVDR. For instance, the MDR also requires manufacturers to provide instructions for use of medical devices—but the EU AI Act will add additional compliance elements. Other substantive obligations, such as those relating to data and data governance and human oversight, are new obligations that medical device manufacturers will need to grapple with. It is anticipated that industry standards and technical benchmarks will develop in time, but these substantive obligations will present compliance challenges in the meantime.

The EU AI Act also imposes obligations on entities deploying AI systems. Deployers of high-risk AI systems are required to, among other things, use high-risk AI systems in accordance with the instructions of use provided by the provider; ensure that the human overseer has the necessary competence, training, and authority; monitor the operation of the high-risk AI system; report serious incidents to the provider and relevant authorities; and keep the logs automatically generated by the high-risk AI system.

AI Systems That Triage Patients for Emergency Care

Aside from the use of AI in or as medical devices—another way AI could be used in the life sciences sector is to enhance ancillary aspects of hospital care to drive efficiencies. Hospitals are already using AI for a variety of tasks, such as managing and analyzing patients' electronic health records—including to triage patients in emergency care.[29] Triage is defined as prioritizing patients according to the seriousness of their disease conditions and guiding them to the most appropriate clinical care.[30] The effectiveness of triage systems can make a life-or-death difference in the care outcomes of some patients. Studies have reported how sex, racial, and ethnic disparities can be observed in emergency department triage systems,[31] and concerns have been raised about AI encoding and amplifying these unfair biases.[32] The EU AI Act recognizes this concern. The EU AI Act classifies as "high-risk" AI systems intended to evaluate and classify emergency calls by natural persons or to be used to dispatch or to establish priority in the dispatching of, emergency first response services, including medical aid, as well as emergency healthcare patient triage systems.[33]

An important point to call out is that AI medical devices falling within scope of the MDR/IVDR (discussed above) are classified as high risk under Annex I of the EU AI Act; in contrast, AI systems used in emergency healthcare patient triage systems are classified as high risk under Annex III. Providers and deployers of high-risk AI systems classified as such under Annex III are required to comply with both (1) the substantive obligations listed above for high-risk AI systems classified as such under Annex I, and (2) additional obligations set out below:

- Providers of high-risk AI systems under Annex III are required to:

- Follow the internal control conformity procedure described in Annex VI to the EU AI Act;[34] and
- Register the high-risk AI system in the EU database. Registration consists of the submission of the information listed in Annex VIII to the EU AI Act, which must be done before placing the AI system into the market or putting it into service.[35]

- Deployers of high-risk AI systems under Annex III are required to:
  - Inform the individuals that they are subject to the use of the high-risk AI system, if the AI system makes decisions or assists in making decisions related to natural persons;[36] and
  - Deployers of high-risk AI systems that are bodies governed by public law or private entities providing public services must perform a "fundamental rights assessment" prior to deploying the high-risk AI system. Hospitals that are part of the public service network using emergency patient triage systems may fall within these categories. The fundamental right assessment must include elements such as the purposes of use, the categories of individuals affected, and the specific risks likely to impact affected individuals. Deployers must conduct such an assessment ahead of their first use of the AI system and update it should circumstances change.[37]

Annex I lists a number of existing EU product safety laws—such as the MDR and IVDR—which already contain the procedural framework for regulating the relevant product onto which the AI regulatory element is layered on through the EU AI Act. In contrast, high-risk AI systems set out in Annex III are not subject to an existing market access and market surveillance regulatory framework. This means that providers and deployers of Annex II high-risk AI systems are likely to have fewer existing processes (both internally within the company and externally in the industry and regulators) to leverage for EU AI Act compliance.

That said, many of the high-risk AI systems listed in Annex III involve processing of personal data, particularly to make significant decisions about individuals. It is therefore likely that such processing would be subject to existing data protection laws; namely,

the GDPR. This means that in practice, it is likely that the EU AI Act compliance elements will build on top of existing compliance efforts to comply with the GDPR. One of the challenges of EU AI Act compliance will be to ensure alignment with compliance efforts under other EU laws, such as the GDPR.

Chatbots in Healthcare Applications

Chatbots are computer programs that simulate human conversation through voice commands, text chats, or both.[38] Chatbots are already deployed in a number of healthcare applications, including to help healthcare professionals (HCPs) with diagnostic decision support, promoting and increasing physical activity, supporting patients through cognitive behavioral therapy, just to name a few.[39] The use of chatbots in healthcare applications has the potential to improve the efficiency of the delivery of healthcare, provide greater access to affordable healthcare, and provide personalized care to patients. As large language models (LLMs) on the market have become more powerful and their outputs more persuasive and nuanced, policymakers have become highly attuned to the risks of chatbots and the LLMs that power them. LLMs can be susceptible to flaws such as confabulation or hallucination, and bias inherited from the original training data could be amplified by AI models, creating systemic bias.[40] In addition, there is a risk that LLMs could become trained on AI-generated data, creating self-referential feedback loops; and HCPs could become over-reliant on LLMs, potentially resulting in a de-skilling of HCPs.[41]

These concerns about chatbots and LLMs inspired some of the provisions in the EU AI Act, which imposes a transparency obligation on AI systems intended to interact directly with humans.[42] The developer (i.e., the provider) of such AI systems is required to ensure that the AI system is designed and developed in such a way that the human users who interact with the AI system are informed that they are interacting with an AI system, unless this is obvious from the point of view of a reasonable user. It is already common industry practice for chatbots, such as customer service chatbots, to clearly disclose when it is powered by AI, so that users do not believe incorrectly that they are interacting with a human. This is usually done through a label, such as "powered by AI" in the chatbot user interface.

As adopted, the EU AI Act does not require more transparency than such a label. However, it is conceivable that policymakers could consider additional transparency obligations in future—such as providing "instructions of use" to the end users that disclose the level of accuracy and its limitations, similar to that required for high-risk AI systems under Article 13. A notable point to flag here is that some AI-powered chatbots in the healthcare context could be considered medical device software regulated under the MDR. If so, such chatbots would likely be subject to MDR notified body assessment and therefore classified as "high-risk AI systems," subject to the enhanced obligations discussed above in this article.

AI in Drug Discovery

The use of AI in drug discovery is a final use case. Many pharmaceutical companies already use AI in the drug discovery life cycle, and there are a number of AI services available on the market for drug discovery, including to identify novel targets, evaluate drug-target interactions, examine drug mechanisms, improve small molecule compound design and optimization, and study drug efficacy, response, and resistance.[43] Using AI in drug discovery is different from the other applications of AI discussed in this article—using AI in drug discovery does not directly affect the health, safety, or fundamental rights of individuals. In the drug discovery context, AI is used by researchers and experts to gain scientific insights and improve research efficiency—the resulting findings are then tested for safety and clinical efficacy in accordance with applicable rules for obtaining regulatory approval for the drug.

As adopted, the EU AI Act is unlikely to directly apply to AI in the drug discovery context. The EU AI Act contains an express carve-out for "AI systems or AI models, including their output, specifically developed and put into service for the sole purpose of scientific research and development."[44] AI in drug discovery is also unlikely to be covered by any of the expressly regulated types of AI systems in the EU AI Act—it is unlikely to be classified as prohibited, high-risk, limited-risk, or general-purpose AI. For the moment, it can be anticipated that the use of AI in drug discovery will face limited regulatory control in the European Union, though EU regulators are aware that AI in drug discovery is becoming more widely used.

In the European Union, the European Medicines Agency (EMA) is the EU authority responsible for the scientific evaluation, supervision, and safety monitoring of medicines. In September 2024, the EMA published a reflection paper on the use of AI in the medicinal product life cycle,[45] following a public consultation on the draft paper. In this reflection paper, the EMA notes that the application of AI in the process of drug discovery may be "low regulatory impact" essentially where non-optimal performance can only affect the developer and is unlikely to impact or affect the integrity of data used to support an application for drug approval. However, if the use of AI in the process of drug discovery contributes to the total body of evidence presented for regulatory review (and thus the EMA's assessment of the safety and efficacy of a drug for patients), principles for non-clinical development should be followed—including, where relevant, Principles of Good Laboratory Practice as they apply to computerized systems and data integrity. The EMA notes that all models and data sets used in AI for drug discovery should be reviewed to mitigate ethical issues, risks of bias, and discrimination of non-majority genotypes and phenotypes from a data quality and quantity perspective. The EMA has also published a work plan to guide the use of AI in medicines regulation,[46] which includes plans to develop AI guidance in medicines life cycle, including domain-specific guidance (e.g., pharmacovigilance[47]).

Conclusion

AI has the potential to revolutionize the healthcare sector. Clinical practice, biomedical research, and healthcare administrations are sectors where AI has and will have a pivotal role in shaping the healthcare industry. Assisting in selecting patients for clinical trials, medical image quantification in radiology, or patient flow planning are examples of AI use cases that could improve the provision of healthcare services.[48] Notwithstanding the understandable excitement around these developments, all actors involved must regard the risks involved and ensure compliance with all relevant laws, not just those applying horizontally to AI systems, such as the EU AI Act.

It can be anticipated that the EU AI Act will significantly transform the way in which AI is regulated in the European Union. A question that may be at the top of readers' minds, especially those

outside of the European Union, is this: how will the EU AI Act impact the way in which AI in life sciences will be regulated around the world? The answer to this question is not clear at this stage, but as the EU AI Act is one of the first comprehensive AI laws to be adopted globally, there is no doubt that it will set the scene for other AI laws on the horizon. A few observations follow.

First, it seems unlikely that the EU AI Act could be replicated in its current form in other jurisdictions in much the way the EU GDPR was replicated in other jurisdictions. Data protection laws like the GDPR are much more self-contained than the EU AI Act—data protection law regulates, essentially, a single domain: the processing of personal data to protect the fundamental human right to privacy. The EU AI Act, on the other hand, is intricately woven into the fabric of other laws, such as the existing product safety regulatory framework—particularly for Annex I high-risk AI systems like medical devices. Other jurisdictions will inevitably need to find a way to weave AI regulations into the fabric of their existing laws, and each will likely find different ways of doing so.

Second, the substantive obligations that can be found in the EU AI Act—e.g., transparency and explainability, data and data governance, human oversight, accuracy, robustness and cybersecurity, recordkeeping, and risk assessments—are likely to be replicated in other laws. These overlap with the core tenets of responsible AI that have already found international consensus, such as the OECD's AI Principles,[49] the Council of Europe's Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law,[50] and the Global Partnership on Artificial Intelligence's Principles for responsible stewardship of trustworthy AI.[51] The question will be whether other jurisdictions make these principles binding or non-binding, how they procedurally ensure and enforce compliance, and what redress mechanisms individuals affected by AI systems will have access to.

Third, much of how the EU AI Act will function in practice is still not known. How should human oversight be ensured in an AI medical device? How can fair outcomes be ensured in AI emergency triage systems if the training data sets exhibit systemic biases against certain genders or racial minorities? How will the EU AI Act's obligations be allocated to different stakeholders in the AI value chain? The EU AI Act does not contain specific answers to these questions, and practices will necessarily need to evolve over time in response to guidance, case law, and industry norms.

Finally, the EU's AI Act may be a forerunner of AI law, but it is unlikely to be an immutable monolith that will set the gold standard for AI regulation for decades to come. Already, the European Commission has announced plans to review the EU AI Act as part of a "Fitness check on the legislative acquis in the digital policy area" and a "Digital package," both planned for the fourth quarter of 2025.[52] It is likely that the EU AI Act itself will be tested and transformed by new innovations, and other jurisdictions will come up with novel ways of solving issues created by uses of AI, including through regulatory sandboxes or test beds.[53] This is just the beginning of a new field of law that will likely be as diverse as the ways in which AI can be applied, and the jurisdictions in which they will flourish.

Notes

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1. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No. 300/2008, (EU) No. 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797, and (EU) 2020/1828, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32024R1689.

2. In the European Union, "regulations" have direct applicability; by contrast "directives" are not directly applicable and need to be transposed into EU member state national law to be applicable.

3. Article 111(2), EU AI Act.

4. Recital 177, EU AI Act, clarifies that the concept of significant change should be understood as an equivalent of "substantial modification." Article 3(23), EU AI Act, defines "substantial modification" as "a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed."

5. Article 3(1)), EU AI Act.

6. OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0049, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449.

7. For an indication of the European Commission's approach to defining AI, see European Commission, Commission Guidelines on the definition of an AI system established by Regulation (EU) 2024/1689 (EU AI Act) (Feb. 6, 2025), https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-ai-system-definition-facilitate-first-ai-acts-rules-application.

8. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, https://eur-lex.europa.eu/eli/reg/2016/679/oj.

9. Article 5, EU AI Act.

10. Articles 6-49.

11. Article 50.

12. Articles 51-56.

13. Articles 57-63.

14. Articles 64-101.

15. Article 70(1), EU AI Act.

16. Article 74(12), EU AI Act.

17. Article 74(13), EU AI Act.

18. Article 99, EU AI Act.

19. Article 85, EU AI Act. The EU AI Act itself is silent on the issue of liability for harm caused by AI systems. Initially, legislators contemplated handling this issue alongside the EU AI Act with the proposed "AI Liability Directive." However, following the withdrawal of the AI Liability Directive in early 2025, Directive (EU) 2024/2853, known as the revised Product Liability Directive, adopted on October 23, 2024, is set to govern AI liability moving forward.

20. Regulation (EU) 2017/745 on medical devices.

21. Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

22. High-risk AI systems include AI systems that are, or are safety components of products covered by other EU legislation (e.g., motor vehicles; civil aviation; marine equipment); and AI systems that are used in certain specific contexts or for specific purposes (e.g.; for biometric identification; for educational or vocational training). The European Commission can amend the list of high-risk AI use cases via delegated acts (Article 7 EU AI Act).

23. According to article 6(1), an AI system is considered "high risk" where the following two cumulative conditions are fulfilled: (1) "the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I"; and (2) product/safety component referred to in point (1) "is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I [to the EU AI Act]."

24. Article 43(3), EU AI Act.

25. Article 9(1) and 17(3), EU AI Act.

26. Article 11(2), EU AI Act.

27. Article 72(4), EU AI Act.

28. The minimum content requirements include (among others) the high-risk AI system's: intended purpose, the level of accuracy, any known or foreseeable circumstance that may lead to risks to health and safety or fundamental rights; specifications relating to the training data; and information to explain and interpret the output of the high-risk AI system. Article 13(1), EU AI Act.

29. This article considers an AI system not falling within the definition of "medical device" under the MDR. In such a case, the obligations outlined in Section III(a) would apply.

30. Robert A. Love, John A. Murphy, Timothy E. Lietz & Kathleen S. Jordan, "The Effectiveness of a Provider in Triage in the Emergency Department: A Quality Improvement Initiative to Improve Patient Flow," Adv. Emerg. Nurs. J., 34(1), 65 (2012), https://doi.org/10.1097/tme.0b013e3182435543.

31. See, e.g., Mehul D. Patel, Peter Lin, Qian Cheng, Nilay T. Argon, Christopher S. Evans, Benjamin Linthicum, Yufeng Liu, Abhi Mehrotra, Laura Murphy & Serhan Ziya, "Patient Sex, Racial and Ethnic Disparities in Emergency Department Triage: A Multi-Site Retrospective Study," The American Journal of Emergency Medicine, Volume 76, 29-35 (2024), https://doi.org/10.1016/j.ajem.2023.11.008.

32. H. Adam, A. Balagopalan, E. Alsentzer et a., "Mitigating the Impact of Biased Artificial Intelligence in Emergency Decision-Making," Commun. Med. 2, 149 (2022), https://doi.org/10.1038/s43856-022-00214-4.

33. Annex III, paragraph 5(d).

34. Article 43(2), EU AI Act.

35. Article 49, EU AI Act.

36. Article 26(11), EU AI Act. The EU AI Act imposes a similar requirement upon AI systems intended to interact directly with individuals (Article 50, EU AI Act).

37. Article 27, EU AI Act.

38. Louis J. Catania, "Foundations of Artificial Intelligence in Healthcare and Bioscience," Academic Press, 2021, p. 185, https://doi.org/10.1016/B978-0-12-824477-7.

39. Id. at p. 188.

40. C. Peng, X. Yang, A. Chen et al. "A Study of Generative Large Language Model for Medical Research and Healthcare," NPJ Digit. Med. 6, 210 (2023), https://doi.org/10.1038/s41746-023-00958-w.

41. A. Choudhury & Z. Chaudhry, "Large Language Models and User Trust: Consequence of Self-Referential Learning Loop and the Deskilling of Health Care Professionals," J. Med. Internet Res. (Apr. 25, 2024); 26:e56764. doi: 10.2196/56764. PMID: 38662419.

42. Article 50, EU AI Act.

43. For a survey of AI in drug discovery use cases, see R. Qureshi, M. Irfan, T.M. Gondal et al., "AI in Drug Discovery and Its Clinical Relevance," Heliyon, 9(7) (July 2023), e17575, doi: 10.1016/j.heliyon.2023.e17575.

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