



# No Digital Omnibus! Why Europe Owes LMICs the Ethical Regulation of Generative AI in Healthcare

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## Abstract

AI tools hold vast promises to reduce health inequities in LMICs, yet these geographies remain heavily dependent on the technological infrastructures and governance norms from high-income regions. This paper highlights that tech-driven world building, coupled with the lack of firm AI regulation in the US and China, has led to unregulated AI technologies being implemented in healthcare systems and practices in LMICs, often with negative effects. Europe has been seeking to reign in the unfettered powers of digital technology companies with its recent regulations, namely the EU AI Act, Digital Services Act, Digital Markets Act, and the proposed Digital Fairness Act. We argue that these 'gold standard' regulations could work as a multilateralist spine for LMICs to unlock the potential of generative AI safely and ethically. However, we also warn that Europe's recent proposal of a 'Digital Omnibus' package will potentially eradicate the so-called 'Brussels effect'. We therefore urge the EU to carefully consider the weakening of their previously set regulations in the name of competitiveness as this will have an impact on LMICs too. Finally, we make recommendations on how the EU can support the additional transfer of regulatory blueprints to LMICs.

## Introduction

"Digital tools can reduce health inequity in low- and middle-income countries" states the World Economic Forum (2025). Indeed, doctors in Ecuador have started to use AI to triage radiology results (Rabiee, 2026), deploy AI for in-field screening and real-time surveillance of Malaria in Uganda (Fourrage, 2025), or leverage machine learning technology to analyze health data in Yemen (Alhammadi et al, 2024).

Low- and middle-income countries (LMICs) face complex public health challenges due to severe resource constraints. As of 2023, more than half of the world's population was still not covered by essential health services (World Health Organization, 2023).

Digital tools and technologies, including generative artificial intelligence (genAI), have started to be deployed in an effort to improve care and to lower cost (de Vere Hunt, Jin and Linos, 2025). A firm belief is that innovative technologies, such as genAI, can help LMICs overcome geographic and economic access barriers. Advocates believe that genAI systems such as ChatGPT, Google Gemini or Deepseek could be used in LMICs to improve access to information and health support at a patient level; provide triage, screening and remote healthcare including documentation and language support at a healthcare systems level; and promote medical training and efficiency and lighten the workload for professionals (Wang et al, 2025). While genAI technologies hold vast promises to reduce health inequities in LMICs, in reality, these countries remain heavily dependent on - and are therefore vulnerable to - the technological infrastructures and governance norms dominating in high-income regions, such as the United States and Europe, but also other technologically advanced countries such as China and India (Mações, 2025).

This paper argues that the EU's recent digital and AI regulations could work as a multilateralist spine to unlock the potential of generative AI safely and ethically. We see a danger that Europe's recent proposal of a 'Digital Omnibus' package may eradicate the so-called 'Brussels effect', and we urge the EU to carefully consider the weakening of regulations in the name of competitiveness, with unknown effects on other countries including LMICs.

## **Big Tech's Powers, 'AI Arms Races' and Geopolitical Domination**

Geopolitics is no longer just a contest to control physical territories, but also a race to develop and roll-out advanced technologies, including genAI. This race is not dominated by states anymore, but by powerful platform businesses (Birch and Bronson, 2022) and their advanced tools, technologies and infrastructures. Since the release of ChatGPT in 2022, the US and China have entered into an 'AI arms race', whereby each country has tried to expand their power capacity whilst avoiding any regulatory bottlenecks (Holmes, 2025). As of 2025, China had 15 notable AI models while the US had 40 (Davies, 2025). Powerful technology companies, including NVIDIA, Google, Microsoft, Amazon, Baidu, or Alibaba (Fernandez, 2025) have built the 'AI empires' that dominate the landscape today (Hao, 2025). These empires have been enabled and reinforced by their proprietary infrastructures as well as the intellectual property rights (IPR) that protect their foundational models and algorithms (Foss-Solbrekk, 2021). Furthermore, tech-driven 'world building' (Mações, 2025) has been greatly facilitated by a lack of firm regulation in the US and China. As a consequence,

unregulated genAI systems are now being implemented into healthcare systems and practices all over the world, including in LMICs like Uganda, Yemen or Ecuador.

## **Global Regulatory Failures and their Performative Effects for Healthcare**

Essential regulation means that tech companies are required by law to minimize AI's risks and harms, including errors and inaccuracies, biases, data security and privacy, or cost and environmental impact (de Vere Hunt, Jin and Linos, 2025). However, the absence of such regulation has encouraged tech companies to lower any previously existing ethical barriers gradually and steadily. For instance, OpenAI, the maker of the world's most popular genAI chatbot, has recently removed the word 'safely' from its updated mission statement, and the company has also changed its original nonprofit model into a predominantly for-profit one (Ebrahim, 2026). Beyond admitting unregulated, profit-hungry systems into already fragmented and resource-constrained healthcare systems, LMICs have now also become subject to digital colonialist practices, including the exploitation of cheap labour to train genAI models (Rowe, 2025), draining essential resources such as water and energy for operating data centers (Grüner, 2026; Hao, 2025) and so-called ethics dumping, including tech companies offshoring data collection activities to LMICs (van Kolschooten, Parwani and Pehudoff, 2026). In addition, biased algorithmic decision-making as well as automated workflows are leaving the most marginalized people and populations on the globe more vulnerable than ever before (Wagner, 2025).

## **The 'Brussels Effect' of EU's AI Regulation... Followed by the Digital Omnibus 'U-Turn'**

Europe has been at the forefront of reining in some of the unfettered power of large AI firms. Significant efforts have been made to regulate digital technologies, including genAI, through the 2024 EU AI Act, 2024 Digital Services Act (DSA), 2024 Digital Markets Act (DMA) and the proposed 2026 Digital Fairness Act (DFA) (Gross and Geiger, 2026). Setting risk-based classifications, the EU AI Act sets important guardrails for trustworthy and human-centric AI (EU Artificial Intelligence Act, 2024) - though critical commentators would likely argue that many genAI systems in healthcare already fall outside the high-risk classifications and thus evade oversight (Gross and van Kolschooten, 2025). The DSA harmonizes the EU's approach to better protect fundamental rights by increasing control and choice for consumers while requiring

platforms to decrease illegal and harmful content (European Commission, 2024a). The DMA further strengthens the DSA by identifying gatekeeper online platforms and introducing clear obligations as well as prohibitions (European Commission, 2024b), and this applies to digital health companies and markets also. Lastly, the DFA is set to deal with the problems consumers face online, such as dark patterns, influencer marketing, the addictive design of digital products and unfair personalisation practices, especially where consumer vulnerabilities are exploited for revenue-generating purposes (European Commission, 2024c).

As Europe is both a front runner and the apparent global gold standard when it comes to regulating digital technologies, including genAI in healthcare, it could provide the multilateralist regulatory spine that allows LMICs to unlock the potential of AI safely and ethically (Wani, 2025) -this is often called the 'Brussels Effect' (Habriiel, 2025). However, multilateralism tends to suffer in times of balance-of-power politics and geopolitical rivalry (Clark and Leung, 2026). As it stands, geopolitical world-building by Big Tech currently serves to undermine the Brussels effect (Almada and Radu, 2024). What is more, the EU's recent proposal of a 'Digital Omnibus' package (European Commission, 2025) reverses some of these regulations and thus weaken a critical locus of resistance against Big Tech's global dominance. To illustrate: the Omnibus proposes to remove important transparency safeguards for high-risk AI applications in healthcare. This will leave AI providers free to self-regulate and removes visibility of any potential breaches, thus it creates potentially unacceptable risks for health, safety and fundamental rights (European Digital Rights, 2026).

## **Concluding Remarks and a Call to Action**

LMICs should be free to benefit from safe and reliable digital tools, including genAI, to deliver better care, lower costs and increase health inequity. However, AI empires pushing unregulated AI technologies into LMIC territories is a clear and immediate danger. While the EU's regulations for trustworthy and human-centric AI in healthcare, digital rights and health solidarity are neither complete nor error-free, they provide stable and readily adaptable governance frameworks that could benefit LMICs that are currently subject to a US-China-dominated and largely unregulated AI landscape (Kickbush, 2026). The EU, as the second-largest economic powerhouse of the world, needs to stand with LMICs to contest the power of worldbuilding tech companies, challenge structural inequities and address fragmented global AI governance. However, this also means that EU policymakers need to stand by their current risk-based regulations and consider their halo effects on other parts of the world. Any

weakening of these regulations in the name of competitiveness, for instance, through the proposed Digital Omnibus package, should proceed with extreme care. Bearing the Brussels Effect in mind, the broader implications of this proposed regulatory package should be explored by incorporating perspectives not only from key EU stakeholders, including those in the medical field, patients and carers, policy and industry experts, civil society organisations, and NGOs, but also from stakeholders in LMICs, too. Beyond this, the EU will need to strengthen its efforts to support and empower regional bodies, regulators and other key stakeholders in LMICs to ensure that regulatory blueprints for generative AI in healthcare are workable, operational and scalable. 2026 needs to be a year of reimagination and reform, and the EU has a fundamental role to play in making this happen.

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