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Short communication

The critical importance of artificial intelligence legislation for medicines and medical devices

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Introduction

Artificial intelligence (AI) is rapidly reshaping the pharmaceutical and healthcare landscapes, offering opportunities to enhance drug development, patient care and regulatory oversight. However, this transformative potential comes with complex challenges that regulatory bodies must address to safeguard public health. The European Medicines Agency (EMA), Medicines and Healthcare products. Regulatory Agency (MHRA), Food and Drug Administration (FDA), World Health Organization (WHO) and International Council for Harmonization (ICH) are at the forefront of crafting frameworks that balance innovation with ethical responsibility and patient safety (WHO, 2021; GOV.UK, 2025).

As AI applications advance from theoretical computational tools to active drivers of drug formulation optimization and manufacturing quality prediction, their formal inclusion in global legislative frameworks becomes critical.

AI applications in the pharmaceutical industry

The necessity for hard legislation stems directly from the deep integration of AI in drug development (Gallego et al., 2021). This approach transforms drug discovery into a data-driven, predictive engineering process. AI is actively used to optimize drug formulations and enhance product stability (Dangeti et al., 2023). This development methodology cuts down the traditional trial-and-error formulation timelines, ensuring that drug products retain therapeutic efficacy over their intended shelf life. Using comprehensive databases of raw material property, data-driven machine learning models successfully predict critical quality attributes of pharmaceutical dosage forms (Hayashi et al., 2023). These tools enable real-time quality predictions without waiting for destructive physical testing. Large Language Models (LLM) serve as intelligent interfaces to streamline generative engineering pipelines, redefining how smart medical products and devices are fabricated (Bassey et al., 2025).

Evolving regulatory frameworks

Because these AI models directly impact final formulation and product quality, international regulatory bodies are attempting to standardize the oversight. The EMA's 2024 Reflection Paper recognizes AI's dual-edged nature in medicine development (EMA, 2024). It highlights both the promise of AI to accelerate research and the risks related to data quality and algorithmic bias.

The agency's collaborative issuance of ten joint principles with the FDA in 2026 underscores a commitment to human-centric AI design, rigorous risk-based validation, and continuous lifecycle management (EMA & FDA, 2026; PharmaSource, 2026). The FDA's co-development of transparency, robustness and patient-centric safeguards as guiding

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principles with the EMA in 2026, signals a harmonized transatlantic effort to govern AI in drug and biologics development (Browne Jacobson, 2026; FDA, 2026).

The MHRA's focus on AI within medical devices aligns with the United Kingdom's broader strategy, which emphasizes fostering innovation while ensuring safety (GOV.UK, 2025).

The WHO's 2021 guidance on Ethics and Governance of Artificial Intelligence for Health provides a foundational ethical framework for AI in health, human rights, inclusivity, accountability and sustainability (WHO Guidance, 2021). Its advocacy for global harmonization reflects an understanding that AI's benefits must be equitably distributed across diverse healthcare systems.

Although the ICH has yet to issue AI-specific guidelines, its historic role in harmonizing pharmaceutical standards makes it a critical future player in AI regulation (Trial MedPath, 2026; Vitrana, 2025).

The European Union Artificial Intelligence Act

While international regulatory bodies rely on voluntary, non-binding guidelines, the legislative landscape is changing with the introduction of formal statutory law, led by the European Union Artificial Intelligence Act (Artificial Intelligence Act, 2024). It establishes a comprehensive, legally binding risk classification framework for AI systems. The inclusion of the pharmaceutical and device-focused AI tools into formal frameworks shifts the responsibility from passive compliance with voluntary guidelines to mandatory legal liability, backed by severe financial penalties for non-compliance (FDA Guidelines, 2026).

Risks, challenges and harmonization

Data bias remains an existential threat; if the databases used to train predictive algorithms, such as raw material databases (Hayashi et al., 2023) or formulation matrix logs (Dangeti et al., 2023), are incomplete or non-representative, the resulting predictions could compromise product safety. A lack of global harmonization across regional legislative bodies threatens to fragment AI governance, creating compliance bottlenecks for cross-border collaboration and global medicine supply chains (EMA & FDA, 2026).

Conclusion

As the industry moves from basic predictive analytics to complex, automated product design and raw material property modeling, voluntary guidelines are no longer sufficient. Integrating AI directly into global medicines and medical devices legislation and transitioning these principles into enforceable statutory law is essential for global public health.

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