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Short communication

From data to decision: predictive regulatory intelligence for generic medicines in Europe

Izabela Toshevska*

Alkaloid AD Skopje, blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia

Introduction

Regulatory intelligence (RI) refers to the structured process of collecting, evaluating, and interpreting regulatory information to enable informed decision-making. Over the past decade, RI has evolved from a predominantly reactive, compliance-focused activity toward a central strategic function, increasingly integrated within Regulatory Affairs (RA) and broader corporate planning processes (Girgis et al., 2025). This evolution is particularly significant in the context of generic medicines in Europe, where regulatory success requires not only compliance with established bioequivalence and quality standards, but also the ability to effectively navigate varied approval pathways, country-specific requirements and evolving policy frameworks. Furthermore, the increasing volume of regulatory data (combined with ongoing digital transformation initiatives led by European Medicines Agency (EMA)) presents a meaningful opportunity to shift from primarily descriptive analysis toward more predictive, forward-looking, and decision-oriented intelligence.

European regulatory landscape

The European regulatory framework for generic medicines encompasses multiple approval pathways (centralised, decentralised, mutual recognition and national procedures) each associated with distinct strategic considerations. This complexity introduces a fragmented regulatory landscape, often leading to significant differences in launch timelines across Member States. The anticipated reforms introduced under the European Union Pharmaceutical Package (2025-2027) heighten the need for proactive monitoring and subtle interpretation of regulatory changes, thereby reinforcing the critical role of structured RI capabilities (European Commission, n.d.).

From data to insight: the foundation of RI

At its core, RI is built upon three fundamental components: systematic data collection, rigorous analysis, and effective dissemination of insights. Data sources include EMA guidelines, decisions from national regulatory authorities, outputs from scientific advice procedures, competitor submissions, and ongoing policy developments (Girgis et al., 2025).

Effective RI extends beyond passive monitoring to actively translating regulatory developments into actionable insights for stakeholders. For generic companies, this includes anticipating potential changes in bioequivalence requirements, dossier expectations, and labeling standards - factors that can affect development timelines, resource allocation and overall costs. However, the increasing volume and diversity of regulatory data pose significant challenges to traditional manual approaches, thereby

*istojcevska@alkaloid.com.mk

necessitating the adaptation of more advanced analytical methods and tools to ensure efficient and reliable interpretation.

Predictive RI

The integration of AI and advanced analytical techniques is reshaping RA by enabling predictive modeling and real-time data-driven decision support. These technologies empower organizations to process and analyze large volumes of complex data, detect underlying patterns, and generate forecast related to regulatory outcomes, including anticipated approval timelines and the probability of regulatory queries (Patil et al., 2023; Podichetty et al., 2025).

In Europe, both EMA and the Heads of Medicines Agencies (HMA) have acknowledged the strategic importance of data and AI, highlighting horizon scanning and advanced analytics as key priorities within their 2026-2028 strategy (HMA/EMA Network Data Steering Group, 2026).

Predictive RI therefore represents a transition from retrospective analysis toward forward-looking anticipatory intelligence, utilizing the current uprise of AI technology. Generic drug development operates under narrow margins and intense competition, where fast market entry and regulatory efficiency are critical success factors. Given the fragmented regulatory landscape in Europe and varying national requirements, these capabilities can play a pivotal role in minimizing delays and enhancing market positioning.

Challenges, barriers and recommendations

Despite its potential, the adoption of predictive RI faces several challenges including issues with data quality, standardization, and interoperability. The use of AI in regulated environments also raises concerns regarding validation, transparency, and compliance (Niazi, 2025). Organizational readiness remains a key constraint, as RI functions are often fragmented, limiting their effective integration into strategic decision-making process.

The future of RI in Europe lies in a data-driven regulatory ecosystem, supported by initiatives such as the EMA's digital and AI strategies. To realize the potential of predictive RI, key priorities include investing in digital infrastructure and analytics capabilities, integrating RI across functions, adopting standardized and interoperable data systems and building data science expertise within regulatory teams. Together, these measures will enable a shift from reactive compliance to proactive, intelligence-driven decision-making.

Conclusion

RI is evolving from a supportive function to a strategic capability at the heart of RA. For generic medicines in Europe, where regulatory complexity and competitive pressures are high, this shift is both necessary and urgent. Predictive RI (driven by data, analytics, and AI) enables more efficient and informed decision-making. By progressing from data to decision, pharmaceutical companies can improve regulatory outcomes, accelerate patient access to medicines, and strengthen their competitive position in the European market.

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