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R&C risk & compliance

NAVIGATING GLOBAL REGULATORY FRAGMENTATION

REPRINTED FROM:
RISK & COMPLIANCE MAGAZINE
APR-JUN 2026 ISSUE



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HOT TOPIC

NAVIGATING GLOBAL REGULATORY FRAGMENTATION



PANEL EXPERTS

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Patrick Wellens brings 30-plus years' experience in governance, risk and compliance in the pharma, FMCG and manufacturing industries. For the last 11 years, he has worked at a large pharma company as country compliance officer, country data privacy officer and global divisional compliance officer, where he designed and implemented the compliance management system, designed and implemented a global third party risk management system and participated in numerous global compliance projects. Mr Wellens is the chairman of Ethics and Compliance Switzerland.

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Leon Zacharias is senior legal counsel in Siemens' compliance regulatory department, supporting the compliance management system in a complex regulatory environment. Previously, he worked in private practice inter alia as part of an independent SEC/DOJ monitor team, advising clients on complex compliance and regulatory matters as well as forensic investigations.

R&C: How can organisations design compliance frameworks that remain agile amid rapidly shifting geopolitical and trade dynamics?

Wellens: A volatile geopolitical situation will mostly impact trade compliance and export control, expand lists with sanctioned entities, increase licence requirements, and hamper exporting certain technologies. But it will also restrict cross-border flows for national security reasons, lead to increased cyber attacks and espionage, see governments impose additional security requirements on critical infrastructure, and increase bribery risk and pressure to win contracts in more difficult markets. Multinational companies cannot manually manage compliance risks effectively in these volatile times. The technology solutions used within compliance should easily be customisable to new sanction lists, licensing requirements and stricter payment controls. Contract management systems should be 'searchable' so that immediately those contracts affected by localisation laws or stricter security standards can be identified and contract clauses can rapidly be adapted. Rather than having myriad exceptions on company policies, companies might want to go for the stricter standard across all regions and establish more dynamic and more frequent risk assessments. An annual risk assessment is no longer good enough.

Belov: An organisation's compliance framework or programme should be tailored to its risk profile, include real-time intelligence and involve cross-functional coordination. Changes in the geopolitical landscape, as well as regulatory enforcement trends, including trade, can result in changes to that risk profile. It is therefore critical to have a robust compliance risk assessment process that is routinely updated to keep pace with market dynamics and regulatory changes, and used to identify opportunities to make agile enhancements to the compliance programme. Second, leveraging technology, including ongoing automated regulatory monitoring, artificial intelligence (AI)-enabled compliance analytics and monitoring, as well as centralised compliance metrics or dashboards, enables faster identification of emerging risks. Third, cross-functional coordination and collaboration allow for rapid and right-sized response to emerging risks.

Zacharias: Agile compliance frameworks must be built to operate in an environment where regulations change quickly and often without warning. To stay effective, organisations should rely on clear, principle-based standards that remain stable even when specific rules evolve. AI-enabled monitoring helps detect new developments early, ensuring teams are not surprised by sudden shifts. Modular processes make it easier to integrate new requirements without overhauling entire systems.

Agility also depends on strong cooperation across supporting functions and the business to ensure that regulatory changes are understood from both a legal and commercial perspective. When teams work together and have timely information, organisations can adapt quickly, maintain control and reduce disruption.

R&C: What role should automation and artificial intelligence play in tracking and interpreting divergent regulatory requirements across multiple jurisdictions?

Belov: As regulatory frameworks become more complex and dynamic, traditional manual monitoring of regulatory requirements is becoming time consuming and prone to omissions or delays in responding to regulatory changes. The US Department of Justice has made it clear that compliance functions are expected to evaluate potential use cases for AI in their work and be aligned with the organisation's overall approach for using AI. Compliance leaders should be evaluating AI and other technologies to enhance their ability to track new, and changes to existing, laws and regulations, and incorporate them into the overarching compliance risk assessment process to make sure that right-sized and effective

controls are implemented or enhanced. However, AI should augment and not replace human expertise, judgement, assessment and interpretation of regulatory requirements.

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Siemens*

Zacharias: AI is essential for managing the complex landscape of global regulations, scanning updates across jurisdictions, flagging changes and detecting patterns that manual oversight may miss. This reduces administrative burden and ensures important developments are not overlooked. Crucially, AI can also spot emerging trends that have not yet become law but may forecast future regulatory shifts, enabling organisations to prepare proactively. However, AI should complement, not replace, human expertise. The most effective approach is a hybrid model: AI delivers structured

insights, while compliance and legal professionals apply judgment and determine practical responses. This balance promotes accuracy, reduces misinterpretation and enables teams to act swiftly, supporting consistent compliance across regions.

Wellens: Multinational companies are flooded with international laws, European Union directives, national laws, ordinances and case law – tracking them and keeping abreast of and following such legislation would be a very manual process without AI. AI agents can continuously track official sources, such as official gazettes, draft consultation papers and so on, detect new and changed regulations and immediately flag them to the relevant departments in the organisation. AI can not only identify new legislation, but can also help with summarising the important factors, such as scope of the legislation, exclusion criteria and key obligations, among others. This high-level summary of obligations and scope can then be used against the existing company governance framework, such as policies, procedures and controls, to immediately highlight gaps. Given that AI can hallucinate, it is important that the AI-generated output on new or changed laws is critically reviewed by humans for correctness. AI should be used as a high-level screening and decision-support tool,

but final interpretations should be done by legal or compliance teams.

R&C: How can businesses balance the need for global standardisation with local regulatory nuances, especially in highly fragmented markets?

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Ethics and Compliance Switzerland*

Wellens: Companies typically create global principles, such as supplier codes of conduct, apply global minimum baseline controls, such as process standards that apply everywhere – for example vendor due diligence, procurement policies, or travel and expense systems – but then allow for local adaptation and implementation. Local deviations need to be approved by a global committee to ensure that they do not expose the

company to increased risk. The decision to centralise versus localise certain controls will depend on several factors. The first is operational feasibility. A company with one global instance of sourcing and procurement, or with standardised travel and expense tools or procurement systems, can build in global controls, whereas centralised and standardised controls are less likely in a company with myriad different IT systems. In addition, more centralisation is needed when inconsistency in local markets would impact the reputation of the company. If fast decision making in local markets is critical or local laws differ substantially in various markets, the more local guidance is needed.

Zacharias: A strong compliance system needs both clear global standards and targeted local adjustments. Global principles provide consistency and set a common expectation for behaviour and controls across the company. Local teams then add requirements that reflect specific national laws or cultural peculiarities, but only where truly necessary. This prevents unnecessary complexity and ensures that differences are grounded in real legal obligations. AI and digital tools can support this approach by comparing regulatory requirements across jurisdictions and highlighting where meaningful divergences exist. Regular coordination between global and local teams helps maintain alignment and ensures that local additions remain

practical. This balanced model allows companies to operate confidently in fragmented environments without sacrificing clarity or compliance quality.

Belov: Balancing global consistency with local regulatory complexity is a challenge every multinational organisation faces. A practical approach is to standardise a core set of controls and compliance processes to create a common baseline for governance, risk and control. Global standards provide consistency, efficiency and credibility with stakeholders, while allowing teams the flexibility to tailor implementation to meet country-specific regulations, industry requirements and cultural expectations. By using global frameworks as the foundation, and layering in local regulatory requirements where needed, organisations can reduce duplication, manage risk more effectively and scale compliance without sacrificing regional relevance.

R&C: In the context of sanctions and trade regimes, what best practices exist for building adaptive compliance models that minimise operational disruption?

Zacharias: Sanctions and trade rules can change with little notice, so organisations need systems that can respond quickly. Continuous monitoring, supported by systematic screening, helps identify

new restrictions or listings as soon as they arise. Once a change is detected, clear internal procedures ensure fast and coordinated action. Predefined escalation paths and simple internal guidance help avoid delays or inconsistent responses. Analysing value chains and customer relationships in advance further reduces complexity when adjustments are required. By combining early detection, structured decision making and interdisciplinary cooperation, organisations can maintain compliance while minimising disruption.

Belov: Adaptive and agile compliance frameworks call for a risk-based design, real-time intelligence and cross-functional coordination and collaboration. A robust routine compliance risk assessment process, enabled by technology, is critical for keeping pace with the ever-evolving regulatory landscape. We also find that governance structures must clearly define cross-functional accountability to help ensure rapid and right-sized escalation, decision making and response to any regulatory changes.

Wellens: The first step in having compliance models adaptive to changing sanctions and trade regimes is to fully understand and map your supply chain lanes. Secondly, it is worthwhile doing 'what if' scenario analysis to be prepared for new embargos, additional licence requirements and prohibition of exporting technologies. Thirdly, IT systems and

especially master data must have the capacity to screen automatically against sanction lists and automatically 'block' certain products, technologies or services to be delivered to certain destinations or counterparties. As sanction regimes affect payment transactions, destinations, articles and third parties on sanction lists, the compliance or sanction framework and screening model must be rapidly adaptable whenever a new sanction guideline comes into effect.

R&C: What governance structures or cross-functional teams are most effective for managing compliance risk in a fractured global regulatory environment?

Belov: Effective compliance risk management in a fractured global regulatory environment requires a 'three lines of defence' model. One leading practice we have seen is the development of a charter for the compliance programme that outlines the key roles and responsibilities across all three lines of defence. Another leading practice is establishing a global cross-functional compliance committee – an executive-level committee chaired by the chief ethics and compliance officer, which governs, coordinates and strengthens the organisation's compliance programme across regions and functions to ensure consistent standards while allowing for local regulatory differences. Finally,



we have observed significant benefits from implementing a cross-functional compliance champion network to embed compliance into day to day operations, serve as 'first line of defence' compliance liaison, and improve risk identification and early warning.

Wellens: Most organisations will have a small central or global compliance function that is responsible for functional governance, such as defining the framework, policies, procedures and minimum controls that are to be applied globally. In addition, usually there are certain centres of excellence with deep knowledge in a particular topic, such as investigation, antitrust, data privacy or sanctions. Whether it is most effective to have a regional compliance structure, local compliance officers, a combination of regional and compliance officers supported by certain shared service centres or operational hubs, or outsourcing certain compliance tasks, depends on numerous factors. In important subsidiaries with huge revenue and hundreds or thousands of employees, clearly it makes sense to have local compliance officers, whereas in subsidiaries with only 50 employees a compliance officer is not necessarily needed. In countries with higher risks or higher enforcement activity, more likely a compliance officer will be needed. Certain risks, such as cyber security or sanctions, are more likely to follow a centralised

compliance management approach, whereas others could be managed locally, for instance where due to localisation rules data cannot be accessed centrally. The more IT systems are standardised globally, the easier it is to centralise compliance tasks, such as monitoring or audits. Procedures, controls and monitoring can be done centrally; however, integrity and ethical behaviour is a people business. If compliance is not part of the local leadership team and decisions are taken about new business models, new incentive structures for the sales force, new marketing campaigns, and so on, then possible compliance risks are not timely and appropriately addressed. If a company has few investigations, it might be more effective to outsource these activities instead of building up its own department. The scope of the compliance department is totally different in each organisation. In some organisations data privacy is handled by the legal department, human rights issues are handled by a separate department, and sustainability and IT security are handled by another department. In such cases, a cross-functional team that defines the governance, policies, training and detective controls is most effective.

Zacharias: Effective governance combines strong global direction with practical local insight. The central compliance function should define global standards, provide methodologies and ensure

consistent interpretation across the organisation. Local units apply these standards in their regulatory environment and identify emerging risks. Because today's regulations cut across many topics – from cyber security to sustainability – interdisciplinary collaboration is essential. Legal, compliance, technical and operational teams must work together to avoid blind spots and ensure that decisions reflect both regulatory requirements and business realities. Clear reporting lines, shared tools and coordinated alignment help ensure that information flows efficiently. This governance model creates clarity, strengthens risk awareness and supports consistent implementation across diverse jurisdictions.

R&C: How can companies leverage data analytics to anticipate regulatory changes and reduce the cost and complexity of compliance?

Zacharias: Data analytics allows organisations to move from reacting to regulatory change toward anticipating it. By analysing legislative trends, enforcement activities and political signals, companies can identify themes that are likely to lead to new rules. AI enhances this by clustering related developments and highlighting

areas where regulatory complexity is increasing. Legal and operational experts then review these insights and decide how to prepare. Early action helps avoid rushed changes, unnecessary controls and duplicated efforts, all of which contribute to higher costs. Over time, this forward-looking

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BDO*

approach improves resource allocation, strengthens compliance planning and reduces the overall burden associated with managing fragmented regulatory environments.

Wellens: Companies can use data analytics as a preventive tool to conduct enforcement trend analysis to see which topics are trending and which regulators are most active, and to review deferred prosecution agreements and corporate

integrity agreements for the latest expectations from regulators. Additionally, data analytics and AI can be used to detect early on what draft laws, regulations and consultation papers are saying, evaluate the impact of these regulations for the company, map the requirements to existing IT systems and controls, and rapidly provide a gap analysis of what is missing. Because of data analytics, companies significantly reduce the manual time to review upcoming legislation and significantly reduce the time to conduct an impact assessment of new regulations.

Belov: Organisations can use data analytics to shift compliance from reactive to predictive by integrating regulatory intelligence directly into the compliance risk assessment, controls and monitoring lifecycle. In our experience, the goal is a repeatable 'regulatory to control' pipeline that ingests signals, anticipates likely obligations and routes right-sized actions to owners – reducing manual effort, rework and downtime. This all begins with establishing a regulatory data pipeline that unifies external sources with internal risk and operational data. The process should map regulatory obligations to business processes, systems and controls, and then leverage continuous monitoring, process mining and anomaly detection to help identify control gaps early. While leveraging automation and AI is important, these updates should augment, not replace, human judgment.

Strong data governance, model risk management and cross-functional oversight are essential to help ensure reliable, defensible outcomes and to adapt to local regulatory nuances.

R&C: How do you foresee regulatory fragmentation evolving over the next five years? What proactive steps should organisations take now to prepare?

Wellens: Due to the geopolitical situation and increased national security interests, more jurisdictions are likely to come with their own legislation, including extraterritorial application, and more detailed guidance for highly strategic sectors. It is highly likely that national standards and industry codes will expand, rules around AI will move from high-level principles to more specific requirements and increased cross-border enforcement cooperation will occur. For companies, this means higher complexity and compliance costs. Companies should proactively invest in data lakes, flexible and customised IT systems and controls and a central risk register, define clear roles and responsibilities for approving local deviations, and continuously monitor changes in laws across jurisdictions.

Belov: Global regulatory fragmentation will continue at a steady pace, or may even intensify, over the next several years. Geopolitical tensions,

national security concerns and divergent societal priorities are likely to continue to drive regulatory fragmentation. To prepare for increasing regulatory fragmentation, it is advisable for organisations to take a proactive approach to compliance, rather than reacting later. First, organisations should consider performing periodic compliance risk assessments to assist management in identifying and prioritising significant risks and emerging issues. Second, organisations should consider performing mature and effective periodic compliance programme design and performance assessments that provide an assessment of the governance, personnel and technology resources, as well as policies and procedures for prevention, detection and response to acts of non-compliance. Third, organisations need to continue to integrate ethics and compliance in day to day business operations and monitor the performance of compliance programmes.

Zacharias: Regulatory fragmentation is likely to increase as governments respond to geopolitical developments, technological innovation and sustainability goals with their own national rules. Companies should expect more divergent definitions, faster updates and stricter enforcement. Preparing for this requires strong global compliance principles, flexible processes and agile monitoring that provides early visibility into emerging requirements. Interdisciplinary teams help interpret developments and coordinate consistent action across functions and regions. Scenario planning and early engagement with new regulatory topics support long-term resilience and reduce the risk of being caught off guard. By prioritising clear communication, adopting advanced technology and streamlining decision making, organisations can position themselves to navigate an increasingly complex regulatory landscape with greater confidence. **RC**

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