Hogan Lovells

2025 Horizons

Life Sciences and Health Care

Welcome.

In 2025, Life Sciences and Health Care (LS&HC) companies face rapidly evolving regulatory paradigms that create transactional risks and require daily monitoring. After more than 70 national elections in 2024, the dust hasn't fully settled, not least in the U.S., where President Trump has taken office for the second time. Indeed, political shifts across the world – coupled with geopolitical uncertainty – set the tone for changes to come.

As staff cuts hit governmental agencies, LS&HC stakeholders are intensely focused on the policy implications for global financial markets, investment strategies, and M&A opportunities. Among numerous effects, the second Trump administration and "MAHA" influences will shape AI policy, GLP compounding rules, U.S. inspections and enforcement capabilities, drug shortage regulations, ongoing laboratory developed test (LDT) litigation, and reimbursement policies for innovative diagnostics and preemptive health platforms. 2024 also saw Loper Bright replace the former agency friendly Chevron standard in U.S. courts, meaning life science companies now have a new tool in their arsenal for challenging governmental decisions.

In Latin America, the U.S., Europe, the Middle East, and Southeast Asia, we are seeing governments taking aggressive stances on corruption. The life sciences industry in particular faces increasing scrutiny over bribery and corruption practices. Recent developments in False Claims Act litigation, support for patient organizations, and the integration of AI within legal and compliance departments are vital components in addressing bribery and corruption risks. In Europe in particular, key enforcement actions targeted anti-competitive practices in 2024, including pay-for-delay agreements, market disparagement, and patent abuse.

All around the globe, a shift away from fossil fuels and toward sustainable greenhouse gas emissions – the "energy transition" – makes compliance with environmental, social, and governance (ESG) policies more important than ever. Recent geopolitical and economic headwinds are driving an increased focus on strengthening and transforming supply chains, including political pressure to reconfigure supply chains to ensure strategically important industries ("near shoring"). We are also seeing increased scrutiny of fair supply chains and compliance with corporate responsibility standards; a need to digitally transform to better anticipate, mitigate and document supply chain issues; a rethinking of purchasing and supply strategics due to shortage of raw materials and price increases; and industry cooperations forming a new approach to procurement.

In the EU, the Corporate Sustainability Due Diligence Directive (CSDDD) and Corporate Sustainability Reporting Directive (CSRD) have placed greater focus on ESG regulatory enforcement activity. In the U.S., the Drug Supply Chain Security Act (DSCSA) is beginning to be enforced, creating an electronic interoperable system that will identify and trace prescription drug distribution. In addition, new EU directives impose strict requirements on use of genetically modified organisms (GMOs), aiming to mitigate environmental and public health risks, including the need for detailed environmental risk assessments and authorizations.

Meanwhile, AI-enabled technologies are continuing to demonstrate enormous potential to create a healthier world, fueling advances in areas as varied as drug development, software-as-a-service, and analysis of medical images. Aiming to keep pace with these rapid technological developments, regulations including the EU's AI Act, and guidance stemming from FDA's inaugural Digital Health Advisory Committee meeting in November, present unique challenges for AI developers in the health sector, including the possibility of duplicative regulations or even conflicting regulatory obligations.

In the UK, the MHRA has taken a relatively light touch and "pro-innovation" approach so far, as set out in its AI regulatory strategy. In the EU, the Product Liability Directive has taken effect, and focuses on addressing the challenges posed by digital products and other emerging technologies. Policymakers continue to face a steep learning curve, and industry perspectives are vital to advance appropriate regulations that both foster innovation while protecting patients and users from the negative impacts that can come with the promise of AI.

AI developers continue to struggle within the existing legacy coverage and reimbursement pathways. At the same time, the issues around patient data are growing in complexity as regulators, patients, and clinicians become better equipped to understand the challenges and risks of utilizing patient data.

In the dealmaking space, Chinese biopharma companies are increasingly turning to licensing and collaboration deals for external financing due to a challenging fundraising environment. In Japan, we expect more strategic transactional activity (i.e., licensing and M&A) in 2025, as private equity interests grow despite the escalating risks of cross-border transactions, including geopolitical disruptions, fluctuating valuations, and regulatory uncertainties. The U.S. is also seeing increased life sciences deal activity risks associated with antitrust regulatory uncertainty. Proactive M&A strategy is crucial, as regulatory hurdles, financial missteps, and operational disruptions can derail deals.

The Hogan Lovells global Life Sciences and Health Care team – comprised of more than 500 lawyers around the world who support more than 1,000 clients in the industry – stands ready to provide you with creative strategies to help achieve your most promising opportunities, and integrated solutions to protect and support your business. We hope that you find our view of the horizon thought-provoking. We look forward to working together with you as we accelerate faster and further into the future.

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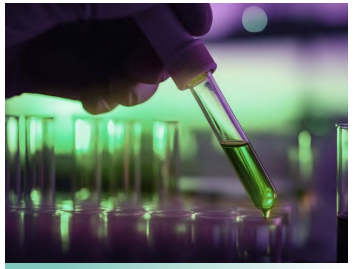

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Supply Chain.

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Drug Supply Chain Security Act: Enhanced drug distribution security requirements

The Drug Supply Chain Security Act (DSCSA) outlines steps to build an electronic interoperable system that will identify and trace certain prescription drugs distributed in the U.S. It initially included a ten-year phase-in period for "trading partners" (i.e., drug and biologic manufacturers, wholesale distributors, dispensers, and repackagers) to implement systems and processes for electronically exchanging required information at the product package level (the "enhanced drug distribution security requirements").

We expect that some stakeholders will continue to experience challenges in meeting applicable timeframes for compliance with these enhanced requirements in 2025. Consistent with other anticipated deregulatory initiatives, new FDA leadership may consider further accommodations and enforcement discretion to address specific regulatory challenges and avoid drug shortages.

Although the requirements were scheduled to take effect in November 2023, FDA announced in August 2023 a one-year "stabilization period" ending in November 2024 that provided trading partners additional time to implement the required systems. In July and October 2024, FDA issued exemptions to provide small business dispensers and certain connected trading partners, respectively, additional time to finalize their systems. Under the exemptions, FDA will not enforce the enhanced drug distribution security requirements against products transacted between eligible trading partners until:

- 27 May 2025 for manufacturers and repackagers,
- 27 August 2025 for wholesale distributors,
- 27 November 2025 for dispensers with at least 26 full-time employees (FTEs) licensed as pharmacists or pharmacy technicians, and
- 27 November 2026 for small business dispensers with fewer than 26 FTEs.

For trading partners to be eligible for the exemptions, they must have initiated data connections with immediate trading partners and have documented those efforts. Trading partners who are not eligible for the above exemptions may continue to request a waiver, exception, or exemption from the enhanced drug distribution security requirements.

In delaying enforcement and issuing exemptions, FDA has repeatedly emphasized the importance of ensuring patient access amid concerns about potential shortages or supply chain disruptions resulting from implementation of the electronic interoperable system. Importantly, FDA's public meetings reflect a clear effort to work with stakeholders to ensure supply chain continuity while standing up the required systems.

Stakeholders continuing to experience implementation challenges should document steps taken, engage with FDA, and consider participating in FDA's upcoming town halls taking place throughout 2025. These town halls provide stakeholders with an important opportunity to share their progress and voice remaining areas of concern to the agency.

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Decentralized manufacturing considerations for cell and gene therapies

Manufacturing and supply chain models for cell and gene therapies (CGTs) are currently complex and expensive. Entities that can scale-up and scale-out the manufacturing and distribution in a cost-effective manner will be market leaders as CGTs become the pharmaceutical industry's "new normal."

Conventional supply chains, where patient cells must be transported to a manufacturing site, processed, and returned to treatment centers, pose various challenges for CGTs, including manufacturing and supply bottlenecks, heightened risks of batch rejections, and high costs (partly due to cold-chain transport requirements). Costly supply chains mean high price points, making reimbursement in relevant markets less likely.

In response, there is recognition that a shift towards decentralized models, where production takes place at or near the point of treatment, is needed. Larger pharmaceutical companies that adopt this approach could have significant annual cost savings. Decentralization models can include:

- setting up facilities at treatment centers (point of care (POC) model);
- setting up manufacturing facilities near treatment centers; or
- appointing a contract manufacturing organization (CMO) with facilities near the treatment center.

At present, most manufacturers with approved CGTs on the market still rely on centralized models, resulting in the challenges mentioned above. The radiopharmaceutical industry has already shifted to decentralized manufacturing to overcome the logistical challenges associated with products with a very short half-life (typically hours). CGT companies could look to the radiopharmaceutical industry for guidance (although requirements for manufacturing sites in the CGT space are different than those for radiopharmaceuticals).

For those wanting to adopt this approach, a central reference (i.e., manufacturing) site should be established and control strategies put in place to ensure decentralized sites follow the same production process as the central site. A quality protocol will also need to be developed to ensure harmonized standards across the sites.

Agreements with decentralized sites should set clear parameters for a successful technology transfer and measures for managing manufacturing capacity. A patient-centered approach to manufacturing capacity is required and will need to align with patient scheduling and treatment administration. Robust systems need to be harmonized and operate across the full bandwidth of potential customers/treatment centers to manage time-sensitive ordering protocols and capacity constraints.

Particular challenges apply for the implementation of POC models where CGTs are manufactured at treatment centers. Many specialized treatment centers are not equipped to manufacture finished medicinal products on a commercial scale, and some points of care are increasingly resistant to adopting any on-site risk or operational responsibility for production.

In addition, the negotiation of CGT-related contracts with health care organizations (HCOs) can be lengthy and challenging. For example, German HCOs often ask for very particular contractual terms and are generally unwilling to take on any substantial financial risks or liabilities.[1] We anticipate HCOs taking similar approaches in other jurisdictions. Contracting with much more customer-friendly and commercially experienced private CMOs may be preferable when working towards decentralizing CGT supply chains.


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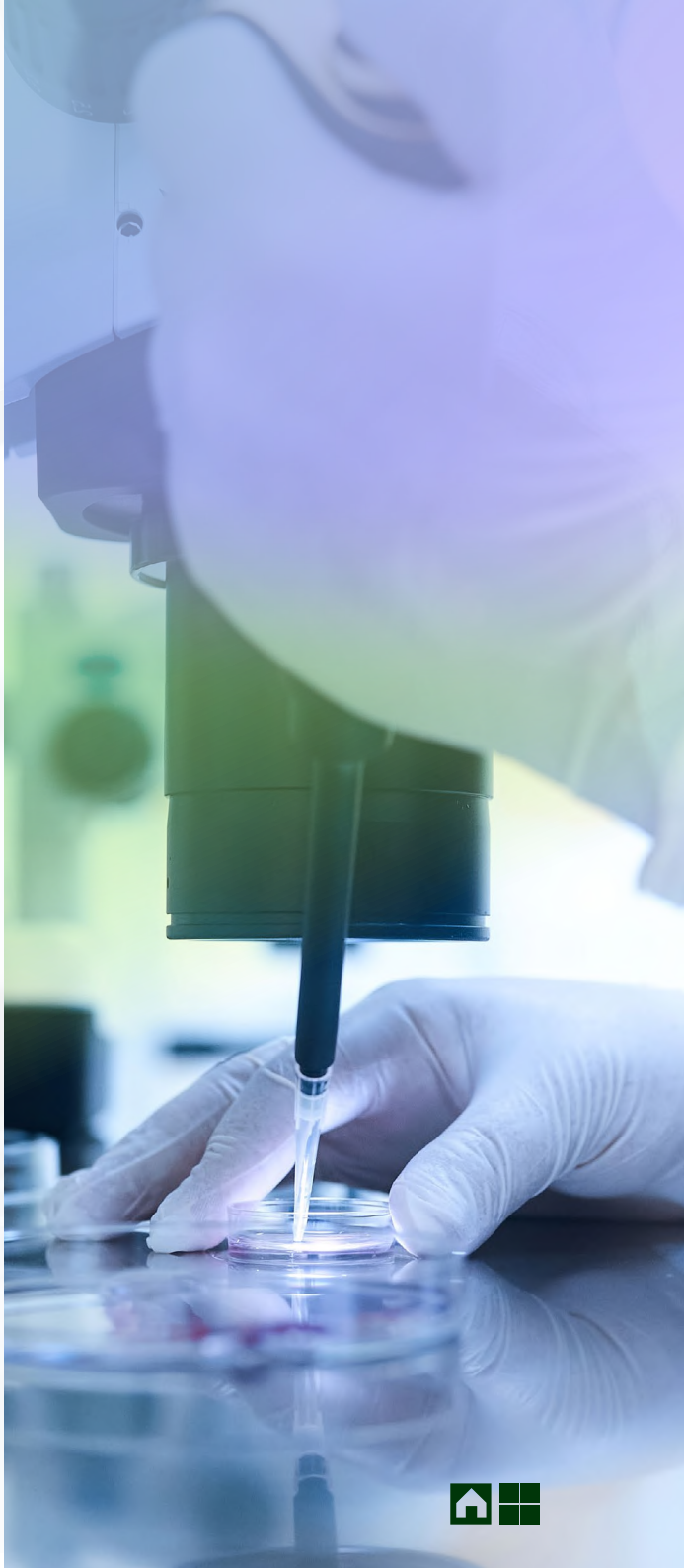
[1] See Planning contract negotiations with treatment centers in Germany article on page 41



Notification duty for device supply interruptions in the EU

As of 10 January 2025, medical device and in vitro diagnostic (IVDs) manufacturers are subject to a new obligation under Article 10a of the Medical Device Regulation (MDR)/IVD Regulation (IVDR) to inform their competent authority, impacted economic operators in their supply chain, health institutions and health care professionals to whom they directly supply devices/IVDs if they anticipate interruption or discontinuation of the supply of certain medical devices and IVDs.

This notification obligation, introduced by Regulation (EU) 2024/1860, aims to help competent authorities and health institutions anticipate foreseeable disruptions in the supply of medical devices and IVDs in the EU with a view to taking measures to mitigate device and IVD shortages where necessary to ensure patient health and safety.

This obligation rests solely with manufacturers, whether established in or outside the EU. Economic operators informed by a manufacturer of an anticipated interruption or discontinuation must pass this information on to the downstream supply chain. This requirement covers all models or types of devices (including legacy devices) placed on the EU market, for which it is reasonably foreseeable that a supply interruption or discontinuation could result in serious harm or pose a risk of serious harm to patients or public health in one or more EU Member States. Notifications should be made six months prior to the anticipated interruption/discontinuation unless exceptional circumstances prevent the manufacturer from doing so (such as natural disasters, a sudden inability to obtain raw materials or components, or economic or financial reasons, etc.).

Manufacturers must assess if Article 10a of the MDR/IVDR is applicable to their devices and document their conclusions. Affected manufacturers should also update their Quality Management System (QMS) procedures and existing agreements with economic operators in the supply chain to ensure compliance and avoid non-conformities during forthcoming Notified Body audits/inspections.

The European Commission published a related Q&A, which explains the conditions for the application of the notification obligation, describes key concepts of this requirement, provides an illustrative list of potential reasons for interruption or discontinuation, and specifies parameters manufacturers must consider when assessing this obligation to their products.

Competent authorities in several EU Member States, including Belgium, France, Germany, the Netherlands, and Portugal, have issued guidance detailing Article 10a notification requirements in their respective jurisdictions.

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Stricter GMP, GDP, and other supply chain rule enforcement in the EU

The supply chain for medicinal products, from manufacture of a pharmaceutical product to import into and distribution within the EU, is increasingly coming under more scrutiny by the competent authorities. EU laws as well as Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) regulations (together, "GxP") impose various requirements on how a supply chain must be designed, affecting importation and the supply chain more broadly.

In the EU, these laws are being interpreted and enforced in a stricter manner. As a result, pharmaceutical companies may be forced to re-assess and potentially re-design or adapt the supply chain for their medicinal products in the EU. Doing so requires consideration of not only regulatory requirements, but also of logistics, customs, and tax concerns.

Since the Court of Justice of the European Union (CJEU) ruled in September 2023 (ECJ, 47/22) that a wholesaler in Europe may not buy medicinal products from entities located outside the EU, there is scrutiny on the compliant design of pharmaceutical supply chains, specifically those where a product comes from outside of the EU. There is particular focus on situations where a product derives from the U.S. or is routed via non-EU countries into the EU (e.g., the "Swiss Model").

Beyond the aforementioned CJEU ruling, there are plans to change EU law and specifically codify that even merely fiscal purchase of products (e.g., distribution without "touching" the products) is a "wholesale activity," for which an EU wholesale license is required. Compliance with GDP rules would also be required, especially with the rule that an EU wholesale license holder can only buy products from entities that hold an EU wholesale license or EU manufacturing license.

An EU wholesaler may no longer purchase products from entities outside of the EU. Fiscally importing products would arguably require holding an EU manufacturing license for the entity that is purchasing from outside of the EU, or otherwise for redesigning the supply chain.

Designing a compliant pharmaceutical supply chain where a product originates from outside of the EU requires holistic thinking and care, and necessitates bringing together stakeholders for regulatory, quality, logistics, intercompany contract designing and tax.

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[1] See Planning contract negotiations with treatment centers in Germany article on page 41

Medical device supply chain in EU: Involvement of ex-EU entities in supply chain

Since the enactment of the MDR and IVDR, the authorities have been issuing several guidances, which form the landscape for medical devices and in vitro diagnostics (IVD) in the EU. This is also true for the supply chain of MD and IVD, especially where products are sold in the EU that originate from outside of the EU (i.e., supply chains where products are either physically shipped from outside of the EU into the EU, or where products are sold by entities located outside of the EU to an EU recipient). In such cases, particular care must be taken when designing the importation and further distribution routes and processes of the MD or the IVD.

The MDR and IVDR both define the roles of an "importer" and a "distributor," and impose certain obligations on those entities. The guidance that clarifies the definitions and obligations of importers and distributors (MDCG 2021-27) states: where a product comes from outside of the EU, the European legal entity which first obtains the product from outside the EU by way of receipt of ownership, possession or any other property right will be deemed the importer. It further says that even an entity which only buys a product and receives ownership – without physically touching the product – will be considered an importer.

Critically, these laws require that the very entity that purchases a product from outside the EU must fulfill the obligations as an importer (*e.g.*, ascertaining on a certain level that the MDR or the IVDR has been complied with, and being the contact point for authorities). Further, the importer has to be mentioned on the product packaging or "accompanying documents."

Clearly, an ex-U.S. devices company selling products directly to EU customers must avoid its customers (*e.g.*, hospitals, orthopedic technicians, medical aid providers) needing to take upon themselves the role and obligation of an "importer." Thus, the distribution and importation chains have to be organized in such a way that a company that is capable of fulfilling that role is introduced into the supply chain.

Once such an importing entity is set up, it must ensure it is able to meet all MDR or IVDR requirements; or, that by way of intercompany or third-party company agreements, the regulatory obligations accompanying the role of an "importer" are sufficiently addressed and fulfilled.

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EU efforts to address medicine shortages expand in 2025

In 2025, the EU continues to strengthen its regulatory framework to address the persistent challenge of medicine shortages. The European Medicines Agency (EMA) and the European Commission have introduced several measures to ensure the availability of essential medicines in all Member States. This article provides an overview of these upcoming changes, which are crucial for pharmaceutical companies operating in the EU.

Launch of the European Shortages Monitoring Platform (ESMP)

One of the most anticipated developments is the full launch of the European Shortages Monitoring Platform (ESMP) on 02 February 2025. This platform will serve as a centralized hub for data collection on medicine shortages, enhancing the EU's ability to prevent, detect, and manage shortages effectively. Marketing authorization holders will be required to report any shortages through the ESMP, ensuring a timely and accurate flow of information. This initiative aims to improve the coordination and response to shortages.

Updated union list of critical medicines

In December 2024, the EMA updated the Union List of Critical Medicines. The list, which includes over 300 medicines, identifies medicines that are essential for public health, and aims to support and accelerate the analysis of the supply chain of critical medicines to identify potential vulnerabilities. By focusing on these critical medicines, the EMA aims to mitigate the impact of potential shortages on patient care and public health.

Upcoming pharma law package

One of the main objectives of the European Commission's proposal to reform EU pharmaceutical legislation with a new directive and regulation (the "Pharma Law Package"), is to prevent shortages. Under the proposed legislation, marketing authorization applicants will be obliged to establish a shortage prevention plan, to anticipate any potential future shortages. The Pharma Law Package and the measures included in this package are still in the law-making process and are not expected to enter into force before the end of 2026.

Conclusion

The measures introduced by the EMA and the European Commission reflect a proactive approach to safeguarding the supply of medicines within the EU. The launch of the ESMP, the updated Union List of Critical Medicines, and the Pharma Law Package are aimed towards a more resilient and responsive health care system. Pharmaceutical companies should stay informed on these regulatory changes to ensure compliance, and to continue providing essential medicines to patients across the EU.

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AI and Digital Health.

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HHS expects AI product monitoring throughout its life cycle

In overseeing health care AI, the U.S. Health and Human Services Department (HHS) is increasingly signaling a focus on organizations' ongoing assessment throughout a product's entire life cycle. This was demonstrated through its recently released Strategic Plan and the frameworks and guidance released by several HHS agencies.

For example, the FDA's recent guidance outlined key regulatory expectations for the use of AI in regulatory decision-making regarding safety, effectiveness, or quality for drugs and biologics, including a risk-based framework to assess AI credibility. The FDA expects that companies develop a life cycle maintenance plan that's integrated into the manufacturing quality system and submitted with marketing applications. The HHS's actions emphasize specific compliance measures that regulators expect companies to implement for AI products used in health care:

- **Continuous monitoring:** Regular monitoring of AI systems allows for improved accuracy and consistency in system performance. AI systems should be monitored after deployment to detect emerging risks and performance issues, like performance drift. Ongoing monitoring should also focus on data quality and management throughout the AI system's life cycle to support long-term performance.
- **Validation of algorithms:** Taking steps to confirm the validity of algorithms is essential to protect patient safety. Systems should undergo rigorous validation processes to confirm that they are appropriately trained and correctly deployed in each specific context.
- **User feedback and reporting:** Establishing a clear process for collecting and responding to feedback is critical for optimizing system performance and building trust in AI systems. This includes transparency about where and how AI systems are being deployed, and what data and entities are involved in the training and deployment of AI systems.
- **Compliance with data privacy and cybersecurity:** Awareness of and adherence to appropriate privacy practices and security safeguards are necessary to comply with existing and evolving privacy and cybersecurity requirements. This includes the need to protect sensitive patient information, and confirm that companies and associated third parties involved in developing and deploying AI systems have the appropriate permissions to collect, use, and share this information.
- **Bias mitigation:** To create AI systems that are fair, accurate, ethical, and trustworthy, potential biases must be addressed. AI systems should be tested on diverse, representative datasets and in real-world scenarios to reduce risk of discrimination based on race, gender, socioeconomic status, or other factors, and to help ensure the system works equally well across different population groups.

As AI adoption in health care continues to rapidly increase and evolve, regulators are prioritizing transparency, equity, and privacy as core guiding principles for responsible AI use. A life cycle approach to AI risk management facilitates prompt identification and mitigation of potential AI risks, enabling trustworthy AI that safeguards patients and fosters continued support of innovative technologies.

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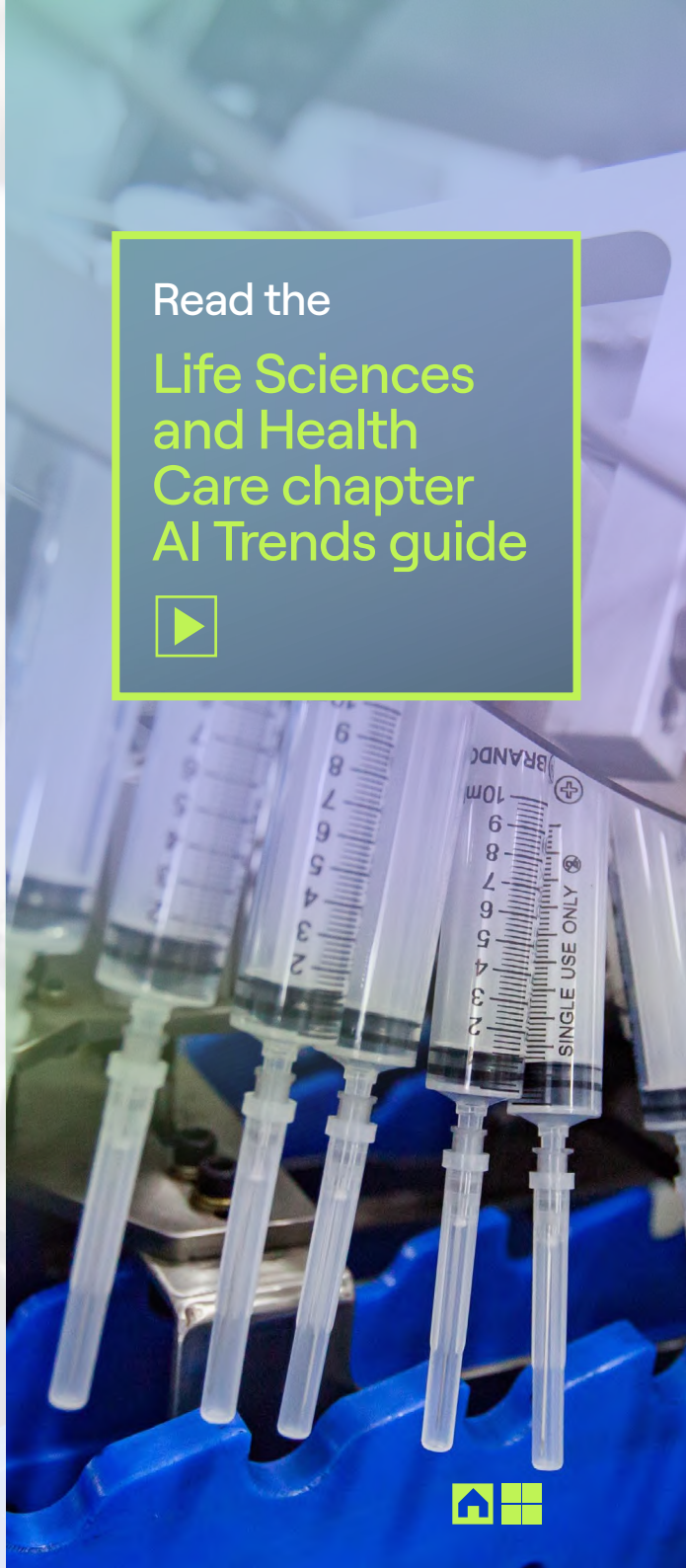

AI reimbursement framework evolves in the U.S.

As we look forward to what we might expect for reimbursement for AI health technology in 2025, it is helpful to first look backwards. The Medicare program, administered by the Centers for Medicare & Medicaid Services (CMS), often is the bellwether for reimbursement policy. However, the program will celebrate its 60th birthday in 2025, and it has changed little since it was first implemented. AI health technology certainly was not contemplated as a reimbursable service when the Social Security Act was first enacted.

This leaves CMS with the hard task of facilitating access to new AI health technology that revolutionizes patient care, while also staying within the statute for coverage and payment. With respect to coverage, AI that is used to screen for certain conditions in the absence of signs or symptoms of disease will continue to have particular challenges unless the statute is changed to provide greater screening coverage.

In terms of payment, to appropriately reimburse physicians for costs associated with AI health technology, modernization is needed for the current Physician Fee Schedule (PFS) methodology, which provides payment for work, practice expense, and malpractice. We continue to work with stakeholders to push for these and other changes.

For investors in and developers of AI technology, ensuring robust clinical evidence is essential both for Medicare and commercial payer coverage. Oftentimes, the minimum evidence required for marketing authorization from the U.S. Food and Drug Administration (FDA) is not sufficient for coverage.

Investors and developers also should focus early on whether AI technology is most appropriate as a separately reimbursed service, or as a technology that can reduce costs for providers or facilitate the provision of different reimbursable services. For technologies pursuing separate reimbursement, an early strategy is essential to identify whether there are existing reimbursement structures applicable to a technology, which can facilitate quicker coverage and payment (but perhaps at a lower payment rate), or whether there is a need or desire to pursue new coding, coverage, and payment, which can potentially lead to better coverage and higher payment, despite coming with its own challenges in terms of timing and uncertainty.

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Using AI for device postmarket surveillance to meet FDA and EU obligations

The regulatory landscape for postmarket surveillance (PMS) is evolving, with stringent requirements set by both the FDA and the EU to ensure the ongoing safety and performance of medical devices. As AI becomes more integrated into regulatory compliance and medical device monitoring, its potential to reduce the burden of monitoring adverse events, streamline reporting, and enhance patient safety will only grow. The combination of Natural Language Processing (NLP), anomaly detection, and predictive analytics allows for a more proactive, intelligent approach to medical device PMS, and will facilitate how medical device manufacturers manage their products and their regulatory obligations with better data and analytics.

AI-driven technologies are transforming PMS by automating adverse event detection, analyzing vast amounts of real-world data, and predicting potential device failures before they escalate into widespread issues. AI enhances regulatory compliance by streamlining data processing and improving accuracy in reporting, offering a pathway toward greater harmonization in global postmarket surveillance.

In the U.S., the primary data sources for monitoring device performance are complaints and real world evidence (RWE), which may well include sources such as electronic health records (EHRs), social media discussions, and patient-reported outcomes. Additionally, for a small number of medical devices, the FDA imposes an obligation to conduct PMS studies (21 CFR Part 822), which provides a more methodical look at a device's performance in larger populations than were studied in the pivotal clinical trial.

The EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) outline comprehensive postmarket surveillance (PMS) requirements to ensure ongoing safety and performance evaluation. These include Postmarket Clinical Follow-Up (PMCF) to continuously gather clinical data, and Periodic Safety Update Reports (PSUR) for regular risk-benefit assessments. Additionally, the EU's vigilance system mandates rigorous complaint handling and adverse event reporting, enabling proactive risk mitigation and enhancing patient safety. A systematic literature review and the use of RWE play a crucial role in PMS by providing valuable insights into long-term device performance, identifying emerging risks, and supporting regulatory compliance.

In both regions, manufacturers must actively monitor available data sources and assess any indications of potential safety concerns. When such concerns arise, they are required to analyze the data and determine whether corrective action is necessary. While both regions share a commitment to device safety, differences in reporting timelines, data collection methodologies, and compliance frameworks pose challenges for global manufacturers. Additionally, complaints and RWE data sources that serve as inputs to PMS are comprised of large data sets that are inherently messy. Historically, monitoring and analyses have been performed using largely human driven methods, such as control limit charting, pareto analysis, run charts, and other signal detection and trend analysis methods.

As the volume of PMS data grows, traditional monitoring methods struggle to keep pace with the sheer complexity and speed of medical device complaint reporting. AI and Machine learning (ML) are revolutionizing PMS by automating data analysis, detecting hidden patterns, and predicting potential failures before they escalate into serious patient safety concerns. AI-powered surveillance enhances regulatory compliance, reduces response times, and improves overall device reliability. Different AI-driven techniques are transforming complaint monitoring.

Using AI for device postmarket surveillance to meet FDA and EU obligations (continued)

Natural Language Processing (NLP).

PMS generates vast amounts of free-text data, including MDR reports, customer complaints, health care provider feedback, online patient forums, and social media discussions. Traditionally, analyzing this data required manual review, making it slow and prone to human bias. Natural Language Processing automates this process by extracting meaningful insights from unstructured text. For example, NLP is capable of taking unstructured information and creating order by mining text and performing sentiment analysis by scanning complaint logs, identifying recurring issues, emotional tone, and negative sentiment patterns in user feedback.

NLP is also capable of identifying key medical terms, device names, symptoms, and adverse event descriptions to classify complaint types. AI can also group similar complaints, helping manufacturers detect emerging safety signals early. Finally, without the limits of language, NLP allows companies to monitor complaints globally, translating and analyzing reports from different languages and geographies in real time.

Anomaly detection models.

Anomaly detection models are capable of identifying unusual patterns or unexpected trends in complaint data that may indicate underlying safety concerns. These models learn from historical complaint data and identify outliers that deviate from expected behavior, enabling early intervention. For example, unsupervised learning models detect rare or unusual complaint patterns without predefined rules, uncovering emerging risks. ML algorithms can be set to continuously analyze incoming complaint data, triggering alerts when deviations occur. Finally, AI can be tasked with examining relationships between reported failures to identifying systemic issues across multiple devices or manufacturers.

Predictive analytics.

By its nature, traditional complaint monitoring is reactive and must be coupled with the company's obligation for risk management, which is designed to be predictive of possible failure. With AI's power of predictive analytics, manufacturers may be able to better forecast potential failures, allowing manufacturers to take earlier and more effective preventive action. Using time-series forecasting, AI can analyze historical complaint trends to predict when and where future failures might occur. Risk scoring models could be used to assigns risk scores to devices, prioritizing those most likely to experience defects or adverse events. Failure mode prediction models could also be used to supplement existing risk management tools to correlate real-world usage data (e.g., device sensor readings, hospital reports) with past complaints to anticipate malfunction risks.

As AI becomes more integrated into regulatory compliance and medical device monitoring, its potential to reduce the burdens of monitoring adverse events, streamline reporting, and enhance patient safety will only grow. After validation as part of the quality management system, the combination of NLP, anomaly detection, and predictive analytics allows for a more proactive, intelligent approach to medical device PMS.

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Increasing regulatory oversight of AI now includes mitigation plan expectations

Many pharmaceutical and medical device companies are now using chatbots that utilize AI to respond to human language, or other general-purpose AI tools for their in-house work. When a life science company uses general-purpose AI, such use is often related to supporting employees in the life cycle of a pharmaceutical or device product, i.e., used in supporting research and development, clinical trials, application procedures, postmarket surveillance, promotion, or reimbursement.

Where companies use *company-adapted*, general-purpose AI (e.g., their own in-house adapted chatbot), they must ensure compliance with nation-specific AI legislation. Compliance requires determining whether the in-house adaptation of general-purpose AI means that company is now deemed a "provider" of that AI, rather than merely being a "deployer" of the AI tool. There are significantly greater legal obligations imposed on AI "providers"; for example, providers need to map the different AI use cases to ensure that such use happens in a compliant and informed manner.

Where AI is used in a life science product, such as a medical device, that use needs to comply with sector-specific regulatory requirements, e.g., the performance and safety requirements pursuant to the European MDR, or FDA requirements. However, beyond that, the use of AI in the life cycle of the regulated pharmaceutical or device product (where that product does not incorporate AI itself) further requires care from the regulatory side. Some global regulators have asserted that any use of AI in the research development and approval process of pharmaceutical and device products also needs to undergo a risk assessment process.

The European Medicines Agency has released a reflection paper on the use of AI in medicinal product development and regulation, emphasizing the need for greater transparency, accountability, and ethical considerations in AI applications. It identifies two primary risks that companies using AI should address:

- **Regulatory risk** which is the potential effect on the quality of data submitted within a dossier or authority decision-making.
- **Patient risk** which is whether AI use in preparing a clinical trial design may pose risks on patients, or when AI is used for adverse event or incident tracking or reporting.

Once these AI risks are identified, regulators expect that they are appropriately addressed in a "risk mitigation plan."

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Increasing regulatory oversight of AI chatbots used by HCPs and patients

The use of AI-facilitated chatbots by health care professionals (HCPs) – and by patients in relation to pharmaceutical and biological products – is accelerating quickly. Chatbots may provide recommendations as to when a product can be prescribed, or regarding the reimbursement and coding landscape for a product. For patients, chatbots offering instructions on the proper use of a drug and answering related questions are becoming increasingly common as well.

In the EU under the AI Act, AI-facilitated chatbots for HCPs or patients may be classified as "high risk" if they are a “medical device,” or part of a medical device. Thus, sponsors of these products must consider whether the chatbot has a *specific medical* use and meets the definition of a “medical device.” If so, and the product is found to be “high risk,” then those AI systems must comply with strict legal requirements, including risk management, data governance, and conformity assessment procedure.

However, even where a chatbot that deploys AI will not be deemed a “medical device,” certain minimum requirements of the AI Act must be met. These AI-related requirements include conscious use based on AI literacy, transparency requirements, and privacy considerations, among others.

Beyond the legal requirements stemming from AI legislation, there are regulatory considerations and requirements as well. Where the chatbot is used adjacent to product use by HCPs and patients, e.g., in a clinical trial or in real world use, this may have an impact on patient safety, and could also have an impact on compliance with regulatory obligations. For example, in a clinical trial that aims to ensure data submitted in a dossier is accurate, a chatbot must ensure proper use of the product in accordance with the label.

The European Medicines Agency (EMA) has released a reflection paper on the use of AI in medicinal product/drug development: Hereunder, deployers of AI have to perform a risk assessment considering and addressing both patient risk as well as regulatory risk. This has to be done in the structure and documented process, ideally based on underlying company SOPs.

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Digital Health and AI

LATAM patchwork of AI regulations raise compliance and liability risks

Despite fascinating innovations, implementing AI in health care presents critical challenges for AI developers and health care providers, including the increasing prevalence of cybersecurity attacks. In addition, regional AI regulatory frameworks in Latin America often lack common legal standards, leading to different criteria and enforcement by regulators in several countries that require complex analyses before a company can safely launch an AI tool while simultaneously ensuring legal compliance.

In Mexico, for example, there is currently no regulatory framework for AI aside from data protection and general guidelines. Nonetheless, existing regulations for Software as a Medical Device could serve as a foundation for future policies. Meanwhile, countries such as Brazil are already taking steps to implement regulations that include technical and ethical standards for AI´s development in health care, setting an important precedent for the LATAM region, which we are already seeing Mexico, Colombia, and Chile beginning to follow.

In other national developments, countries including Mexico, Brazil, Colombia, and Argentina have enacted regulatory frameworks for "sensitive" data. In addition, novel cybersecurity regulations are emerging in countries like Chile and Colombia, in the aftermath of high-profile cyber-attacks. Sponsors of health care AI products must therefore make country-by-country decisions on how to ensure compliance with national standards, and carefully explore technical solutions when applying for approvals in the LATAM region, as needed.

For medical devices, functionalities of many AI-powered health apps can fall under the concept of "medical consultation" or "health service," which have different interpretations in each LATAM country. This results in additional aspects that are worth considering, including scope of liability of developers and health professionals, compliance with requirements for the rendering of such type of health services, and even requiring the registration of these apps before the competent national health authorities. Forward-looking AI solutions require the expertise of legal experts who understand the regulatory frameworks for health care, as well as the technical aspects of AI, cybersecurity, and privacy, to ensure responsible AI use in the Latin American region.

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Fostering innovation through emerging regulatory trends in Mexico

The digital revolution has spurred remarkable innovation in health care, with software applications, platforms, and programs transforming how diseases are diagnosed, monitored, and treated. As the health care technology sector experiences unprecedented transformation, Mexico is positioning itself at the forefront of a regulatory revolution that promises to reshape medical device development and deployment. The regulatory landscape is evolving to meet the demands of this new era, emphasizing innovation while safeguarding patient safety. This balance is crucial as the country aims to become a leader in the development and adoption of digital health solutions, mainly within the medical device and R&D sector.

One of the most significant regulatory advances in recent years was the 2021 update to NOM-241-SSA1-2012, which governs Good Manufacturing Practices for Medical Devices. This revision formally introduced the concept of software as a medical device (SaMD), setting a precedent for how digital tools designed for diagnostics, therapy, or monitoring should be regulated.

The publication of Supplement 5.0 of the United Mexican States Pharmacopoeia for Medical Devices in May 2023 further underscores Mexico's commitment to innovation. This supplement introduced a detailed framework for classifying and regulating medical software based on risk levels, providing clear guidance for developers. By incorporating standards for design, manufacturing, and quality control, Mexico has created a foundation for fostering innovative solutions while maintaining high safety standards. It ensures compliance but also encourages innovation by seeking to reduce uncertainty for technology developers and investors.

In addition to these regulatory milestones, regulators in Mexico are actively exploring mechanisms to evaluate advanced technology, focusing on algorithm performance, bias mitigation, and mechanisms for protecting patient data while enabling technological advancement and integration with existing health care systems. By addressing these factors, Mexico aims to build a robust ecosystem where cutting-edge technologies can thrive.

Moreover, the Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) is embracing digital transformation within its own processes, implementing e platforms for accelerated approval mechanisms, streamlined documentation processes, and real time monitoring. These tools streamline regulatory procedures, enabling innovators to launch their products more efficiently while ensuring continuous oversight through a collaborative innovation platform.

Mexico is not just adapting to the digital health revolution: it's actively shaping it. For forward-thinking medical device manufacturers, researchers, and innovators, this represents an opportunity to redefine health care delivery. Collaboration among industry stakeholders and policymakers will be essential to overcome these barriers and fully realize the potential of digital health innovation in Mexico.

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Drug Enforcement Administration proposes new framework for telemedicine prescribing

In the waning days of the Biden Administration, the Drug Enforcement Administration (DEA) released long-awaited final and proposed rules permitting DEA-registered practitioners to prescribe Schedule II-V controlled substances via telemedicine under certain circumstances.

During the COVID-19 public health emergency, DEA had allowed practitioners to prescribe controlled substances via telemedicine without first conducting an in-person medical evaluation. Since then, DEA has made unsuccessful attempts to develop a permanent framework for telehealth prescribing. In March 2023, DEA proposed a stringent rule on telemedicine prescribing that was poorly received by stakeholders. DEA eventually withdrew the proposed rule and extended the COVID-era flexibilities in May and again in October 2023.

Then, in June 2024, DEA submitted a new proposed rule to OMB that was never published, but widely thought to be as restrictive as the March 2023 proposal. In November 2024, DEA extended the flexibilities for a third time through 31 December 2025.

The final and proposed rules represent DEA's latest attempt to develop a framework that balances the legitimate need for telemedicine services with diversion concerns. The recently published final rule focuses solely on buprenorphine, allowing practitioners to prescribe an initial six-month supply of buprenorphine for opioid use disorder treatment via telemedicine without first conducting an in-person evaluation.

The new proposed rule would establish three Special Registration pathways for practitioners to prescribe certain controlled substances via telemedicine without first conducting an in-person evaluation:

- Telemedicine Prescribing Registration, applicable to qualified practitioners prescribing Schedule III-V controlled substances;
- Advanced Telemedicine Prescribing Registration, applicable to qualified specialized physicians and board-certified mid-level practitioners (e.g., psychiatrists, hospice care physicians) prescribing Schedule II-V controlled substances; and
- the Telemedicine Platform Registration, which authorizes covered telemedicine platforms to dispense Schedule II-V controlled substances.

DEA would also require the special registrant to maintain a state telemedicine registration for every state where the special registrant treats patients. DEA is accepting comments on the rule until March 18.

Given the public and stakeholder interest DEA received each time it has attempted to develop a telemedicine rule, we anticipate the proposed rule will trigger a significant number of comments, and is unlikely to be finalized as-is. If the proposed rule is not finalized before 31 December 2025, DEA may need to extend its COVID-era flexibilities again as it reworks the telemedicine framework.

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Software as a medical device (SaMD) regulation: Navigating an evolving landscape

Software as a Medical Device (SaMD) is emerging as one of the fastest-growing sectors in the medical device industry. Referring to standalone software that performs medical functions without being part of a physical device, SaMD can range from AI-driven diagnostic tools and clinical decision support systems to mobile health apps and wearable-integrated software. However, the very nature of SaMD – its ability to rapidly evolve through software updates, machine learning (ML)-based algorithms, and cloud-based functionalities – are not easy to fit within FDA's traditional medical device regulatory framework.

FDA's Center for Devices and Radiological Health oversees the regulation of SaMD. The agency applies a risk-based approach that aligns with international standards, particularly those set by the International Medical Device Regulators Forum, which takes into account the severity of the condition the software addresses and its level of involvement in clinical decision-making.

In the past year, FDA has developed more granular guidance clarifying the requirements for training and clinical validation of AI-based algorithms to mitigate bias and ensure adequate explainability, so that users can evaluate whether the software is appropriate for their patient populations and clinical contexts of use. FDA has also been focusing increasingly on the need to demonstrate not only that a device "works," but that its outputs are clinically meaningful and can improve patient outcomes.

Unlike traditional medical devices, software can undergo frequent updates and AI-driven modifications that significantly alter performance postmarket. FDA has recently focused on how to ensure that software with an AI/ML component continues to function as intended post-commercialization, through appropriate real-world performance monitoring and communication with users. The agency has also issued updated guidance on predetermined change control plans (PCCPs), defining how sponsors can obtain "pre-approval" of narrowly defined modifications they expect to make to their software-based devices after obtaining FDA authorization. Highlighting how regulation lags behind innovation, the agency has yet to authorize a fully adaptive (i.e., continuously learning) AI model.

Real-world performance data is particularly critical for AI-driven SaMD, where algorithms may drift over time as they encounter new patient populations and evolving clinical data. This was a key topic of discussion in the recent inaugural meeting of FDA's Digital Health Advisory Committee in November. Related topics of significant focus are cybersecurity and data privacy compliance, given that SaMD often relies on cloud-based storage and interacts with electronic health records (EHRs) and other medical devices to import and transmit patient data. Under FDA's recently updated guidance, sponsors must submit detailed cybersecurity risk management plans with their premarket applications.

By engaging in early interactions with regulators and embracing robust design controls, comprehensive clinical validation, and postmarket performance monitoring, developers can navigate the evolving regulatory landscape. In the coming years, we expect:

- Continued effort to standardize the regulatory approach with that of other key regulators, enhancing harmonization in multiple global markets.
- Additional attention to developing methods for appropriate pre- and postmarket review of generative AI-based devices, as industry presses to be able to commercialize continually learning models.
- Greater emphasis on cybersecurity and patient data protection, particularly as SaMD integrates with broader health care IT ecosystems.

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Privacy and Cybersecurity

3

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Cybersecurity paramount in cross-border clinical trials

While some countries´ regulations (including those in Mexico) recognize the importance of international collaboration, there is still a need to make progress in regulating key aspects of cross-border partnerships, such as the international transfer of personal health data. We also see the need to establish heightened cybersecurity measures to protect information in digital environments as increasingly paramount in 2025.

Data breaches are not the only vulnerabilities for which cross-border clinical trial organizations should be vigilant; the rise in cybercrime, particularly ransomware attacks, have become a significant threat. Indeed, cybercriminals may attack clinical trials through other means besides ransomware, including phishing attacks or through supply chain tampering. Although cyberattacks are never 100% preventable, cross-border clinical trial sponsors must be sure to:

- implement a cybersecurity program,
- maintain physical, technical and administrative cybersecurity measures, and
- train all the involved parties on the ever-evolving subject of cyberthreats.

Cybersecurity is not only important to prevent risks and attacks in clinical trials, but also to ensure the integrity of trial results, and to maintain the accuracy and reliability of data through security mechanisms including encryption, multi-factor authentication, and intrusion detection.

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AI and cybersecurity in life sciences: A path to resilience

Despite AI's transformative potential, it presents significant cybersecurity challenges. AI systems can be exploited through hacking or manipulated with erroneous, misleading, or intentionally harmful data. Additionally, vulnerabilities within the supply chain may be exploited to compromise or alter AI-driven processes. The consequences of cyber incidents can have a significant impact: not only can they compromise data and systems, but they can also undermine the integrity of research findings and treatment outcomes, erode public trust, and impede the progress of life-saving innovations.

As part of its digital strategy, the European Union prioritizes cyber resilience and AI regulation. Key legislative frameworks such as the Network and Information Systems Directive 2 (NIS2), the EU AI Act, and the EU Cyber Resilience Act play a vital role in shaping regulatory requirements. From a cybersecurity standpoint, these regulations emphasize the necessity for companies to implement proportionate and effective technical, operational, and organizational measures to safeguard networks and systems against cyber threats.

Enhancing AI and cybersecurity governance

To harness AI's benefits securely and in compliance with evolving regulations, organizations must proactively strengthen their AI and cybersecurity governance frameworks. Key considerations include:

- Conducting periodic cybersecurity risk assessments and AI impact assessments to identify and mitigate risks and vulnerabilities.
- Implementing and monitoring robust technical and organizational measures and controls to ensure AI system security, accuracy, and reliability.
- Developing or updating existing cybersecurity policies in relation to cybersecurity governance, risk-management measures, and incident reporting obligations.
- Forming a dedicated AI governance team with expertise in cybersecurity to oversee and adapt security strategies.
- Conducting regular cyber awareness training sessions, and regular tabletop exercises with the involvement of the board and C-suite executives.

The convergence of AI and life sciences presents remarkable opportunities, but it also necessitates a vigilant approach to cybersecurity. By implementing comprehensive security measures and fostering an adaptable approach to AI and cybersecurity governance, organizations can navigate AI's evolving landscape with confidence.

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EU Data Act: Connected devices and data sharing obligations

The EU Data Act ("Regulation (EU) 2023/2854") introduces new changes for manufacturers of connected medical devices and wearable health products that collect or produce data from the user or their environment. The Act aims to put users of connected products in control of their data and allows them to access and share data generated by these products. This includes data entered by users and data created or collected by the device, whether in active use or in standby mode. However, the EU Data Act will not require companies to share data that has been processed or analyzed to create new information, such as health conclusions generated by software.

Manufacturers will be required to design connected products and services in a way that ensures data generated by their use is easily accessible to users. Upon the user's request, manufacturers will have to provide this data to the user or to a third party chosen by the user. Third parties will only be able to use the data for purposes and under conditions agreed upon with the user. Users and third parties may not use the data to develop products that compete with the original product or to derive insights about the economic situation, assets, and production methods of the manufacturer.

To navigate these changes effectively, manufacturers must take a proactive and strategic approach. As a first step, we advise to:

- **Perform an impact assessment and gap analysis** to assess the impact on the manufacturer's business, products, policies and procedures.
- **Develop or expand existing data governance framework** to ensure compliance and optimized data use.
- **Update existing design and development strategies** to ensure that connected products are designed in such a way that product data and related data are by design directly accessible to users.
- **Develop or expand existing trade secret protection strategies and data use and sharing strategies** to ensure appropriate technical and contractual safeguards are in place to protect trade secrets and confidential business information and to safely share data with users and third parties.

The EU Data Act entered into force on 11 January 2024, with most provisions becoming applicable from 12 September 2025. Manufacturers placing connected medical devices and health wearables on the EU market are advised to assess their obligations under the EU Data Act and take steps to work towards compliance.

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EU Data Act: FRAND requirements for B2B data sharing

The EU Data Act requires that manufacturers that hold data collected and generated by their connected products ("data holders") allow users to access these data, and share them with third parties selected by the user. To encourage and promote fair data sharing practices between companies, data sharing must be based on fair, reasonable, and non-discriminatory terms (FRAND).

Companies are free to negotiate the data-sharing terms. Terms more commercially favorable to one party are allowed. Different terms for comparable data recipients are allowed if this is based on objective, non-discriminatory considerations. The data holder must demonstrate that the terms are fair, reasonable, and non-discriminatory. The European Commission will develop – and likely adapt before September 2025 – non-binding contractual clauses that may be helpful for creating and negotiating data-sharing terms.

The use of data-sharing terms must not be contrary to good faith and fair dealing, and must not grossly deviate from good commercial practice in data access and use. The EU Data Act provides a non-exhaustive list of **always unfair terms** and **presumed unfair terms**. Data holders must demonstrate that the presumed unfair terms are not unfair in the specific case. The FRAND test applies:

- only to **terms relating to data use and data sharing**, such as access to and use of data, liability, remedies for breach of contract, and termination of data-related obligations; and,
- when these terms are **unilaterally imposed without the influence of the other party**, such as take-it-or-leave-it situations or situations where a stronger bargaining power has been abused and resulted in excessive terms. Terms negotiated, influenced, and agreed upon by parties are not subject to the FRAND test.

Unfair and unilaterally imposed terms will not be binding. If a term is deemed unfair, the contract remains valid without it, unless the term is inseparable from the contract.

To navigate these challenges effectively, data holders must take a proactive and strategic approach. As a first step for preparing for data sharing requests, we advise data holders to:

- assess and implement technical and organizational measures to be able to fulfil data transfer requests;
- assess existing measures and implement additional measures to protect IP rights, trade secrets and confidential business information and safely share data with users and third parties; and,
- prepare contractual terms for third-party data recipients to protect business interests, trade secrets and IP rights.

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Ongoing risks remain for online tracking technology use in the U.S.

Health and life sciences organizations are navigating heightened regulatory and litigation risks stemming from their use of third-party online tracking technologies. This focus continues years after use of trackers first attracted widespread attention from media, regulators, and litigants.

HIPAA-regulated organizations especially must be cautious after HHS indicated in guidance that use of trackers may result in violations of HIPAA. Although a federal court curtailed a portion of that guidance, HHS continues to investigate use of trackers by HIPAA-regulated entities on their online properties. Whether and how HHS will adjust enforcement priorities in light of the court decision and administration change remains to be seen, but the issue will likely continue for years to come.

Meanwhile, organizations also face scrutiny from the U.S. Federal Trade Commission (FTC) and state attorneys general (AGs). The FTC has enforced against organizations that deploy trackers in ways that conflict with their stated privacy promises or that fail to obtain affirmative consent prior to processing health data. State AGs have similar enforcement authority under state statutes and privacy laws and will likely have a prominent role in enforcement during the Trump administration.

Litigation risks remain as plaintiffs test novel claims. Courts have allowed state wiretap claims to proceed past a motion to dismiss, and plaintiffs have increasingly tested the viability of claims alleging that trackers have been used inconsistent with user preferences.

Health organizations can effectively manage these risks by developing, implementing, and maintaining a governance program. We have helped numerous organizations implement and defend such programs.

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Future of Energy & ESG.

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Navigating the energy transition: Challenges and opportunities in life sciences

The life sciences sector faces significant hurdles in reducing Scope 3 emissions, which constitute the majority of the industry's carbon footprint and are largely outside direct control. Key strategies to address these challenges include broadening decarbonization efforts to encompass the entire supply chain (not just tier-one suppliers) and ensure comprehensive emission reductions. Strengthening internal capabilities in R&D and procurement is essential to foster innovation and sustainability. Implementing sustainable product design principles can lower carbon emissions and operational costs.

Effective collaboration is crucial for the energy transition. Partnering with suppliers to source low-carbon materials and investing in sustainable R&D are essential steps. Additionally, adopting circular business models that emphasize recycling and refurbishment can significantly cut waste-related emissions.

Strategic tools including acquiring companies with advanced sustainability practices or innovative technologies can accelerate the energy transition. Forming joint ventures with other companies can pool resources and expertise, facilitating the development and implementation of sustainable solutions. Entering into power purchase agreements (PPAs) allows companies to secure renewable energy at competitive rates, ensuring a stable and sustainable energy supply.

The recent political shift in the U.S., with the new administration's stance on Environmental, Social, and Governance (ESG) policies, is expected to influence the regulatory environment. The potential rollback of Biden-era ESG regulations may reduce federal pressure on companies to demonstrate climate action. However, stringent state-level regulations and international rules, particularly from the European Union, will continue to demand robust climate disclosures. This evolving landscape requires a strategic approach to sustainability, balancing compliance with long-term business objectives.

The journey through the energy transition is complex but essential for the life sciences sector. Proactively addressing decarbonization can enhance operational efficiency, secure supply chains, and contribute positively to global climate goals. This strategic approach is crucial for ensuring a sustainable future for the industry.

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EU CS3D brings rising ESG compliance and litigation challenges

The EU Corporate Sustainability Due Diligence Directive (CS3D) was formally adopted in 2024, adding to the risk of ESG-related compliance and litigation issues, as companies are increasingly held responsible for human rights and environmental risks and violations in their deeper global supply chains.

Starting in July 2027[2], the CS3D will gradually apply, initially to EU companies (including ultimate parent companies) with an average of 5,000 employees and a net worldwide turnover exceeding EUR 1.5 billion. By July 2029, it will extend to EU companies with an average of 1,000 employees and a net worldwide turnover of more than EUR 450 million. The CS3D will also apply to non-EU companies (including ultimate parent companies) with equivalent turnover in the EU and to certain franchising and license agreements.

The CS3D requires companies to systematically assess and monitor ESG risks across their entire chain of activities, including their own operations and subsidiaries, as well as upstream and limited downstream business partners. It requires companies to integrate human rights and environmental due diligence into all their relevant policies and risk management systems.

This broad scope requires extensive information gathering, annual disclosures, plans to address identified risks for and actual violations of human rights or certain environmental positions, and the implementation of a grievance mechanism. Companies must also continuously assess and adjust compliance measures at multiple business levels. Moreover, companies must put a climate transition plan into effect. This creates a vital overlap to the sustainability reporting under the Corporate Sustainability Reporting Directive (CSRD).

Non-compliance with the CS3D may result in maximum fines of not less than 5% of the company's net worldwide turnover, as well as civil liability for victims of human rights violations in the supply chain, exposing companies to potential litigation from affected individuals or groups.

For pharmaceutical & biotechnology companies, CS3D is but one of many significant challenges in ensuring safety and sustainability in the manufacturing supply chain. This evolving landscape, shaped by continuous ESG legislative developments and related political discussions, is leading to rising supply chain compliance and litigation risks for companies in the life sciences & health care sector, which are typically accustomed to navigating a highly regulated environment. Implementing strong compliance and due diligence measures, designed with a holistic approach and responsive to evolving ESG legal frameworks, helps to reduce compliance, litigation, business, and reputational risks.

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[2] The CSDDD is, like the CSRD and other pieces of EU legislation, subject to the so-called Omnibus proposal aiming at simplification of ESG obligations. Amongst others, the Omnibus proposal suggests to postpone the application date to July 2028 for the first set of companies. At the editorial deadline, it was not possible to foresee whether and in what form the omnibus proposals would be adopted.

Sustainability and digital transformation to reshape global supply chains

Over the next five years, we expect to see increased digitalization of supply chain processes, particularly in relation to supply chains supporting biologics (such as mRNA vaccines) and complex, novel products, like cell and gene therapies, where end-to-end visibility and collaboration across stakeholders is required for successful product delivery to patients. Digital transformation has been reported as a top industry priority in recent research[3] : approximately 60% of participants across the U.S., Europe (including the UK), and Asia reported increased Gen AI investment in their executive plans. Further, a significant proportion reported in their plans the scaling of digital twin capabilities, which create a virtual representation of a physical asset or process at a point of time.

The shift in focus to digital twins is particularly interesting, as this technology could improve processes and increase supply chain resilience. For example, it could model disruption scenarios and identify supply chain vulnerabilities. This would complement the industry's current digital supply chain-tools: dashboards with real-time visibility into suppliers operational performance, command centers and sensor-enabled track and trace for end-to-end material and product visibility.

With these developments, we will see greater collaboration between pharmaceutical and biotech companies, and tech stakeholders developing and/or licensing these tools. We also anticipate increased complexity in upstream and downstream supply chain arrangements to support rolling out these measures, including in relation to data collection, assurance and ownership, licensing, and possible handling & implementation fees.

Numerous key markets require biopharmaceutical firms to commit to certain sustainability requirements with the aim of reducing the environmental impact of the pharmaceutical product life cycle specifically and new regulations are planned. For example, the EU Pharma Package of reforms proposes a broader environmental risk assessment (ERA), which would have a reinforced role before granting marketing authorization, alongside other concrete measures that would apply post-marketing authorization. If an applicant fails to submit a complete or sufficiently substantiated ERA, or to propose risk mitigation measures to address risks identified in the ERA, it may be refused a marketing authorization.

The UK National Health Service, the top purchaser of medicines in England, requires all suppliers to evidence net zero progress and commitments by 2030. Companies will be required to address emissions at three levels:

- **Scope 1:** self-generated emissions through manufacturing and transporting its goods;
- **Scope 2:** emissions produced by energy consumption; and
- **Scope 3:** the emissions of suppliers.

Scope 3 emissions are responsible for approximately 90% of the industry's carbon footprint, with the production of APIs, process chemicals and excipients, and single-use packaging being the key contributors.

With increased concerns about the demand for clean methanol outstripping supply by 2035, and increased regulation of single-use packaging, we expect upstream API suppliers and downstream packaging suppliers to be key focus areas. It is not immediately clear how companies will adjust their supply chains to address these concerns. However, these challenges create the opportunity for innovative collaborations with suppliers, including investment in the development of new manufacturing & packaging processes in return for long-term, secure supply agreements for cleaner materials.

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[3] Research conducted in 2024 by The Deloitte US Center for Health Solutions with respect to 150 C-suite executives from pharmaceutical, biotechnology, biosimilar, and medical device manufacturing companies.

Radioactive material licensing compliance concerns

Nuclear and radioactive materials play a critical role in modern medicine for many types of diagnostics and treatments. As demand for precision medicine grows, so does the need for health care companies to integrate nuclear capabilities. We are seeing it happen; companies in this space are actively developing medical isotope manufacturing capabilities, leveraging nuclear and radioactive materials infrastructure, and addressing shortages of isotopes essential for diagnostics, therapies, and medical innovation.

Although nuclear regulatory approval concerns often come to light during M&A activity, companies in the radiopharmaceutical space should also assess their compliance when bringing new drug treatments to market. For example, current nuclear reactor companies and universities with research reactors should think strategically about the production and sale of medical isotopes and emerging nuclear medicine technologies in order to ensure compliance with nuclear and pharmaceutical regulatory requirements.

Whether it's evaluating production capabilities or identifying market opportunities, aligning technical innovation with regulatory and commercial strategies is critical to navigate the evolving landscape of nuclear medicine, while maintaining the highest standards of safety and compliance. We are also seeing companies in the radiopharmaceutical space around the world facing novel issues involving nuclear regulatory distribution compliance, contracting concerns, and international distribution and supply chains issues, noncompliance for which often comes with the risk of sanctions.

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EmpCo directive restricts environmental claims in the EU

The Directive for Empowering the Consumers for the Green Transition Directive ("EmpCo Directive") entered into force in the EU on 26 March 2024; however, Member States have until 27 March, 2026 to implement its provisions into their national laws, and the amended provisions must then be applied by the EU Member States by 27 September 2026. It introduced a number of restrictions on green claims in the EU.

Under the EmpCo Directive, companies are not allowed to make generic environmental claims without providing a specification on the same medium (e.g., on the product or in the same TV advertising spot) or demonstrating the "recognized excellent" environmental performance of a product. Absent further specification, claims about a product being "climate-friendly," "CO2-neutral," "energy-efficient," "green," "biodegradable," "eco," or "environmentally friendly" will not be allowed, unless they refer to "recognized excellent" environmental performance, such as the EU Ecolabel. Under the new rules, it will also be prohibited to use climate claims such as "climate neutral" or "carbon neutral" if such claims are based on the compensation of CO2 emissions.

The EmpCo Directive will also require companies to clarify whether a positive impact exists for the entire product or business, or merely for parts thereof. Environmental claims about an entire product or entire business must not be made if they can only be substantiated for a certain aspect of the product or a specific business segment.

In addition, private sustainability labels promoting environmental and/or social benefits will not be allowed unless they are based on a third-party certification system or established by a government agency. This will effectively result in a prohibition of sustainability labels independently developed by private companies.

If a company advertises "green goals" for the future, the EmpCo Directive requires to clarify the steps it will take to achieve those goals to be "clear, objective, publicly accessible, and verifiable." The Directive also requires a "realistic implementation plan." Further, compliance with the plan must be regularly reviewed by an independent expert.

Last, it should be noted that the EmpCo explicitly prohibits the presentation of requirements imposed by law on all products within the relevant product category as a "distinctive feature." The Directive aims to prevent companies from misleading consumers into thinking that the company went beyond taking the minimum steps required by law.

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EU planning for green claims directive

The Green Claims Directive is still in the active planning phase in the EU. It will provide lex specialis regulations in addition to the EmpCo Directive. Due to its strict requirements, trade associations and other organizations are still attempting to change the envisaged rules. The Directive is planned to be adopted in the course of 2025.

According to the proposed Directive, Green Claims and Green Labels will require substantiation and third-party verification. In addition, extensive transparency and consumer information requirements apply.

Explicit environmental claims shall only be allowed after ex-ante verification by an accredited third-party conformity assessment body. This means, in future, any "green claim" must be approved before it can be used. The required substantiation and evidence of environmental claims shall be re-assessed and updated at least every five years.

In addition, for environmental labels, there shall be a separate ex-ante verification by an accredited third-party conformity assessment body for the environmental labelling schemes underlying the label. New labels will only be accepted if they provide for an additional benefit compared to existing labels. Environmental labels developed by companies for their products or environmental plans will not be allowed unless they undergo the required verification procedure.

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Navigating evolving U.S. national security laws: Implications for biologics companies

With the growing emphasis on reducing U.S. reliance on and threats from foreign adversaries, pharmaceutical companies must navigate evolving laws and policies designed to protect national security by prescribing the role of certain foreign companies in the U.S. biotech industry and by safeguarding the data of U.S. persons from weaponization by countries of concern. This is particularly important in sectors like biotechnology and genomics, where sensitive personal data are at risk. As the U.S. government seeks to impose new statutory, regulatory, and policy mandates aimed at these objectives, such as the proposed BIOSECURE Act and the Department of Justice (DOJ) final rule on data transfers, pharmaceutical companies must ensure compliance with increasingly strict laws and regulations.

Although the BIOSECURE Act did not pass in 2024, it remains a strong possibility for future legislation. The Act would have prohibited U.S. government contracts, loans, grants, and subcontracts involving the "knowing use" of services from companies of concern. By targeting companies perceived to be advancing interests of foreign adversary regimes, BIOSECURE aimed to reduce the risk of compromising national security through foreign influence or data misuse of U.S. citizens' data.

Also this past year, the DOJ finalized its rule to restrict transactions involving sensitive U.S. personal and genomic data, including biospecimens from which genomic data can be derived. The rule also establishes bulk data thresholds, including transactions involving bulk human genomic, epigenomic, proteomic, or transcriptomic data. While the rule includes certain exemptions, involving regulated clinical trials, biospecimens intended to be manufacturing into finished medical products, and requirements associated with obtaining and maintaining regulatory approval, these exemptions may not cover all necessary data transfers or vendor agreements.

Pharmaceutical companies should proactively assess vendor agreements, supply chain dependencies, and data management practices to mitigate the risk of disruption from such national security laws and mandates. It is essential to review the destinations of products containing human genomic data and ensure the data are pseudonymized or de-identified as required. Companies should also implement ongoing policies, controls, and audits while strengthening due diligence processes to manage risks from these new regulatory frameworks. Changes in contract manufacturing and research organizations may require supplemental regulatory submissions to FDA. Adapting to emerging U.S. national security laws will be critical for mitigating legal and regulatory risks, maintaining supply chain stability, and ensuring compliance with evolving requirements.

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Manufacturers beware: Trump "America First Trade Policy" could change the "Buy American" landscape in 2025 for drug, biologic, and medical device contracts

Just after taking the oath of office as president, President Trump signed an Executive Order titled "America First Trade Policy." Viewing the EO in conjunction with actions taken to increase domestic procurement of "essential medicines" during the final year of the first Trump administration, it is reasonable to expect that "Buy American" preferences for domestic supplies may soon be expanded on acquisitions of pharmaceuticals, biologics, and medical devices for U.S. Federal health programs.

The Executive Order primarily required that a review of existing trade agreements impacting U.S. procurement be undertaken, making the specifics and timing of any changes uncertain. Manufacturers should keep a close eye on this issue over the coming year, both to express any concerns to policymakers before decisions are finalized, and to ensure they are positioned to comply with – and maximize any potential benefit from – the new requirements.

Domestic preferences – requirements to favor U.S.-made product – have been a fact of life in U.S. government contracting since the "Buy American Act of 1933." This depression-era effort to protect U.S. industry required application of a percentage premium to the price of "foreign" offers during price evaluation to help steer awards to U.S. industry. Over the years, Federal "Buy American" requirements have expanded under both Republican and Democratic administrations alike, with domestic manufacture and content requirements being extended beyond the Federal procurement context to apply to Federally sponsored state government projects.

However, under various trade agreements, including the seminal World Trade Organization Agreement on Government Procurement, the U.S. has agreed to waive application of domestic preferences vis-à-vis products of signatory countries, while prohibiting access to non-signatory country products. These efforts have removed obstacles U.S. companies have faced when competing in foreign government tenders and also have facilitated access to non-domestic products in U.S. health programs. But, they inevitably dilute the impact of U.S. domestic preferences.

The Trump "America First Trade Policy" executive order can be viewed as a sign that trade agreement commitments giving reciprocal access to national procurement to signatory countries will be on the chopping block. This order could also be part of a more expansive effort to expand the U.S. industrial base for drugs and biotechnology. We will be closely watching Buy American efforts over the coming year as the Trump administration's plans unfold.

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Anti-corruption risks facing companies in the Middle East

The Middle East is seeing rapid growth in the pharmaceutical and medical device market. This is being driven by a number of factors, including regional government investment in health care infrastructure and technological innovations.

However, this growth brings with it a heightened risk of exposure to corruption and bribery. Life sciences companies operating in the Middle East must navigate a complex web of regulations, including a variety of local laws and regulations dealing with anti-bribery and corruption, in addition to international laws with extra-judicial effect, such as the U.S. Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act. A failure to properly manage these risks can result in substantial financial penalties, reputational damage, and potential criminal liability.

Regional and local anti-corruption regulations

Regional governments have ramped up measures to clamp down on bribery and corruption in recent years, including by ratifying and acceding to the United Nations Convention Against Corruption (UNCAC) and the Arab Anti-Corruption Convention. In addition, governments in the region have implemented – and continue to implement – their own set of anti-corruption and bribery frameworks that are often modelled after international standards such as the FCPA and UK Bribery Act, but tailored to local contexts and industries.

Navigating this landscape can be complex. In addition to considering national anti-bribery and corruption legislation, which may not be consolidated into a single source, companies in the region are often required to look at supplementary laws and regulations that are specific to the sector or industry in which they operate. For example, in the UAE, laws dealing with bribery and corruption can be found in the UAE Penal Code (Federal Law No. 31 of 2021) and the Anti-Money Laundering Law (Federal Decree-Law No. 20 of 2018). Both criminalize bribery, including bribing government officials and private individuals. In addition, the UAE's Dubai Health Authority (DHA) and Ministry of Health and Prevention (MOHAP) impose stringent regulations on the interaction between pharmaceutical companies, health care professionals (HCPs), and government entities (for example, in the "Dubai Health Authority Code of Conduct for Health care Professionals").

Saudi Arabia has a similar legal structure, with its Anti-Bribery Law (Royal Decree No. M/36 of 1992, as amended) targeting both public and private sector corruption. The Saudi Food and Drug Authority (SFDA) plays a central role in regulating pharma and medical device companies, ensuring that companies comply with both anti-bribery laws and sector-specific regulations (Saudi Food and Drug Authority Law, Royal Decree No. M/6 of 2007).

Regional enforcement trends

As a result of countries like the UAE and Saudi Arabia bolstering their legal frameworks to combat corruption, regulators in these countries have begun to target both domestic and foreign companies operating in the region, with penalties for non-compliance that can include hefty fines, contract suspensions, and criminal prosecution.

Indeed, there have been several notable cases involving pharmaceutical companies and health care centers in the region in recent years, emphasizing the need for robust compliance practices. For example, most recently in February 2024, the Abu Dhabi Department of Health imposed a one million dirham fine and referred several individuals for criminal investigation on suspicion of misappropriating public funds.

Elsewhere in the GCC, countries such as Qatar, Kuwait, and Oman have introduced anti-corruption laws that are increasingly being enforced with greater frequency, often in response to international calls for higher standards of corporate governance (see, e.g., Qatar Law No. 11 of 2004 on the Penal Code and Kuwait Penal Code No. 16 of 1960).

Anti-corruption risks facing companies in the Middle East (continued)

Whistleblowing

In many jurisdictions, whistleblowing is an invaluable tool for enforcement authorities in detecting and taking action against corrupt practices. Historically, this has been less commonly relied upon in the Middle East, in part due to a lack of appropriate whistleblowing protections. However, that is also beginning to change, although there remains work to do.

Recent legislative amendments in the UAE have been designed to encourage whistleblowing with a view to detecting and eliminating bribery and corruption. A recent change to the UAE's Penal Code has made it an offense for an individual to fail to report a criminal act, such as an instance of bribery, thereby mandatorily encouraging the practice of whistleblowing. Similarly, in July 2024, the Abu Dhabi Global Market introduced the Whistleblower Protection Regulations, which require companies to implement measures that protect individuals making disclosures – for example, by concealing their identity.

In Saudi Arabia, the national anti-corruption authority, Nazaha, offers whistleblowers a financial incentive for disclosures in certain circumstances, in addition to full protection and anonymity. This compensation ranges from a minimum of SAR 1,000 (c. USD 260) to a maximum of SAR 1,000,000 (USD 260,000). As a result, uptake is significant but can result in the making of spurious reports.

Impact on pharmaceuticals and medical device companies

Pharmaceutical and medical device companies operating in the region must carefully manage relationships with HCPs, hospital administrators, and regulatory bodies, making it essential to ensure compliance with both local and international anti-corruption laws.

These challenges are particularly pronounced in emerging markets within the region, where corruption risks are often higher due to the interplay between local customs, regulatory practices, and global business pressures. Pharmaceutical companies must be especially cautious when working with intermediaries who may engage in corrupt practices to facilitate market access or expedite regulatory approvals.

As the Middle East continues to grow as a key market for pharmaceutical and medical device companies, navigating the region's anti-corruption laws is becoming increasingly critical. Companies must be vigilant in monitoring the evolving legal landscape and implement comprehensive compliance programs to mitigate the risks of corruption. By doing so, they can protect their reputation, avoid hefty fines, and ensure sustainable, ethical business practices in this dynamic region.

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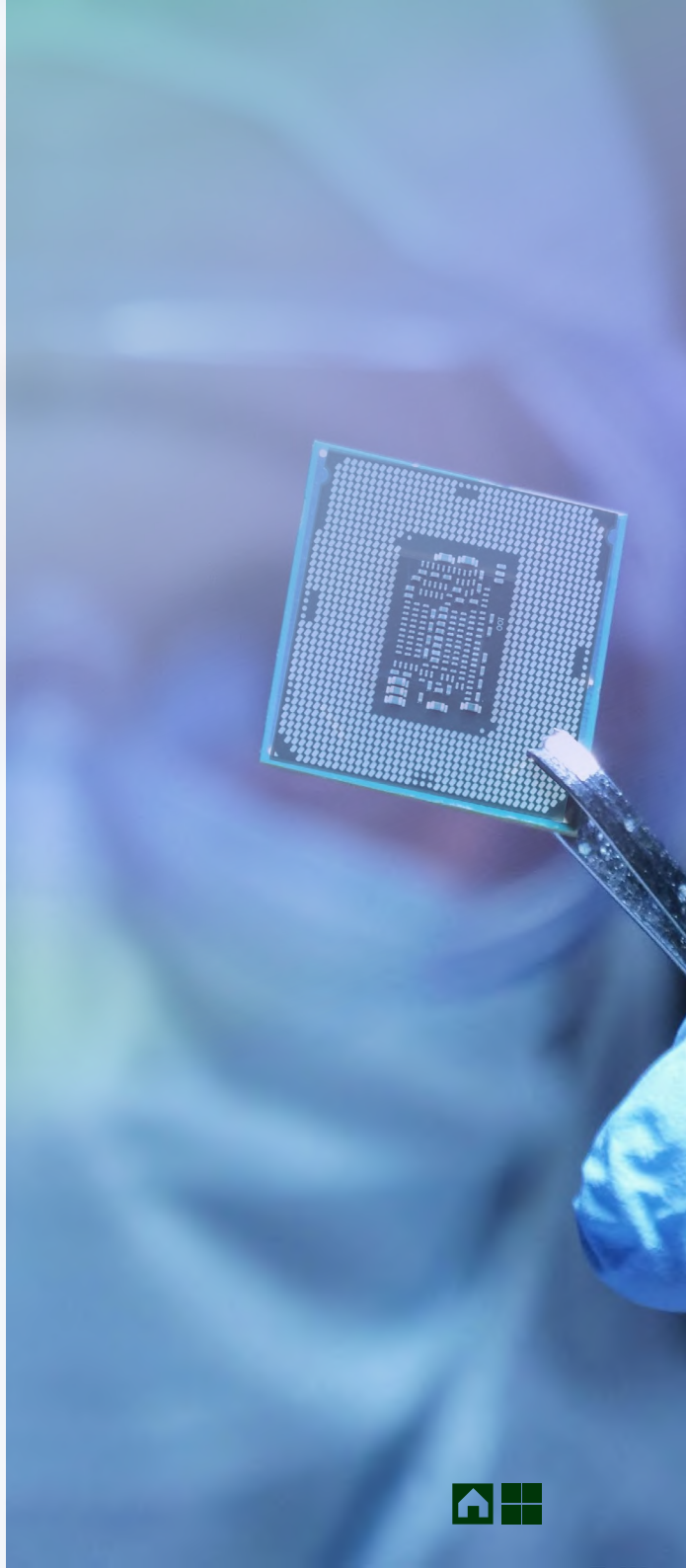

Cell, Tissue, Gene Therapies.

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Product sameness considerations for cellular and gene therapy products

Determining whether two cellular or gene therapy products are the "same" for FDA regulatory purposes continues to be an important and developing area of the law. Product "sameness" has broad implications on a number of regulatory decisions, including exclusivity, priority review vouchers, patent term extension, and approval actions. The complexity of cellular and gene therapy products challenge FDA's existing regulatory framework and its traditional notions of product sameness.

FDA issued guidance in 2021 establishing a general sameness framework for determining whether gene therapy products are the same for purposes of orphan drug exclusivity, which considers both the transgene and vector. FDA implemented its framework with the licensure of the cell-based gene therapy CAR-T product, Breyanzi® (lisocabtagene maraleucel). In particular, FDA determined that Breyanzi® was not the same as a previously licensed CAR-T product for orphan drug purposes. In part, FDA determined that the products used different transgene hinge and transmembrane sequences. FDA also noted that the final cell compositions of the products are different, and Breyanzi® is administered at a defined ratio of T cell subsets.

FDA's approach to cellular products will likely become more important as FDA analyzes more complex cell-based gene therapy products with differing cellular compositions. In a December 2023 draft guidance, FDA recognized that many cellular and gene therapy products consist of a complex mixture of different cell types where the contribution of each to the activity of the product is difficult to determine. In these cases, FDA does not necessarily consider the product to have multiple active ingredients. Rather, the activity of the product is considered to be derived from the totality of the mixture of the cells, and the mixture itself is considered the active ingredient, not the individual cellular components.

This past year, FDA applied its "sameness" framework in the context of Priority Review Vouchers (PRVs), which require a showing that the active ingredient has not been previously approved. The issues involved products comprised of transduced autologous CD34+ cells from patients. Of note, FDA denied a PRV in one case based on the determination that the product contained a previously approved active ingredient, illustrating the ongoing complexity of "sameness" determinations for such products.

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Trends, innovations, and growth potential between the U.S. and Mexico

The recent ruling by the U.S. Court of Appeals for the Ninth Circuit in USA v. California Stem Cell Treatment Center, Inc. has made a significant impact on the stem cell treatment industry. This decision confirms that certain stem cell products are "drugs" under the Federal Food, Drug, and Cosmetic Act (FDCA) - a determination that will have far-reaching implications for companies developing innovative stem cell therapies. Consequently, these companies must navigate the complexities of the FDA's premarket approval process.

One potential option is for companies to explore regulatory frameworks outside the U.S. that are more accommodating, particularly in countries where stem cell products are not classified as "drugs." Mexico is an attractive choice among these options due to its proximity to the U.S. and its more flexible regulatory environment.

Mexico's regulatory agency, COFEPRIS (Federal Commission for the Protection Against Sanitary Risks), has established a framework that many regard as more flexible for stem cell therapies compared to FDA's oversight. Unlike in the U.S., where FDA approval requires extensive premarket clinical trials, COFEPRIS takes a more flexible approach for certain stem cell-based products and therapies. This flexibility enables companies to bring their treatments to market faster, meeting patient needs without the prolonged delays, and high costs associated with FDA approval.

By leveraging Mexico's more lenient regulatory landscape, companies can significantly reduce development timelines and costs, giving them a competitive advantage and the ability to respond to market demands more efficiently. However, to succeed in this new environment, companies must collaborate closely with local partners well-versed in Mexico's legal and regulatory framework. This collaboration will be critical for navigating challenges and ensuring compliance with local laws, regulations, and ethical standards.

In sum, the Ninth Circuit's ruling highlights the increasing regulatory challenges for stem cell companies in the U.S., prompting the need for creative solutions. Mexico's more flexible regulatory environment offers a promising opportunity for companies looking to accelerate product development and reduce costs. However, success in this space requires more than just crossing borders; it demands strategic collaboration with local experts and a clear understanding of Mexico's regulatory landscape. With the right approach, companies can navigate the shifting landscape and continue driving innovation in stem cell therapies to benefit patients worldwide.

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Planning contract negotiations with treatment centers in Germany

For autologous cell and gene therapies, the collection of patients' cells is the first step in the manufacture of the medicinal product. In Germany, this step is usually conducted by specialized treatment centers that have their own cell collection unit and thus handle both the cell collection as well as the later storage, handling, and administration of the finished drug product.

Due to GMP requirements and contractual risks arising from the cell collection, and from the handling of the collected cells and the finished drug product, a pharmaceutical company must implement appropriate agreements with treatment centers.

Usually, German treatment centers with the ability to provide cell collection services and to handle and administer complex CGTs are university hospitals, and therefore public entities. This fact heavily impacts the contract negotiations, which differ quite significantly from negotiations with private companies. In particular, treatment centers are very reluctant to take on financial risks, arguing they have limited financial resources, and strict budgets that cannot permit unplanned costs.

Hence, there is a heightened focus in the following elements of contracts negotiated with treatment centers in Germany:

- Cancellation of orders if product cannot be administered as planned;
- Loss of product after delivery;
- Payment of apheresis services fees when there is no supply of a finished product; and,
- Liability and indemnification, including the demarcation of product liability and liability for medical malpractice.

As a result, companies negotiating with German treatment centers should discuss these contract elements – at an early stage (ideally starting 12 months before the contemplated product launch date) – and carry out an internal risk assessment to identify possible solutions. This may help expedite the negotiation process, which is critical as review processes at treatment centers are often lengthy due to limited resources. Negotiations can also be expedited – at least to some extent – by using contract templates that address common concerns, and by planning fallback positions for key terms in advance of the process.

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Clinical Trials.

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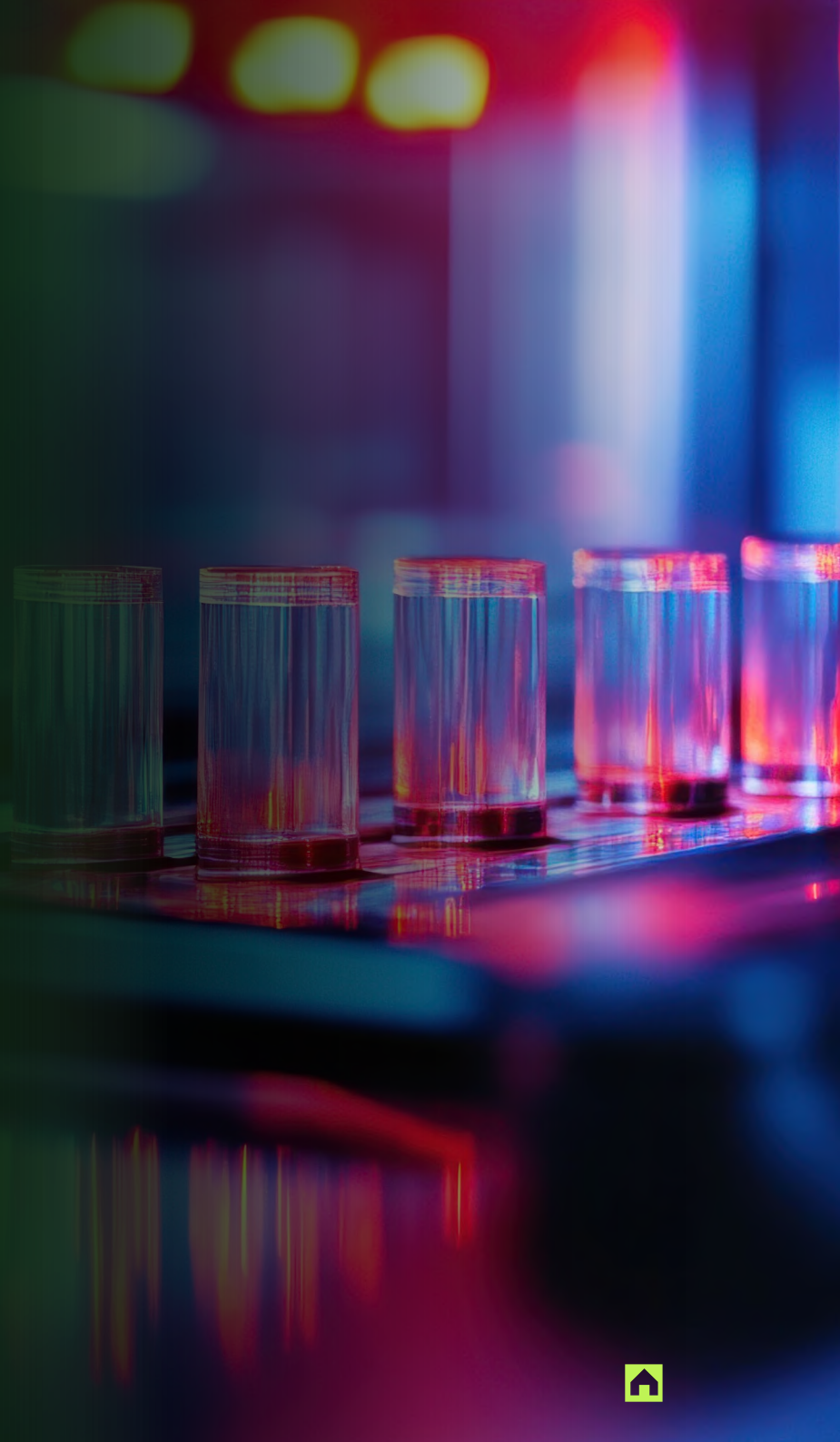

Clinical trial diversity in the EU: Women in general, and pregnant and lactating women

Gender equality continues to be a hot topic in the EU, and significant advancements have been made to increase the inclusion of women in clinical trials. The Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) began producing gender focused clinical trial guidelines as far back as the 1990's. However, it is only comparatively recently that representation of women in clinical trials has improved.

The Clinical Trial Regulation (Regulation (EU) No 536/2014, CTR), which came in to force on 31 January 2022, requires that, unless otherwise justified, trial subjects must be representative of the target population for the applicable medicinal product, but there are no binding metrics in the EU for the inclusion of women, or subsets of women, in clinical trials. The trial protocol should include a justification for the gender allocation of subjects and, if a specific gender group is excluded from or under-represented in the clinical trial, an explanation of the reasons and justification for these exclusion criteria.

The European Parliament ("EP") has raised concerns regarding the CTR. In 2016, the EP called for the implementation of the CTR to be evaluated as it does not specify any considerations regarding women, other than for pregnant and lactating women. In 2023, members of the EP acknowledged that women are significantly underrepresented in clinical research, as sex and gender differences are not a focus in the design and analyses of clinical trials; even for conditions where women are often disproportionally affected, such as neurological disorders. Some field experts argue that not having specific requirements on the proportion of woman trial subjects or separate sample size calculations for both sexes, is problematic from a benefit-risk point of view.

The conditions for inclusion of pregnant and lactating women in clinical trials focus on the care that must be taken to avoid any adverse impact on the health of the (unborn) child. At the same time, there is an increasing acknowledgement of the need to generate data for medicinal products in pregnant and lactating women. The inclusion of pregnant and lactating women in clinical trials, provided appropriate safeguards are in place, can be useful in identifying pregnancy related changes in pharmacokinetics and/or efficacy essential to provide an appropriate benefit-risk evaluation. The ICH is working on robust guidance on the inclusion of pregnant and lactating women in clinical trials which require an assessment of the potential benefits of the investigational medicinal product, and of clinical trial participation of pregnant and lactating women against the uncertainty and potential risks.

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How to collect tissue samples during clinical trials for further research

Collection of tissue samples in clinical trials is increasing, particularly in the context of the development of advanced therapy medicinal products. At the end of the clinical trial, what are sponsors allowed to do with the remaining tissue samples? Potentially, tissue samples can be used as materials for further research. To do so, additional requirements under local laws will need to be met, which differ across jurisdictions, making reuse of samples more complex in multijurisdictional trials. Requirements in France and the UK can be used as common standards to devise a global approach in Europe, which can then be fine-tuned depending on specific local requirements.

- **Donor consent:** Obtaining informed consent from donors is crucial. Participants should be made aware that their samples may be used for future research. Best practice is to secure clear and enduring consent at the time of collection, even if the specifics of future research are unknown, and to consider implementing a two-part consent process where participants can agree to both current study participation and future sample usage, or offer tiered consent allowing participants to specify certain types of future research they are comfortable with. If future research may involve DNA analysis, then donor consent should cover this specifically as well.
- **Ethics approval:** Any proposed use of tissue samples in future research must receive approval from an REC, ensuring that all ethical guidelines are followed.
- **Storage of samples:** The tissue samples will need to be transferred to a facility that has an establishment license from local authorities (e.g., the UK Human Tissue Authority (HTA) and the French Ministry of Research) following the completion of the clinical trial.
- **Participant information:** Clear patient information sheets will need to be prepared that outline how samples will be used, including potential sensitive areas of research, and they must ensure participants understand what they are consenting to.
- **Confidentiality and data protection:** Donor identities must be protected in compliance with data protection laws, particularly when analyzing DNA or other identifiable biological materials.
- **Governance procedures:** Robust governance frameworks will need to be put in place to manage consent preferences effectively and comply with donor wishes regarding sample usage over time.
- **Export authorizations:** If tissue samples collected for future research will be exported to research sites located in different countries, specific authorizations may be required from local authorities (e.g., the Ministry of Research in France). In the UK, an export license is not required from the HTA.

Note that the EU SoHO Regulation (EU) 2024/1938) (SoHO Regulation), due to enter into force in 2027, will harmonize blood and tissue regulations across the EU and extend the requirements for tissue and blood sample-collections during clinical trials to all substances of human origin (other than organs). The UK government is considering whether similar changes are necessary in Great Britain.

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GDPR creates privacy issues for EU sponsors at U.S. sites

When European Union sponsors conduct clinical trials at U.S. sites, the General Data Protection Regulation (GDPR) imposes privacy obligations that may be unfamiliar to U.S. organizations. This often results in significant pushback from U.S. sites, and protracted contract negotiations with EU sponsors. U.S. sites are also subject to domestic privacy laws – including the Health Insurance Portability and Accountability Act and its implementing regulations, (collectively, "HIPAA") and state privacy laws – which are not always compatible with the GDPR, and thus may cause further tension between the U.S. and EU parties.

One challenge is the inconsistent interpretation of GDPR within the EU in the research context. In some EU countries, U.S. sites are considered "vendors" (i.e., "*processors*") of sponsors; while in others, they are treated as "partners" (i.e., "*controllers*"). This discrepancy triggers different privacy agreements depending on the EU sponsor's country, further confusing U.S. site organizations.

HIPAA compliance adds another layer of complexity, as U.S. sites may be "covered entities" (akin to a "controller") under HIPAA (and may not be able to be considered a "processor") with regard to their patient medical record data. In addition, GDPR rights granted to data subjects differ from those offered under HIPAA. This causes compliance challenges for U.S. sites when GDPR transparency requirements affect the content of the informed consent form (ICF) and are not necessarily compatible with U.S. laws or understandable to U.S. data subjects, resulting in site pushback and institutional review board (IRB) objections.

Another issue arises with the transfer of personal data from the U.S. to the EU, which qualifies as an "international transfer" under the GDPR. This requires specific safeguards, typically implemented through the EU's standard contractual clauses. These clauses are lengthy and impose significant obligations on U.S. sites, which may hesitate to accept them. Strategies that sponsors have been employing to address these challenges include the following:

- Preparing an explanatory document for U.S. sites explaining GDPR applicability and outlining the implications of GDPR compliance.
- Developing "light" template agreements and a negotiation playbook with fallback options and alternative wording that will likely be more palatable to U.S. sites in an effort to streamline the negotiation process.
- Preparing ICF templates that address GDPR requirements in a manner more consistent with U.S. site and IRB expectations.
- Engaging a legal team with expertise in both U.S. and EU privacy laws to ensure robust compliance and alignment with regulatory requirements, while minimizing potential conflict during negotiation of clinical trial agreements and the content of ICFs.

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FDA increasing IRB enforcement efforts

Throughout 2024, FDA's Bioresearch Monitoring (BIMO) program increased its efforts to ensure that Institutional Review Boards (IRBs) adhere to FDA's human subject protection regulations, issuing four warning letters to address non-compliance, up from only one warning letter issued in 2023.

BIMO inspections of IRBs are generally focused on IRB written procedures, IRB membership, IRB meeting minutes, and study records (protocols, informed consent documents, correspondence between the IRB and the investigator, study sponsor, or FDA). FDA has described the deficiencies found in its 2023 IRB inspections as centered on four themes:

- IRB communications / meeting minute deficiencies;
- failure to develop or follow written procedures;
- IRB membership deficiencies; and
- operational deficiencies.

The 2024 warning letters, issued to two academic medical center IRBs and two hospital IRBs, demonstrate the agency's continued focus on IRB meeting minutes and written procedures.

The most reoccurring violation detailed in the recent warning letters was the failure to prepare, maintain, and follow written procedures. FDA's regulations require IRBs to prepare and maintain adequate documentation of their activities, including written procedures describing IRB functions and operations and the reporting to FDA of unanticipated risks to study subjects, investigator noncompliance, or the termination of IRB approval. BIMO cited IRBs for failing to follow their own policies on reporting serious adverse events and investigator noncompliance (e.g., enrollment of an ineligible participant) to FDA, and for failing to have written procedures providing a procedure for reporting events to FDA.

FDA's enforcement actions against IRBs also demonstrate the agency's reliance on IRB meeting minutes in BIMO inspections. FDA cited IRBs for failing to maintain adequate documentation of IRB activities, identifying instances where the IRB failed to have an up-to-date list of board members and where the meeting minutes failed to reflect an accurate vote tally. FDA also relied on an IRB's meeting minutes to cite the IRB for reviewing research at meetings where an IRB member was absent.

The increased number of warning letters and the cited violations reflect FDA's heightened focus on IRB documentation practices and IRB prompt reporting of serious compliance issues and risks to study subjects to the agency. Moving forward, it is increasingly paramount that IRBs ensure their BIMO inspection readiness, including reviewing written procedures and conducting mock inspections.

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U.S. clinical trial diversity recommendations under review

In June 2024, FDA released its draft guidance on Diversity Action Plans (DAPs) for clinical trials, titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies."

This guidance was mandated by the Food and Drug Omnibus Reform Act of 2022 (FDORA), which established a new framework to promote clinical trial diversity. Under FDORA, certain drug and device sponsors are required to submit DAPs for pivotal trials demonstrating the sponsor's goals for enrolling representative numbers of participants from historically underrepresented populations in clinical trials, the rationale for the goals, and the strategy to achieve the goals. FDA's June 2024 draft guidance provides recommendations to sponsors on developing DAPs, including by offering insights on waiver criteria, DAP submission timelines, potential postmarketing requirements, applicability of DAPs to multinational studies, and the use of real-world evidence to estimate disease prevalence in different demographic groups.

The DAP requirement is scheduled to become effective 180 days after FDA finalizes the guidance. However, since taking office, President Donald Trump has shown strong opposition towards diversityrelated activities that were commonplace in recent years. President Trump has terminated the federal government's diversity, equity, and inclusion (DEI) activities and directed the Department of Justice to closely scrutinize related activities of private companies. With this in mind, it appears likely that the Trump administration will delay finalizing or choose not to finalize the DAP guidance. If the Trump administration moves forward with finalizing the DAP guidance, the final version may bear little resemblance to what is currently in effect.

Regardless of whether DAPs are required and enforced, enrollment of appropriate demographic subgroups in clinical trials has been a longstanding priority for FDA and is rooted in the critical tenet that clinical trial data must support safe and effective use of the product in the intended patient population. This priority has been reflected in other guidance documents addressing diversity in clinical trials, including guidance on collecting and reporting race and ethnicity data, and recommendations for sexspecific analyses. Because the collection and reporting of demographic data to ensure clinical trials are appropriately representative informs the safety and efficacy of medical products, sponsors should review their efforts in this space to confirm that their studies will meet all statutory and regulatory requirements. We expect that diversity in clinical trials will remain a closely-watched topic in 2025.

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Germany's Medical Research Act benefits domestic clinical trials

The Medical Research Act ("Medizinforschungsgesetz"), passed by the German Parliament on 04 June 2024, is part of a larger national strategy to incentivize pharmaceutical and medical device research and production. For clinical trials, it has three key provisions:

Standard contract clauses for CTAs:

As the conclusion of clinical trial agreements (CTAs) has been identified as one aspect to delay commencement of clinical trials, Germany's Federal Government will issue standard contractual clauses. These will cover key terms like IP and publication rights, liability, and data privacy. The standard clauses will be mandatory unless the sponsor and the institution agree to deviate from them. We anticipate that deviations from these standard clauses will require heavy negotiations with health care organizations (HCOs) complicating sponsors' efforts to address specific needs related to novel technologies and therapeutic contexts. In any case, it is highly recommended to thoroughly review the standard clauses once published, conduct a comparative analysis with the company's current CTA template, and identify necessary deviations and negotiations strategies.

Benefits for clinical trials at German sites:

Following the launch of a medicinal product (or of an existing product in a new indication), the Federal Joint Committee (G-BA, "*Gemeinsamer Bundesausschuss*") assesses and categorizes the benefit of a medicinal product in contrast to the comparison therapy. This benefit assessment (the so-called "AMNOG-process") is then followed by price negotiations with the Head Association of the German Sick Funds ("*GKV-Spitzenverband*") with the price already being affected by the outcome of the benefit assessment. In the future, the G-BA will have to determine whether a relevant part of the clinical trial has been conducted in Germany, which is when at least 5% of the overall clinical trial participants have been enrolled at German clinical trial sites. This determination will have a significant impact in the price negotiations, if the G-BA at the same time comes to the conclusion that the medicinal product has no quantifiable or (only) a minor additional benefit; in such event, the thresholds for the price will be less strict.

Confidential reimbursement price for research in Germany:

Once the reimbursement price is set, a pharmaceutical company can make a request to the Head Association of the German Sick Funds (*GKV-Spitzenverband*) for the negotiated reimbursement price to be treated confidential. However, to receive this benefit , a pharmaceutical company will have to demonstrate that it has a research department in Germany, as well as relevant preclinical or clinical projects and cooperations with public entities in Germany (e.g., university hospitals). If the Head Association of the German Sick Funds acknowledges these requirements, then the pharmaceutical company will have to grant an additional 9% rebate on the agreed price until the end of the regulatory exclusivity period. This provision aims to hinder the reference pricing in other countries to the German reimbursement price and currently applies until 30 June 2028.

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AIFA's new guidelines on non-interventional clinical studies: A step toward streamlined research and real-world data integration

In August 2024, the Italian Medicines Agency (AIFA) released updated guidelines on non-interventional (observational) clinical studies, aimed at clarifying key regulatory aspects and simplifying processes.

The new guidelines are dedicated, like the previous ones, to pharmacological, observational studies. However, AIFA took care to specify in their preamble that these guidelines can be taken "as a reference" also in the evaluation activities of non-pharmacological, observational studies, legitimizing a consolidated practice in the absence of a codified procedure for observational studies that do not involve medicines. (e.g., CE marked medical devices).

For years, industry groups have called for clearer regulatory guidance on designing study protocols and managing ethical review processes. AIFA's new guidelines address these concerns, streamlining the approval process and providing clarity on regulatory requirements. This simplification is expected to reduce delays, enhance research efficiency, and increase Italy's competitiveness in global pharmaceutical research.

Non-interventional studies, which observe patient outcomes without altering treatment regimens, are essential in assessing drug efficacy and safety in real-world settings. With the increasing availability of health data from electronic health records, wearable devices (e.g., smartwatches), and other digital health tools, these studies can now provide valuable insights into how treatments perform outside clinical trial environments. AIFA's guidelines acknowledge this shift, highlighting the integration of pharmacogenetics and pharmacogenomics, and the potential for generating knowledge from compassionate use programs.

The guidelines also stress the importance of data protection and patient consent, ensuring that observational studies comply with GDPR and maintain transparency throughout the research process. With the increased volume and complexity of health data, AIFA emphasizes the need to integrate information from diverse platforms while safeguarding privacy.

For pharmaceutical companies, adapting to these updated guidelines is essential for navigating the changing regulatory environment and taking advantage of new opportunities in observational research.

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LATAM: Clinical trials benefits to sponsors

Latin America has emerged as a vibrant hub for clinical trials, offering a blend of untapped opportunities and unique regulatory landscapes. The region's diverse populations, cost-effective operations, and growing infrastructure position it as a strategic choice for pharmaceutical and biotechnology companies seeking to expand their clinical research programs. As the region continues to evolve, strategic stakeholders are recognizing the immense potential of this dynamic market, characterized by unique advantages and emerging regulatory frameworks.

LATAM has made significant strides in harmonizing clinical trial regulations across different countries. Regulatory agencies like Brazil's ANVISA, Mexico's COFEPRIS, and Argentina's ANMAT have been instrumental in creating more transparent, efficient approval processes. These agencies have implemented comprehensive guidelines that align with international standards, try to reduce bureaucratic barriers and attracting global pharmaceutical investments.

Recent legal reforms have focused on streamlining ethical review processes, enhancing data and patient protections, and establishing more robust quality control mechanisms, demonstrating the region's commitment to maintaining high scientific and ethical standards.

One of the region's compelling attributes for clinical trials is its genetic diversity, including host populations with mixed origins that provides researchers with access to genetic variations rarely found in more homogeneous populations, enhancing the global applicability of trial results. This demographic complexity is particularly valuable from a diversity perspective and in understanding complex diseases, drug responses, developing targeted therapies, and addressing health disparities.

LATAM also offers faster patient recruitment rates compared to other regions. High levels of unmet medical needs, combined with centralized health care systems, facilitate rapid identification and enrollment of participants. In addition, the cost-effectiveness of conducting clinical trials in LATAM remains a significant draw for international pharmaceutical companies. Compared to other markets, the region offers lower operational costs and high research quality: skilled medical professionals, high level research facilities, and a growing clinical research infrastructure contribute to this attractiveness.

LATAM represents a dynamic frontier for clinical trials, offering opportunities for growth while addressing global health care challenges. By understanding the region's nuances, building strong local collaborations, embracing innovation, maintaining rigorous standards, and leveraging its distinctive advantages, the region is poised for companies to unluck its full potential, contributing to advancements in medical research and patient care worldwide.

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Transactions.

7

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Amid regulatory uncertainty, medical device mergers & acquisitions show promise in 2025

The U.S. is experiencing political, regulatory, and economic changes that impact medical device M&A. While some companies may hesitate in uncertain times, others see opportunities for short- and long-term value growth through portfolio expansion and adoption of cutting-edge technologies, provided risks are well managed. A proactive M&A strategy is crucial, as regulatory hurdles, financial missteps, and operational disruptions can derail deals. Successful acquirers are focusing on strategies to maximize value and mitigate unexpected liabilities.

Specialized regulatory due diligence

Regulatory complexities make due diligence in medical device M&A critical. For example, unlike in other industries, acquiring a company does not automatically mean acquiring full market access for all indications for all acquired products as FDA approvals, Premarket Approvals (PMAs), 510(k) clearances, and EU MDR/IVDR certifications may need to be reevaluated for alignment of the indications with the priorities of the transaction. This dynamic has the potential to delay commercialization, negatively impact deal value, and in some cases, saddle acquirers with unanticipated or uncovered risks and regulatory liability. Further, incorporating technologies used in already approved devices does not necessarily mean that regulatory clearance of subsequent products will be straightforward. Worse still, a target company with a history of regulatory violations — such as FDA warning letters, product recalls, or quality system deficiencies — could foist significant post-close risks on the acquiring company if not dealt with at the time of the transaction.

Accordingly, sophisticated acquirers have had a renewed focus on highly specialized regulatory diligence, which builds confidence throughout the M&A process, mitigates and properly allocates risk, verifies and preserves value, and prepares firms for day-one integration and operational readiness. It also allows those acquirers to discover new information about a target that refine and support different valuations than their competitors who have not engaged in the same level of diligence.

Integration efforts

Beyond regulatory concerns, post-merger integration is rarely seamless, and if not managed properly can lead to inefficiencies, talent loss, and operational setbacks. One of the biggest risks is losing key personnel who are essential to innovation and compliance. Supply chain vulnerabilities also loom large as many medical device companies rely on third-party manufacturers and component suppliers, and failure of these vendors to meet FDA or international quality standards could result in severe business disruptions and dislocations. Additionally, cybersecurity threats are increasing, especially with the rise of connected medical devices and digital health platforms, making IT integration a critical part of post-merger planning.

A robust, and well-documented diligence process greatly reduces post-merger integration risks and associated costs that can erode overall deal value. In particular, medical device firms are increasingly focused on utilizing formal and informal deal processes in the earlier deal stages, including engaging with key personnel and stakeholders to better understand how to best incentivize and maximize growth.

Getting valuations right

Medical device firms remain fixated on reducing financial risks as the industry continues to have many unknowns: rapid technological advancements can quickly render a newly acquired product obsolete; hidden legal liabilities may lead to costly litigation; and shifting regulatory landscapes may lead to reimbursement challenges. External market pressures can also impact valuations. For example, regulatory environments in and the relationships between the U.S., EU, and China are fluid, creating new obstacles for companies looking to scale internationally. At the same time, economic uncertainty, trade policies, interest rate fluctuations, and increased competition mean that a deal that is favorable today could become financially burdensome tomorrow.

To respond, firms are continuing to deepen their valuation models to adjust for factors that can hamper long-term revenue potential. Acquirers are also continuing to use contingent consideration as a means of de-risking future regulatory and operational uncertainties.

In short, 2025 promises to be a defining year for medical device M&A with vast opportunities for companies that boldly employ strategies throughout the deal process that uncover and creatively mitigate liabilities to effectively structure acquisitions in an increasingly competitive and uncertain market.

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Pharmaceutical antitrust enforcement under new U.S. and EU leadership

In the U.S., with the inauguration of President Trump, Republicans have taken the helm of the Federal Trade Commission (FTC). During the Biden administration, the FTC under Democratic leadership had a clear mandate to target the pharmaceutical industry, bringing cases based on traditional as well as more novel theories of competitive harm. The FTC under Trump is likely to continue to focus on the pharmaceutical industry. However, we expect the FTC to hew more closely to traditional antitrust theories, and away from the more novel theories that were a hallmark of the Biden-era FTC.

The FTC may also broadly be more "merger-friendly" than in recent years, with greater receptivity to divestitures to resolve deal concerns. Nonetheless, there may be potential exceptions: notably, it was during the first Trump administration that the FTC announced that it would no longer accept divestitures of inhalant and injectable pipeline drugs in pharmaceutical mergers where one party has a marketed product. Finally, state attorneys general have been increasingly active in antitrust enforcement in recent years, and states may increase enforcement on health care issues if there is some perception of the FTC "stepping back" on this front.

Over in the EU, on 01 December 2024, Teresa Ribera was appointed the First Executive Vice-President of the European Commission for a Clean, Just, and Competitive Transition. Ribera is also responsible for driving the EU's competition policy. With respect to mergers, Ribera has spoken about guarding against "killer acquisitions," and has expressed interest in revisiting the EC's ability to call-in below-threshold transactions. Life sciences companies doing deals should consider carefully their EU filing strategies and whether approaches to the EC would be advisable.

Ribera has also hinted at the EU's deployment of a variety of enforcement tools — including merger and foreign direct investment reviews and foreign subsidies regulation investigations — to protect European businesses, reflecting a broader "pro-Europe" sentiment that could translate into protectionist measures for EU companies. With respect to competition enforcement, Ribera is expected to continue focusing on the pharmaceutical industry, in particular with regard to abuse of dominance cases. Issues such as excessive pricing and competitor denigration are also expected to remain on the EC's radar. Ribera has also suggested the possibility of issuing guidance on abuses of dominance relating to exploitative practices.

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Health care joint ventures: Navigating antitrust risk in a void of guidance

Health care providers (HCPs) have long partnered with each other through independent physician associations, clinically integrated networks, group purchasing organizations, service line joint ventures, and other collaborations to provide better access to quality and affordable care to the communities they serve. For almost 30 years, HCPs have been able to rely on policy statements issued by the United States Department of Justice's Antitrust Division (DOJ) and the Federal Trade Commission (FTC) for guidance on structuring these arrangements and conducting joint activities in compliance with Federal antitrust laws. However, over the last two years, the DOJ and FTC rescinded much of their guidance for competitor collaborations.

Federal antitrust law generally prohibits agreements among competitors that unreasonably restrain competition. Although some agreements are per se illegal (e.g., agreements to fix prices or allocate customers, territories, or services), most collaborations among competitors are evaluated under the "rule of reason" to determine whether the agreement harms competition. The rule of reason requires a fact-specific, detailed analysis; and guidance from the DOJ and FTC has helped health care entities assess their collaborations with competitors. Under the Biden administration, however, the DOJ and FTC withdrew the following guidance statements, leaving health care entities without clarity about their collaborations with other industry participants:

- **DOJ and FTC Antitrust Enforcement Policy Statements in the health care area (1993)** and **Statements of Antitrust Enforcement Policy in health care (1996)**, which, among other guidance, provided safety zones for certain hospital mergers, joint ventures to purchase expensive health care equipment, exchanges of anonymized historical price and cost information, joint purchasing arrangements, and physician network joint ventures;
- **Statement of Antitrust Enforcement Policy regarding Accountable Care Organizations participating in the Medicare Shared Savings Program (2011)**, which established safety zones for certain ACOs and provided guidance for ACOs outside of the safety zones; and
- **Guidelines for collaborations among competitors (2000)**, which provided a safe harbor for competitor collaborations, in any industry, when the collaboration and its participants collectively comprise less than 20% market share.

Despite the current void in guidance, partnerships are often necessary in health care to reduce costs, provide value-based care, and reach traditionally underserved communities. As HCPs consider new partnerships, structuring these relationships to minimize antitrust risk will be important. In negotiating collaboration agreements, parties should consider the antitrust risk associated with their desired levels of financial, operational, and clinical integration; the equity division among partners; and the governance structure. Certain structures could require strict firewalls, which could hinder the goals of the partnership. It will be increasingly important in the future that antitrust and corporate counsel collaborate; and many times, creative structuring can minimize antitrust risk and support the parties' goals.

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Private health care investments in France: First responses to growing financialization

Private health care in France has been attracting increasing investment from private stakeholders, including health centers and private health care establishments. Among these, some are structured as companies formed by self-employed practitioners (sociétés d'exercice libéral, or "SEL companies"), whose legal framework was recently amended and took effect on 01 September 2024.

While this reform did not drastically change existing regulations, it clarified key aspects, particularly regarding capital ownership and governance. It also reaffirmed the current model, which allows third-party investors to hold minority stakes, provided that practicing health care professionals retain over 50% of the capital.

At the same time, several national boards representing health care professionals have raised concerns about third-party investments, particularly from financial investors, warning that they could compromise practitioners' professional independence. In response, the French Senate's Social Affairs Committee published a report on 25 September 2024, analyzing the impact of private investors on the health care sector. The report highlights increasing market concentration, particularly in for-profit hospitals (dominated by four major investment funds), medical analysis laboratories (controlled by six major groups), and medical imaging groups.

The report identifies several factors driving the financialization of health care, including legal provisions allowing non-health care professionals to invest in SEL companies and the need for cost-sharing to maintain high-quality care. However, it warns that the consequences of this financialization are poorly understood and controlled, raising concerns about monopolies that could reduce competition and limit health care options. It also questions whether regulatory bodies, such as Regional Health Agencies (ARS) and health insurance providers, can effectively oversee these financialized health care services while maintaining accessibility and quality. Additionally, it points out that health care services are increasingly seen as a "profitable and secure" investment.

To address these issues, the report proposes 18 recommendations, including stricter oversight of health centers, better regulation of health care service authorizations by ARS to ensure balanced territorial coverage, and the creation of a "financialization observatory." It also suggests protecting the independence of health care professionals by tightening rules on capital ownership and voting rights in SEL companies and introducing a minimum investment period for SEL capital.

The committee emphasizes that these recommendations are not meant to exclude investors, but rather to ensure that financial involvement prioritizes public health over profit. It also calls for a clear and consistent doctrine governing SEL operations to maintain professional control. In response, some national health care boards have begun drafting their own guidelines, though certain decisions have already been legally challenged. Court rulings expected in the coming months will help shape a more balanced regulatory framework. In the meantime, private investors should implement the initial guidance elaborated by national boards and ensure compliance with current market practice with the objective to maintain a balance between profitability and professional independence and improvement of care quality.

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China licensing transactions checklist

Chinese biopharma companies are increasingly turning to licensing and collaboration deals for external financing due to a challenging fundraising environment. In 2023, out-licensing deals (i.e., Chinese companies licensing IP to foreign companies) increased significantly, while in-licensing deals (i.e., Chinese companies obtaining licenses from foreign companies) decreased. The following is a checklist of matters that should be considered in any licensing transaction with Chinese counterparties.

Due diligence:

Conduct thorough due diligence on Chinese licensors or licensees, considering whether the party is private, public, or state-owned, their experience with licensing, and their IP portfolio. Language and communication differences may impact deal efficiency.

Applicability of Chinese law:

While the licensing and collaboration agreements can be governed by foreign laws, Chinese law mandatorily applies to the protection of workers' rights, food and public health safety, environmental safety, financial security, and anti-monopoly or anti-dumping issues. Also, the agreements cannot damage the social and public interests of China.

Marketing authorization holder (MAH):

For drugs manufactured outside China, the MAH must be a foreign entity, even if it is the Chinese licensee that commercializes the products. However, the foreign MAH can appoint the Chinese licensee as its local agent.

Technology import/export restrictions:

China categorizes technologies as "prohibited," "restricted," or "permitted." In-licensing technologies related to highly pathogenic microorganisms and out-licensing technologies such as certain traditional Chinese medicine resources, cell cloning, and gene editing technologies are subject to restrictions.

Data and human genetic resources (HGR):

Development involving HGR or data of Chinese patients requires regulatory approval from the National Health Commission.

Two-invoice requirement:

The "two-invoice requirement" impacts drug distribution, allowing only two invoices between the manufacturer and the hospital. The exclusive China licensee of imported drugs can be considered a "manufacturer" in in-licensing deals.

Foreign exchange controls:

Cross-border licensing deals involving payments in or out of China will be subject to foreign exchange controls.

Dispute resolution:

The Hong Kong International Arbitration Centre (HKIAC) is a popular forum for resolving licensing disputes due to its cost-efficiency and track record of awards being recognized and enforced in China.

Bankruptcy risks:

China lacks a provision equivalent to Section 365(n) of the U.S. Bankruptcy Code, which protects non-debtor licensees. Foreign licensees should use drafting mechanisms to protect their rights if the Chinese licensor ends up in bankruptcy proceedings.

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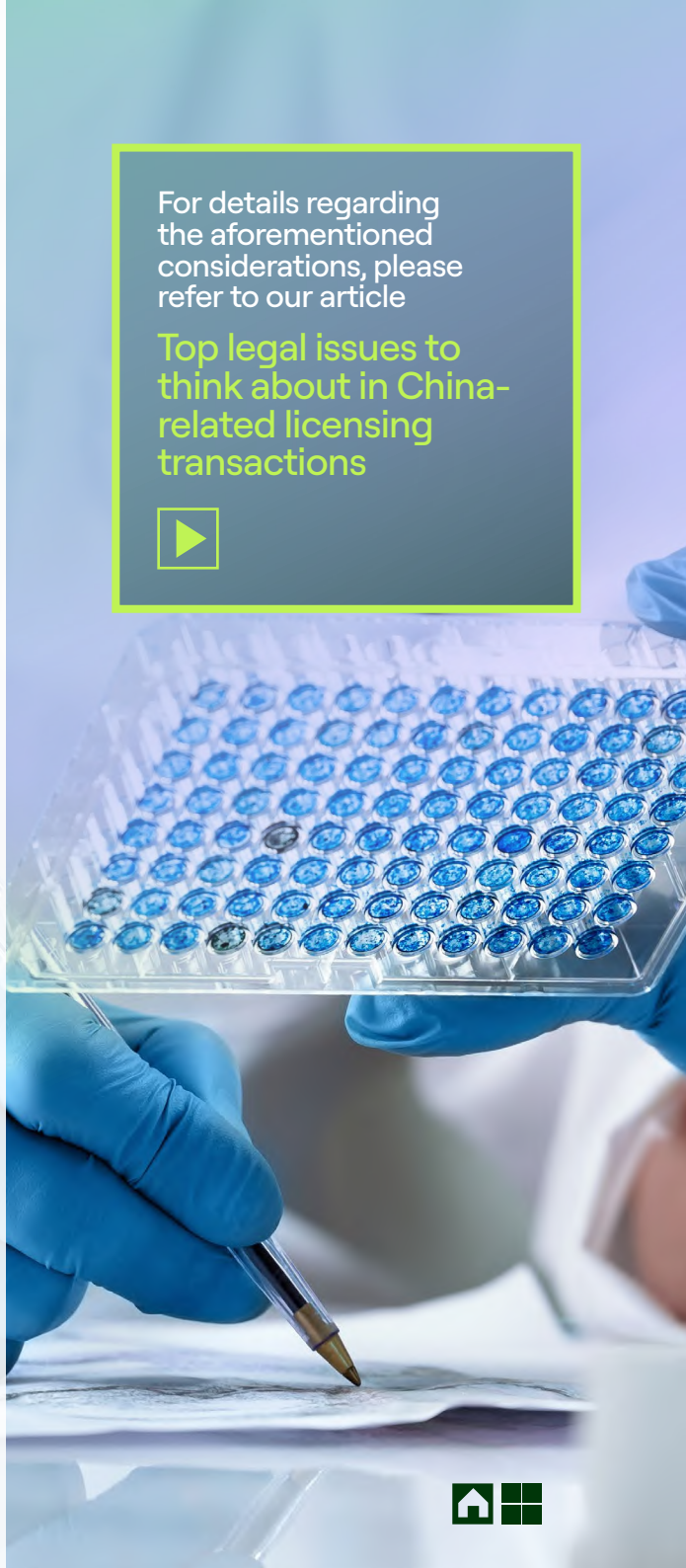
For details regarding the aforementioned considerations, please refer to our article

Top legal issues to think about in China-related licensing transactions



How to navigate demergers in China

Demerger is an attractive option for multinational life sciences sector companies to rationalize business portfolios and achieve strategic growth. Whether through a split-off or a spin-off, these transactions require careful planning to navigate China's complex legal, regulatory, and tax landscape. Several factors drive the popularity of demergers in pharmaceuticals and medical devices sectors in China:

Market positioning: Standalone companies focused on innovative drugs or devices are more attractive for public listings.

M&A readiness: Acquirers often require pre-closing restructuring to remove non-core assets.

Strategic growth: Separating core businesses can improve operational efficiency and valuation.

Tax advantages: Properly structured demergers can achieve tax efficiency, such as being eligible for the High and New-Technology Enterprise status, which offers a reduced corporate tax rate.

Below we summarize the four key considerations for demergers.

Alternative Structures:

Instead of a formal demerger, companies might consider:

- **Asset transfers:** Moving assets to a new company, though this requires capital injections and triggers various taxes.
- **Asset assignment:** Transferring assets to a wholly owned subsidiary in exchange for increased registered capital, though this comes with a one-year freeze on M&A activity after closing.

Regulatory and procedural hurdles:

Chinese law imposes strict procedural requirements, including creditor notifications and public disclosures, which some companies may find sensitive. Additionally, regulated sectors like pharmaceuticals face complex approval processes, making early regulatory engagement crucial.

Operational and legal complexities:

- **Manufacturing & real estate:** Many life sciences companies operate multiple plants on shared land. Transferring facilities requires careful handling of land use rights, regulatory approvals, and potential negotiations with local governments.
- **Licensing & permits:** Drug and medical device marketing authorizations are currently not transferable; instead, companies (but see "Chinese draft medical devices law unveiled" for forthcoming developments in this regard on page 76) must obtain new permits, potentially causing operational delays.
- **Employee transfers:** A key advantage of demergers is that employee contracts transfer automatically, but labor union consultations may still be necessary.

Financial & Tax Structuring:

- **Capital allocation:** Shareholders have flexibility in allocating registered capital between the original company and the new company; provided that the total registered capital and paid-in capital of the two companies after the demerger are equal to the corresponding amounts of the original company before the demerger.
- **Debt & contracts:** Creditors must be consulted, as demerger rules in China impose joint liability on the new and original entwities, unless negotiated otherwise.

Demerger deals in China's life sciences sector offer compelling strategic benefits but demand thorough advance planning. Engaging experienced advisors can provide valuable guidance throughout the process, ensuring a successful outcome.

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For further details, please refer to
Key considerations for life sciences demerger deals in China

Litigation.

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Chevron doctrine's demise brings promises & perils for life sciences firms

In June 2024, the U.S. Supreme Court issued Loper Bright Enterprises v. Raimondo, its highly anticipated decision overturning the 40-year old doctrine established in Chevron v. Natural Resources Defense Council, which had provided judicial deference to administrative agencies' interpretations of ambiguous statutes under certain circumstances. The decision to eliminate Chevron deference is placing increased pressure on administrative agencies – including FDA and CMS – when interpreting and applying the law in instances where Congress was either unclear or left gaps, as such decisions may be open to challenge by regulated industries and increased scrutiny by the federal courts.

Loper Bright replaces the former agency-friendly *Chevron* standard with a framework under which a reviewing court must determine the "best" interpretation of a statute, without giving any deference to the agency on ambiguous statutory language. The decision could open the door for challenges to long-held agency positions, allowing for increased scrutiny of efforts by an empowered Executive branch to interpret its statutory mandates.

Agencies, including FDA, are still entitled to some amount of discretion on questions of fact, science, and policy to varying degrees. They also retain the power to persuade the courts of the "best" statutory interpretation when they are able to do so convincingly. In many ways, fights that used to focus on legal interpretations of statutory language may now morph into disputes about the facts and science to which those legal interpretations are applied. We have already seen, and expect to continue to see, FDA providing more scientific and factual justification or explanation for its decisions going forward. This may also result in FDA deprioritizing rulemaking efforts, given the increased burden to develop, implement and defend such regulations, without the promise of *Chevron* deference as the reward for its efforts. This is likely to be particularly true under an administration that is prioritizing the removal of existing regulations before any new regulation can be issued. We also should expect explanation in writing on the agency's current thinking through guidance if such positions could give a court reason to question the agency's thinking.

The upshot? Life science companies now have a new tool in their arsenal for challenging agency decisions, especially those for which Congress has not delegated express or implied authority to HHS or FDA. While we await future court decisions to clarify the bounds of *Loper Bright*, we highlight the following key areas below that we are closely monitoring in 2025 and beyond:

- FDA's determinations on marketing exclusivity.
- FDA's efforts to assert sole regulatory authority over laboratory developed tests (LDTs), supplanting CMS authority over the laboratory developers and HHS oversight of both FDA and CMS.
- Product designations prior to marketing and reimbursement/coverage decisions impacted by those designations.

Now more than ever, it will be important for affected parties to follow developments and engage with the relevant agencies, such as through commenting on proposed regulations or guidances, and to focus their correspondence with regulators on helping the agencies determine and substantiate the best interpretation of relevant statutory text.

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U.S. Supreme Court to address class certification and Article III standing

In January 2025, the U.S. Supreme Court agreed to answer a hotly-contested question in class action litigation, which will have substantial impact throughout the life sciences U.S. litigation space: "Whether a federal court may certify a class action pursuant to Federal Rule of Civil Procedure 23(b)(3) when some members of the proposed class lack any Article III injury." The answer to that question has been the subject of intense litigation, especially in consumer and other class actions affecting pharmaceutical and other life sciences companies, and there is currently a three-way circuit split over the issue. The Supreme Court's decision will thus significantly impact cases where, for one reason or another, there is reason to believe that some members of the proposed class are not injured within the meaning of Article III of the U.S. Constitution.

The case at issue is called *Laboratory Corporation of America Holdings, dba Labcorp v. Luke Davis, et al.*, Case No. 22-55873. Plaintiffs are visually impaired individuals who claim they were denied equal access to touchscreen check-in kiosks at Labcorp facilities. Plaintiffs brought claims – individually and on behalf of a class of thousands of other allegedly similarly situated visually impaired individuals – against Labcorp. Plaintiffs moved to certify a damages class that included legally blind individuals in California who could not use Labcorp's kiosks.

In opposing class certification, Labcorp argued that Plaintiffs could not show standing for each class member under Article III, because they could not demonstrate that each class member personally encountered – and were unable to use or discouraged from using – Labcorp's kiosks. The District Court nevertheless certified the damages class.

An appeals court affirmed class certification, ruling that it did not matter "that some potential class members may not have been injured" because, under the law of the Ninth Circuit Court of Appeals, the rules do not bar "certification of a class that potentially includes more than a de minimis number of uninjured class members." *Davis v. Lab'y Corp. of Am. Holdings*, No. 22-55873, 2024 WL 489288, at *2 n.1 (9th Cir. Feb. 8, 2024).

The Ninth Circuit's ruling is but one of many decisions in recent years taking different approaches to evaluating whether a class may be certified when some of the proposed class members have not suffered an Article III injury. And this issue frequently arises in large life science, health care, and pharmaceutical cases. A decision is expected from the U.S. Supreme Court by the end of June 2025.

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The False Claims Act, health care, and AI-related risks

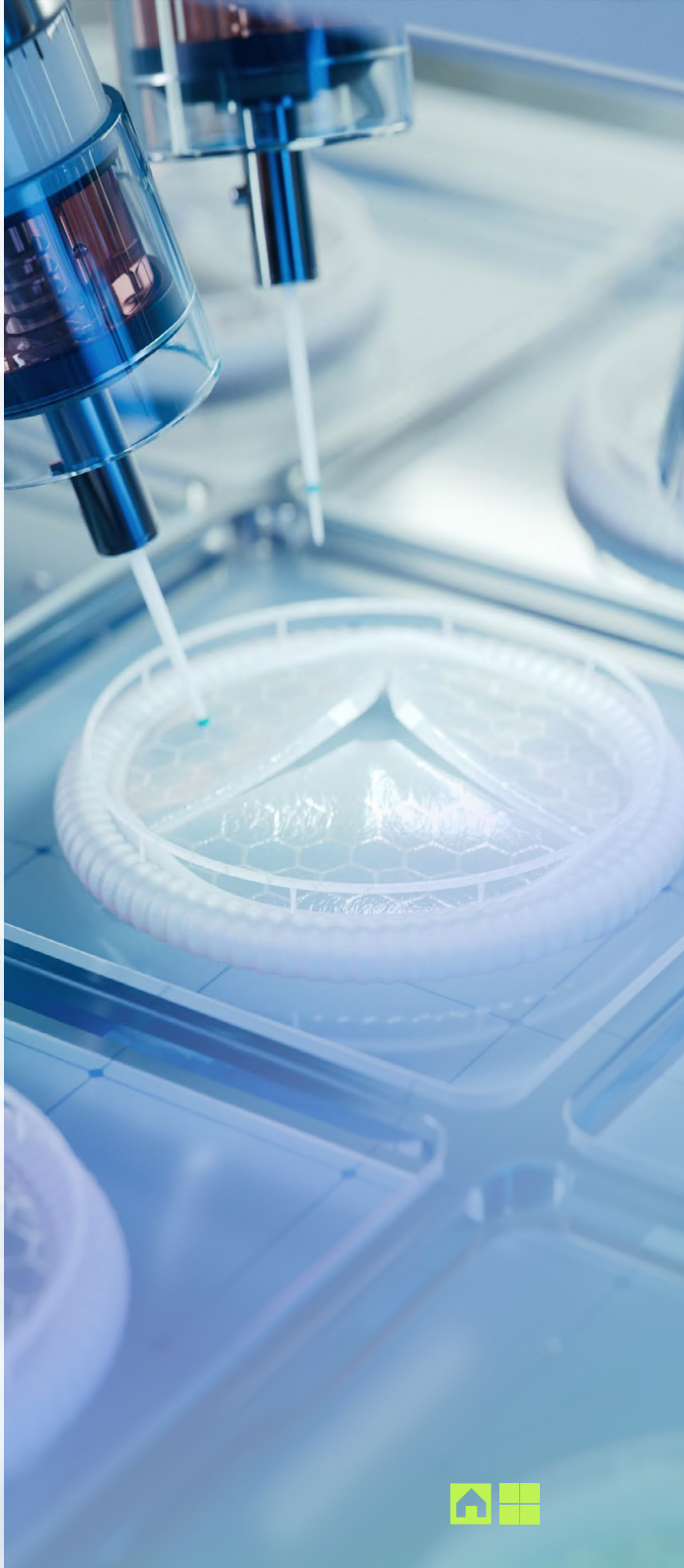
As artificial intelligence (AI) develops, its use in the health care sector creates new risks and benefits. The technology is evolving quickly, and its increased utilization has grabbed the attention of regulators and lawmakers. In the past several years, the Department of Justice (DOJ) intervened in False Claims Act (FCA) qui tam actions alleging that providers used AI to generate false diagnosis codes submitted under Medicare Advantage.[4] And in 2024, the U.S. Senate Subcommittee on Investigations released a report on the "proliferation of information resources, assessment tools, and organizations that [make] case-by-case review of proposed services feasible on a large scale." [5]

AI in health care has rapidly developed from a more predictive technology that uses machine learning (ML) to identify patterns and implement them in future coverage determinations, to the advanced ability to produce convincingly human work product that generates new content based on provider input. Previously, companies used predictive AI to output codes assigned to billing claims. Now, AI demonstrates a greater ability to review a patient's medical records, compare to a large swatch of data on diagnoses, and offer a completely new conclusion for the patient's care. With AI doing more tasks independently instead of in support of human workers, this transition raises the potential for government enforcement.

Using AI in health care where government programs require precise recordkeeping creates unique FCA risks. New technology does not necessarily require new theories of liability. The government and relators can still rely on certification and false statement theories to pursue companies using AI to generate or submit false claims. If a health care provider expressly or impliedly certifies compliance with legal requirements when submitting government claims – including, for example, certifying the services billed were performed or were performed accurately despite the use of AI – and the provider was mistaken, FCA enforcement could follow.

For now, litigation on algorithms leading to the submission of false claims is largely nonexistent.[6] DOJ has, however, increased its warnings towards companies and individuals using AI, which could be a preview for enforcement to come. In July of 2024, for example, the Criminal Division of the DOJ submitted its annual report to the U.S. Sentencing Commission, which recommended enhanced penalties for defendants who use AI.[7] DOJ expressed its concern that AI "can make crimes easier to commit; amplify the harms that flow from crimes once committed; and enable offenders to delay or avoid detection." Its recommendation includes a Chapter 3 enhancement for the misuse of AI during commission of an offense, which involves an increased penalty separate from a sophisticated-means or special-skill enhancement. Companies should not ignore the DOJ's increased focus on AI and criminal activity: while the FCA is a civil statute, the government can also bring a parallel criminal action. If not properly monitored and audited, AI technology could lead to new FCA actions under the same familiar theories.

Resource: The False Claims Act Guide: 2024 and the road ahead



[4] See, e.g., https://www.justice.gov/opa/pr/government-intervenes-false-claims-act-lawsuits-against-kaiser-permanente-affiliates (Osinek v. Permanente Medical Group, 640 F. Supp. 3d 885 (N.D. Cal., 2022)).

[5] See, https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf.

[6] The consolidated Kaiser Permanente case, which led to partial government intervention, is the only standout FCA enforcement involving AI. See, https://www.justice.gov/opa/pr/government-intervenes-false-claims-act-lawsuits-against-kaiser-permanente-affiliates (Osinek v. Permanente Medical Group, 640 F. Supp. 3d 885 (N.D. Cal., 2022)).

[7] See, https://www.justice.gov/criminal/media/1362211/dl?inline.

The False Claims Act, health care, and AI-related risks (continued)

The rapidly evolving AI technologies also present unique opportunities. Companies harnessing this advanced technology to accelerate their business interests can – and should – use the technology to avoid FCA liability. The DOJ has urged companies to identify and mitigate AI risks through their compliance programs. In its updated guidance for the Evaluation of Corporate Compliance Programs (ECCP), the DOJ indicated it will now evaluate how companies manage AI-related risks in both their business and compliance program.[8]

This update creates both positives and negatives for companies using AI, but if compliance programs are improved with the ECCP in mind, the benefits are two-fold. First, companies can deploy algorithms to more efficiently assess their compliance with government regulations. Second, in the event of an investigation or potential FCA liability, companies can point towards their compliance program's ability to manage AI-related risks. Even if a company's own technology led to an alleged FCA violation, they can demonstrate a lack of knowledge or reckless disregard based on their compliance system's identification of AI risks.

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[8] See, https://www.justice.gov/opa/speechprincipal-deputy-assistant-attorney-general-nicole-m-argentieri-delivers-remarks-society. The DOJ will consider technologies companies use to operate and whether they have both considered and mitigated the risks associated with those technologies.

Product liability in the EU for AI-powered medical devices

Current European Union (EU) product liability law and industry-specific regulations, including the Medical Device Regulation (MDR), were primarily designed for traditional medical devices that rely on predictable algorithms and well-established protocols. In contrast, AI-powered medical devices are often highly complex, interconnected with other devices and utilize machine learning (ML) algorithms that can autonomously evolve over time as they process new data. This complexity introduces new product liability challenges, including the risk of algorithm bias, device hallucination, and software malfunctions.

To address these regulatory challenges in the era of AI, the EU legislature has particularly enacted Regulation (EU) 2024/1689 (AI Act) and amended the EU Product Liability Directive (EU) 2024/2853 (PLD), which took effect on 01 August 2024 and 08 December 2024, respectively. In addition, the EU Commission had also announced a specific AI liability directive, which provided for certain simplifications of the burden of proof. However, in February 2025, the Commission has unexpectedly withdrawn this legislative initiative.

The AI Act establishes harmonized rules for AI systems across various sectors, including medical devices, following a risk-based approach. AI systems deemed to pose an unacceptable risk are prohibited, while those classified as limited risk must meet transparency requirements. For low-risk AI systems, only voluntary codes of conduct apply. AI-powered medical devices, which are typically classified as high-risk AI systems, must undergo a conformity assessment before being placed on the EU market. Furthermore, the AI Act introduces additional obligations beyond those under the MDR, including requirements concerning data governance, transparency, and human oversight.

The obligations set forth in the AI Act will be introduced progressively. Although the general application date is scheduled for 02 August 2026, conformity assessments for high-risk AI systems will not commence until 02 August 2027. Stakeholders will need to perform a gap analysis to identify their existing AI technologies, categorize them by risk level, and incorporate the additional requirements under the AI Act into their governance framework. At the same time, stakeholders must adhere to sector-specific requirements under the MDR, particularly when these obligations are more stringent than those outlined in the AI Act, as is the case with reporting requirements for (potential) incidents with serious consequences.

Product liability in the EU for AI-powered medical devices (continued)

The revised Product Liability Directive (PLD) updates and enhances the EU's legal framework for product liability, with a particular focus on addressing the challenges posed by emerging technologies and digital products. In the absence of a specific liability regime for medical devices, the Medical Device Regulation (MDR) refers to both EU and national liability laws and thus also to the revised PLD. The revisions significantly increase liability risks, with notable changes including an expanded definition of "product" to include digital manufacturing files and software, which explicitly encompass AI, a broader list of potentially liable parties, and new criteria for determining product defectiveness, such as interconnectedness and ML capabilities. Additionally, the revised PLD simplifies the process for injured parties to prove liability by easing the burden of proof and introducing legal presumptions of defectiveness and causation, especially if the probability is too complex due to the nature of the product, as it will be in particular with AI. Given these new rules, future product liability cases will involve more complicated defenses, and manufacturers will need to be prepared to provide technical documentation during legal proceedings due to changes in the evidence requirements.

To navigate this complex regulatory landscape, stakeholders should implement risk mitigation measures to safeguard against potential liabilities. It is essential to create an AI governance strategy with clear guidelines for developing, deploying, and monitoring AI systems to ensure compliance with regulations and ethical standards. AI governance should encompass continuous monitoring, comprehensive documentation, and secure data storage. It should also include a robust response plan for potential issues and ensure regular employee training to maintain adherence to AI regulations and safety standards. Stakeholders are advised to address liability risks by incorporating clear contractual clauses that outline their responsibilities and provide safeguards against disproportionate claims due to unexpected situations. Moreover, securing specialized insurance early on can safeguard against litigation expenses and liability claims.

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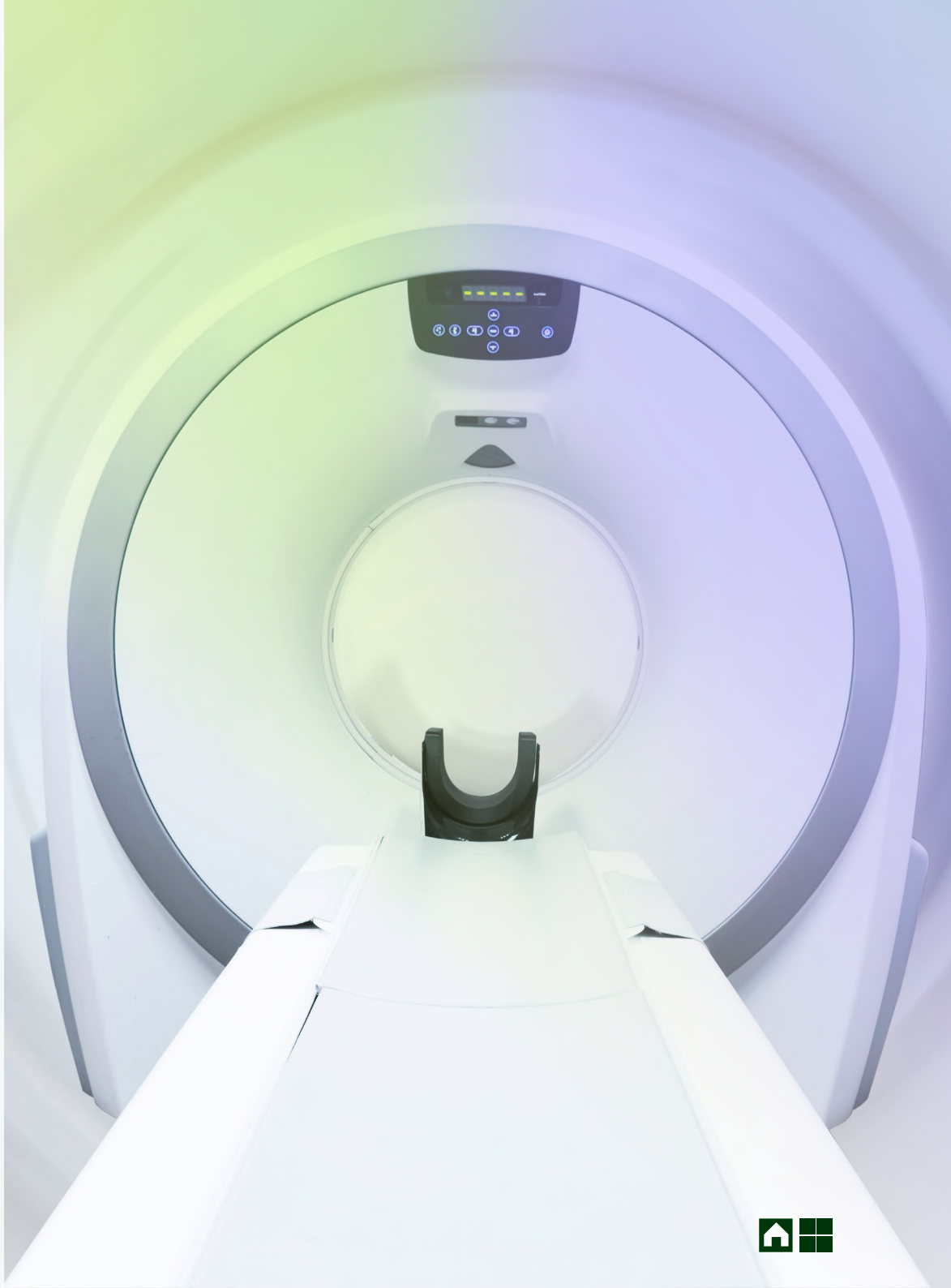

PL directive liability extended to many economic operators in the EU

The PL Directive aims to improve the effectiveness of the consumer's right to compensation by broadening both the concept of the product and the responsibility for defective products. Now, any manufacturer involved in the production process can be held liable if their product or component is defective. Article 8 of the PL Directive replaced the reference to "manufacturer" with a list of responsible "economic operators," including: the product manufacturer, the manufacturer of a defective component, the importer, the authorized representative, the logistics service provider, and the distributor. However, the latter are only liable if they fail to designate an economic operator or their own distributor.

The PL Directive also imposes liability on any provider of an online platform that allows consumers to conclude distance contracts with traders, unless they identify an economic operator established in the EU. Online platforms acting solely as intermediaries are exempt from liability unless they mislead consumers into believing that the product is supplied by the platform itself or by a trader under its control.

The aim is to ensure that all consumers in the EU are protected, and can rely on the jurisdiction of Member States. Consumers can take action against any entity that holds itself out as the producer, and uses any distinctive element that may give the impression that it has been involved in the production process, pursuant to recitals 36 and 38.

The Court of Justice of the European Union (CJEU) has supported this approach in its judgment of 19 December 2024, interpreting that a supplier of a product can be held liable if their name or a distinctive element is identical to that of the manufacturer. The CJEU concluded that a supplier holds itself out as the producer if it benefits from the coincidence between their name and that of the producer, thereby creating in the consumer a confidence similar to that which it would have if the product were sold directly by the producer.

In summary, both the 19 December CJEU judgement and the new PL Directive aim to extend consumer protection and ensure that products are linked to European legislation by extending liability to all economic operators that are involved in production and distribution, and those presenting themselves as producers within the EU.

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Product liability directive burden of proof lowered

The main objective of the PL Directive is to guarantee the right to compensation in an effective and harmonized way. To this end, significant changes have been made to reduce the burden of proof on claimants by establishing specific presumptions as set out in recital 46. Article 10 deals with these presumptions in two aspects: defect and causal link.

A defect is presumed to exist where:

- the defendant fails to comply with the obligation to disclose documentation under Article 9;
- the product does not comply with the mandatory safety requirements laid down in national or EU legislation, such as Regulation (EU) 2023/988; and
- the damage occurs as a result of a malfunction during the normal or foreseeable use of the product. In addition, a causal link is presumed where, once it is established that a product is defective, the nature of the damage is consistent with that defect.

Article 10 is particularly worrying because it provides that, even if the defendant has provided information on the product, the defect must be presumed if it remains excessively difficult to prove the defect or the causal link, or if it is "probable," at the discretion of the national court, that the product is defective. Recital 48 justifies this measure as a way of prioritizing the right to compensation in view of the technical or scientific difficulty of proving the defect or the causal link.

This measure raises a legal debate as to when it is considered "excessively difficult" to prove the defect and the causal link, even if the defendant has disclosed information proving the absence of the defect or the causal link. The harmonization intended by the Directive is not complete, as such important presumptions depend on national law, and their application varies from one Member State to another.

For example, the Spanish Supreme Court ruled on 1 March that a product was defective because it did not offer the expected level of safety, on the basis of a health warning issued by the manufacturer, the voluntary withdrawal of the product and tests carried out in accordance with the manufacturer's recommendations. The Supreme Court held that the "concept of expected safety" was not satisfied, and thus assimilated product liability to strict liability. Similarly, the European Court of Justice (ECJ) ruled in its judgment of 5 March 2015 (Joined Cases C-503/13 and C-504/13).

Moreover, this presumption may render Article 9 meaningless, as the national authority will have to presume the damage, despite the defendant disclosing the requested information, if the product is technically or scientifically complex.

Given the increasing technical complexity of the products covered by the PL Directive, this presumption allows claimants to obtain compensation with a lower burden of proof, effectively reversing the burden of proof on the defendant. This creates legal uncertainty for responsible economic operators (Article 8), as it will depend on the discretion of each court, tilting the balance in favor of the plaintiff and reinforcing strict liability.

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EU clarifies regulations governing online medical product sales

The recent CJEU ruling on regulation of third-party platforms involved in the online sale of medicinal products (Case C-606/21, issued September 21, 2023) marked a pivotal moment for online health platforms in the EU. The Court clarified that such platforms, when their services are distinct from the sales process managed by pharmacies, qualify as "information society services" under EU law.

While outright prohibitions or unjustified restrictions on these platforms are not permitted, EU Member States have retained the right to enforce measures aimed at "protecting public health," provided these are "proportionate" and "non-discriminatory." Member States can impose limits, but only if they demonstrate that no less restrictive alternatives exist.

The ruling emphasizes that platforms providing specified and distinct services from the sales process are protected under EU principles governing the internal market. However, these services must not interfere with the independent role of pharmacies as the sole sellers.

Pharmacies and third-party platforms must therefore adopt a business model consistent with the CJEU ruling and the regulations of the individual Member States involved to avoid regulatory challenges and litigation. Particular attention must be paid to how the entire sales process is structured and managed, the roles of the pharmacy and the platform, the configuration of the website, interactions with customers, and other factors that could impact compliance with the law as interpreted by the ruling.

The ruling also creates significant opportunities for both platform providers and pharmacies. Platforms can now safely expand their service offerings in compliance with the law. Pharmacies, while facing increased competition, also have new opportunities to reach a broader customer base, innovate their operations, and integrate digital tools into their business models. By leveraging these opportunities, pharmacies can not only safeguard their market position but also enhance their service offerings to better meet evolving consumer needs.

The CJEU decision is a milestone for digital transformation in the pharmaceutical sector. By clarifying the role of third-party platforms, it opens new avenues for innovation while balancing public health priorities.

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EAEU compulsory licensing: Spot and address threats

Compulsory licenses remain a matter that requires constant monitoring in Eurasian Economic Union's (EAEU) countries.[9] While the governmental compulsory licenses have been exceptional to date, they have also been sought by generic drug ("Gx") producers before the courts due to patent non-use or insufficient use, or based on dependent patents.

Proactive monitoring may substantially help in shielding originators from potential compulsory license grants (e.g., by proceeding with a patent invalidity claim against "dependent" patents filed by Gx producers when the relevant patent application is granted. Equally important remains proactive reaction to Gx producers' requests for licenses, because an originator's silence enhances the Gx's chance to obtain a compulsory license.

Addressing compulsory license requests can be accomplished in full compliance with applicable EU, UK, U.S., and other regulatory restrictions and limitations introduced against EAEU countries (such as Russia and Belarus); however, ignoring compulsory license requests makes originators vulnerable in the EAEU and beyond. This is partly because the EAEU region has the potential to become a manufacturing platform for supply of Gx products – not only to local distributors, hospitals, and patients, but also to those located in so-called "friendly" countries in Africa, Asia, and Latin America. The risk is very high for those countries where patent enforcement is not straightforward, where benefits of "launch at risk" are higher than the liability for patent infringement, or where compulsory licenses can be easily obtained.

Such business expansion, apart from respecting patent rights, will require Gx producers to obtain regulatory authorizations, both for export and import of the pharmaceutical products; therefore, when monitoring Gx activities in the EAEU, it is wise to do so in parallel with regulatory efforts in EAEU friendly countries such as India, China, and Brazil. However, depending on local laws, export of pharmaceutical products can be accomplished without obtaining marketing authorization in the importing country (e.g., if import is necessary for a particular patient due to vital indication).

Taken together, these factors highlight the importance of monitoring developments in the EAEU and taking action – while adhering to regulatory restrictions – to prevent requests for compulsory licenses for the manufacturing of Gx products in the EAEU.

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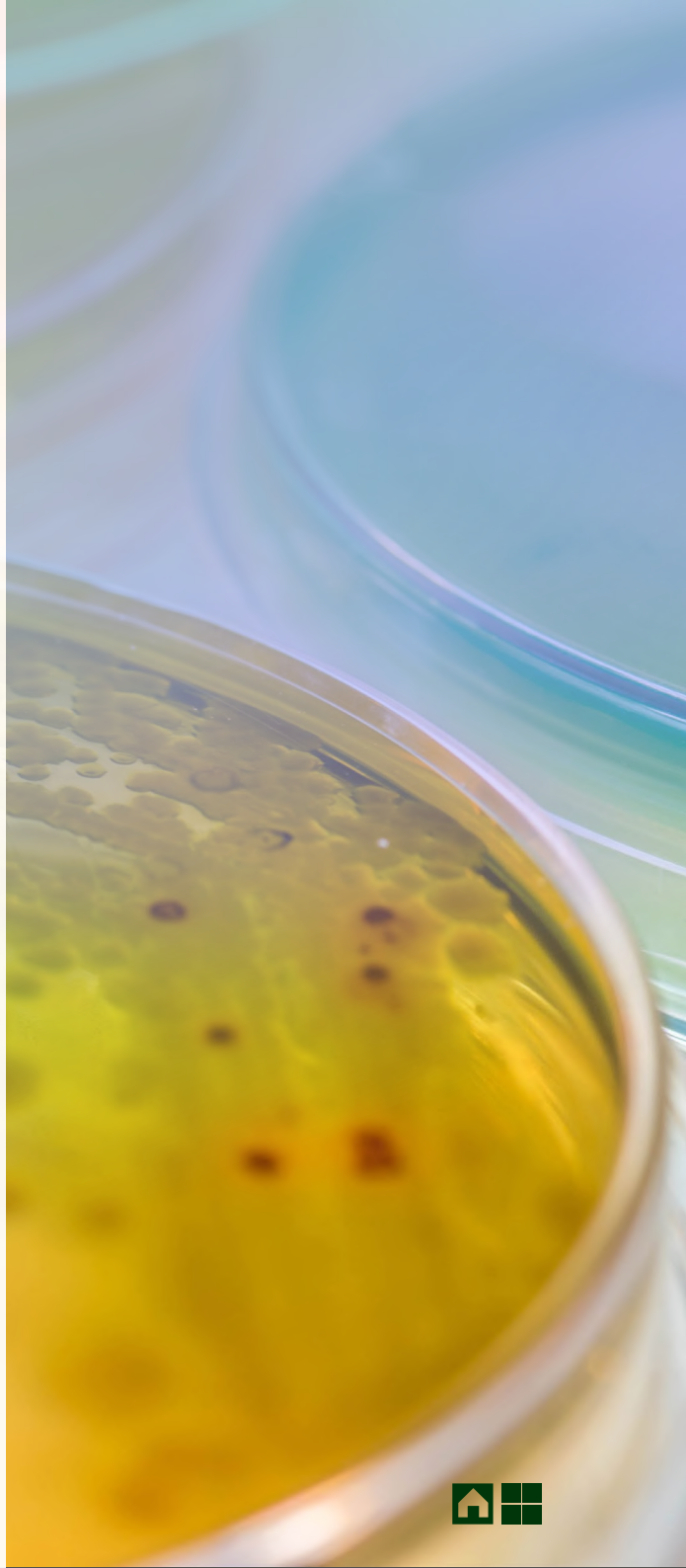

[9] EAEU single pharmaceutical market includes Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia and continues to provide for a simplified generic marketing authorization approval for the EAEU member states.

Patent litigation rising in Japan as linkage system evolves

In Japan, "originator versus generics" patent litigation cases continue to rise, and we expect the non-statutory "patent linkage" system to evolve further in 2025 and beyond, especially in respect of the grant of marketing authorizations for generic products.

In essence, Japan's "patent linkage" system delays the grant of marketing authorizations for a generic product until there are no relevant originator patents covering such product (due to the relevant patents expiring or being invalidated). The main objective of the system is to prevent potential disruption to a stable supply of pharmaceutical products to the Japanese market, which may occur, for example, if an originator company successfully obtains an injunction against an approved generic product through patent infringement proceedings.

Recent issues have related to the nature of "relevant originator patents" – which has generally been understood to mean patents that cover, for instance, the active ingredient or a specific indication – and the regulator's apparent readiness to grant generic marketing authorization in certain cases. Notably, we understand that the regulator may reach its own view on the scope of originator patents, and does not examine their patentability, which can potentially lead to complications.

Unlike other jurisdictions, Japan's patent linkage system is based on notifications from the government, which creates both flexibility and uncertainty from which a number of generic companies appear to have benefited in the past few years. In particular, the regulator recently approved generic versions of two or more drugs the active ingredients of which may still have been protected by relevant patents or patent term extensions. In one case, a preliminary injunction order was granted promptly after the grant of such generic marketing authorization; at least one other case is ongoing. Once those cases are fully resolved, there may be important changes to the regulator's practice in the future in favor of originators and patentees, and also potentially regarding the scope of patent term extensions.

Finally, we have observed a number of biologics and biosimilar patent cases continuing to be the subject of dispute resolution in Japan, somewhat mirroring cases in the U.S. and Europe. It remains unclear whether the Japanese courts will take similar positions on these issues to courts' conclusions elsewhere. For instance, regarding antibody patenting, Japan's current approach appears to be more similar to Europe's than to the position taken in the U.S., in that the Japan Patent Office tends to focus on the new functions or properties of a claimed antibody in determining "inventiveness" or "non-obviousness". Notably, expert evidence seems to have made a significant contribution in certain disputes.

We expect that the number of biologics patent cases will increase in coming years, and therefore suggest carefully tracking and analyzing the practical implications of relevant changes as they arise.

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APAC.

9

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Japanese life sciences industry poised for change

The Life Sciences industry in Japan is poised for significant developments in 2025, influenced by global trends, geopolitics, and domestic factors. We anticipate the following areas may be especially active in the year ahead.

Regulatory changes and compliance

As set out in more detail on page 72, Japan's regulator (the Ministry of Health, Labour and Welfare (MHLW)) has been focused on addressing "drug loss" and "drug lag", and restoring and enhancing the Japanese market's attractiveness; for example, the MHLW is encouraging simultaneous global development of drugs.

There are renewed efforts to improving the drug discovery infrastructure in Japan. We recommend closely monitoring regulatory developments to facilitate smoother product approvals and market entry and to minimize the risk of non-compliance with evolving regulations.

Digital transformation and AI integration

Japan is embracing digital transformation, and we expect further implementation of digital technologies, especially wearable technology and personalized data-driven care. We also anticipate growth in generative AI, with companies seeking to enhance operational efficiencies, drive innovation, and improve patient outcomes.

Cybersecurity threats and data breaches remain on-going risks. In addition to periodic relevant "health checks," we recommend continual assessment of compliance with applicable laws and regulations, including rules related to the handling of data and strengthening cybersecurity, such as Japan's Act on the Protection of Personal Information.

IP litigation

We expect originator versus generics – as well as biologics versus biosimilars – patent litigation cases to persist for some time in Japan, as we analyze in more detail on page 69.

Interestingly, a number of generic companies appear to be benefitting from Japan's non-statutory "patent linkage" system and the regulator's apparent readiness to grant generic marketing authorization in certain cases (for instance, where a patent has been held invalid by the JPO but not all avenues of appeal have yet been exhausted and the decision finalized), potentially conflicting with the Japanese regulator's long-held position of ensuring a stable supply of pharmaceutical products to the Japanese market.

It remains prudent to carefully track the nuances of these on-going developments – particularly in the context of complex pharmaceutical patent litigation matters that span multiple jurisdictions – to ensure a coordinated approach that maximizes the likelihood of success in one of the world's largest markets.

Transactions

We expect strategic transactional activity (i.e. licensing and M&A) to increase in Japan as companies seek growth, diversification, and enhanced competitive positioning. Recent trends include interest by private equity companies and activist efforts.

The key risks to cross-border transactions remain geopolitical disruptions, fluctuating valuations, and regulatory uncertainties, some of which may be managed through effective and targeted due diligence, as well as a meaningful assessment of geopolitical risks and complex regulatory landscapes.

Personalized medicine, genomics, telemedicine, and remote health care services

We expect that Japan will continue to encourage advances in genomics and tailored therapies, which may improve treatment efficacy and patient satisfaction. We also predict that Japan may continue to expand telemedicine services following certain relaxations that occurred during the COVID-19 pandemic.

We recommend being especially mindful of evolving regulatory, telemedicine, and compliance changes, especially in respect of data privacy rules and those governing the handling of sensitive genetic information.

Navigating these trends requires a proactive approach, including staying informed about regulatory updates, investing in compliance and cybersecurity measures, and planning ahead to mitigate risks effectively.

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Japan aims to accelerate regulatory approvals, promote innovation

We anticipate that Japan will become an increasingly attractive market for innovative international companies, particularly in the light of recent proposals and changes to the country's regulatory and pricing system.

After a few years of advocacy for suitable pricing (e.g., for the "price maintenance premium system") for innovative drugs, improved commercial predictability, and enhanced transparency, the Japanese government and regulator appear to be making a concerted effort to eliminate "drug lag" (i.e., products being approved and launched in Japan much later than in the U.S. and Europe) and "drug loss" (i.e., products approved in the U.S. and Europe but then not reaching Japan at all). The regulator has introduced various initiatives to incentivize market participants, which may be partly catalyzed by on-going demographic pressure and the need for cost efficiencies.

Specifically, in 2024, various changes have meant that, for example, products benefiting from the price maintenance premium do not suffer reductions in their list price, and there are pricing incentives to introduce new drugs to Japan earlier. As a result, we predict that a range of companies will now be keen to bring more innovative products to Japan; some commentators are further predicting a virtuous cycle, especially as the Japanese government commits more generally to improving the drug discovery infrastructure in Japan.

Some of the specific areas of improvement include:

- a simplification of development requirements;
- accepting regulatory applications in English (for applicants not established in Japan);
- accelerating the cycle for regulatory approvals;
- establishing a drug development hub to encourage foreign start-ups to come to Japan; and
- an "innovation box" tax break and other financial incentives, especially for venture capitalists and overseas investors, as the Japanese government seeks to double private investments in domestic drug discovery start-ups in the next five years.

Overall, Japanese government initiatives to accelerate regulatory approvals and assist with regulatory processes are likely to lead to growth, innovation, and heightened opportunities in the next year ahead and beyond.

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China ups AI regulatory oversight to drive innovation while ensuring control

China's regulatory landscape for AI is evolving rapidly, reflecting the country's ambition to become a global technology leader while ensuring robust oversight and control to ensure that AI developments are in line with national interests. Since 2021, China has introduced several national regulations to govern AI technologies, including measures to address deep synthesis technologies, algorithmic recommendation technologies, and generative AI technologies.

China has also implemented an algorithmic record-filing mechanism, which requires deep synthesis, algorithmic recommendation, and generative AI service providers to register their AI algorithms with the Cyberspace Administration of China through the Internet Information Service Algorithm Record-Filing System. In June 2023 and May 2024, the General Office of the State Council twice announced plans to draft a comprehensive Artificial Intelligence Law in China.

Recognizing the potential of AI to revolutionize life sciences and health care, the Chinese government has integrated substantial support for innovation into its regulatory framework. This includes funding for AI-driven medical research and development and the establishment of an AI innovation center, as well as initiatives to construct smart hospitals, and to promote the use of AI in drug discovery, medical imaging, surgical robots, intelligent diagnosis, treatment planning, and personalized medicine.

Similar to the U.S., one of the most developed areas of application and regulation for AI in the life sciences space in China relates to AI-enabled software as a medical device (SaMD) and AI-enabled software as an integral component of a physical medical device (SiMD). In June 2022, the National Medical Products Administration (NMPA) issued the *Guiding Principles for the Registration Review of Artificial Intelligence Medical Devices* ("Guiding Principles"), which classifies AI software with less mature algorithm applications used for auxiliary medical decision as a Class III medical device; while AI software with mature algorithm applications used for non-auxiliary medical decisions is classified as a Class II medical device.

The Guiding Principles emphasize management of AI software medical devices throughout their entire life cycle, including:

- ensuring the quality and integrity of data used to train AI algorithms;
- developing robust and reliable AI algorithms;
- conducting thorough testing to validate the performance of AI algorithms; and,
- managing updates to AI software to maintain compliance and performance.

The NMPA's approach to AI-enabled SaMD and SiMD may provide a blueprint for future regulations in other areas.

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Band 1

Life Sciences in Japan and Asia-Pacific in Chambers Asia-Pacific, 2025

China strengthens support for CTGT development and products

Recent years have witnessed the rapid growth of Cell, Tissue and Gene Therapy (CTGT) treatments and products in China and around the globe. According to a report by the Center for Drug Evaluation under the National Medical Products Administration (NMPA) on 20 May 2024, a total of 81 clinical trials for cell and gene therapy products were registered in 2023, nearly doubling from 46 clinical trials in 2022. Looking ahead, this number is anticipated to continue to grow in 2025, with CTGT expected to remain a focal point of intense interest and development in the coming years.

On 7 September 2024, the NMPA, jointly with other authorities, issued the "*Notice on Carrying Out Pilot Programs to Expand the Opening-up in the Healthcare Sector*," which permits foreign-invested companies to engage in human stem cell, gene diagnostics and therapeutic technology development and application within free trade zones in Beijing, Shanghai, Guangdong, and Hainan for product registration and manufacturing.

Since then, local governments have been progressively rolling out supportive policies, facilitating the market entry of products derived from such cutting-edge technologies. For example, on 5 December 2024, the Hainan government issued the policy "*Provisions for Promoting Biomedical New Technologies in the Boao Lecheng International Medical Tourism Pilot Zone, Hainan Free Trade Port*," which has taken effect and provides a pathway for foreign companies or foreign-invested companies in China to convert biomedical technologies in cell and gene therapies into clinical applications through collaboration with medical institution(s) located in the Boao pilot zone, the results of which may be used as references in clinical trial applications. Qualified products that have been marketed abroad may be imported and applied in the Boao pilot zone, from which the real-world data can be used for drug registration in China.

The Beijing, Shanghai, and Guangdong governments, among others, have further emphasized their support for qualified engagement in human stem cell, gene diagnostics, and therapeutic technology development and application.

Despite these policies, foreign companies still face numerous challenges in China, including the ever-changing and increasingly complex legal environment, which particularly impacts lifecycle management and scientific ethics rules. Other challenges include competitive pressure from domestic pharmaceutical companies benefiting from lower prices and government support.

Moreover, China's escalating trade tensions with major economies like the U.S. and the EU may add another layer of complexity for technology transfer and export. Closely monitoring global policy changes and market dynamics will be essential for maintaining competitiveness and ensuring sustainable growth in this promising yet challenging region.


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China's patent linkage system: Key features and practical implications

China's pharmaceutical patent linkage system, introduced through reforms starting in 2021, has evolved rapidly, with numerous administrative rulings and civil judgments shaping its development. We have identified the following key features of the system:

- **Patent information registration platform.** China's Marketed Drug Patent Information Registration Platform (the "Platform"), akin to the U.S. Orange Book, requires drug marketing authorization holders (MAHs) to register patents within 30 days of receiving the MAH certificates. The Platform links Chinese patents for originator drugs to the MAH system (hence the name "patent linkage"), allowing innovators to register patent information related to their approved drugs. The National Medical Products Administration (NMPA) conducts only formal examinations, while MAHs are responsible for the accuracy of the information published on the Platform. Courts and the China National Intellectual Property Administration (CNIPA) will reject cases involving ineligible patents (e.g., chemical drug crystal forms) or if the drug's technical solution falls outside patent scope.
- **Patent declaration requirements and timeline risks.** Similar to the U.S. system, China requires generic applicants to notify MAHs of patent declarations and provide supporting evidence. For Type IV declarations (invalidity or non-infringement claims), MAHs have 45 days from the public disclosure of the drug marketing application to initiate civil litigation or request administrative adjudication. However, MAHs face risks due to (a) the lack of penalties for delayed notifications from generic applicants; and (b) the fact that the 45-day window starts from the public posting date, not when MAHs are notified.
- **Dispute resolution mechanisms.** Patent holders can resolve disputes over patent infringement through civil litigation at the Beijing Intellectual Property Court or administrative adjudication at CNIPA. Civil litigation offers interim injunctions if a case is not resolved within nine months, whereas CNIPA's process is quicker and benefits from technically trained examiners.

For innovative pharmaceutical companies and patent holders operating in China, the key takeaways are:

- **Timely registration:** Register patents promptly on the Platform to ensure access to the early dispute resolution mechanism and protect rights effectively.
- **Strategic patent selection:** Choose patents carefully to avoid ineligible types and ensure the patent covers the drug's technical solution.
- **Vigilant monitoring:** Monitor public notifications of generic drug applications to manage litigation or administrative adjudication timing effectively.
- **Appropriate dispute resolution:** Select the best dispute resolution method based on the case's specifics to protect patent rights.

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China's draft medical devices law unveiled

On 28 August 2024, the National Medical Products Administration, China's equivalent of the U.S. Food and Drug Administration, issued the Medical Device Administration Law (Draft for Comments) (the "Draft MDL") for public consultation. This marks a significant legislative upgrade for the sector, elevating medical device regulation from lower-level administrative rules issued by the industry regulator to the much higher status of formal law, reflecting the industry's rapid growth, the need for a modernized regulatory framework, and perhaps, a reflection of the many compliance issues identified in the sector in recent years. Below is an overview of the notable developments introduced by the Draft MDL.

Transferability of registration certificates

Addressing a long-standing gap in the current regulations, the Draft MDL expressly permits the transfer of a medical device registration certificate. Article 58 of the Draft MDL allows the registrant to transfer a certificate subject to obtaining regulatory approval; *provided* the transferee meets safety, quality, and risk control standards. This change will facilitate industry consolidation – providing new structuring options by way of asset transfer, rather than share deal – and enhance operational efficiency allowing companies to fine tune their portfolios by way of exchange or transfer to meet changing market demand.

Redesign of domestic agent system

Under the Draft MDL, the "domestic agent" system for imported devices is to be revamped, with the former agent now renamed "domestic responsible person" (in Chinese: 境内责任人). Article 88 of the Draft MDL bolsters the agent's compliance obligations for imported devices, making them jointly liable with the overseas registrant. This shift strengthens oversight and ensures greater accountability in product quality and compliance management for imported devices.

Establishment of medical device vigilance system

Article 107 of the Draft MDL introduces a medical device vigilance system to monitor adverse events and other harmful incidents, aligning China's approach with international standards. The expanded scope includes quality issues and device interactions, emphasizing proactive risk management.

Encouragement of multi-center clinical trials

The Draft MDL streamlines multi-center clinical trials within China, allowing participating institutions to carry out abbreviated ethics reviews after the lead institution has given its approval. It also encourages international trials, and provides for accepting foreign data that meets Chinese registration requirements, thereby fostering global collaboration.

Support for medical device innovation

The Draft MDL emphasizes innovation, promoting interdisciplinary research and collaboration among companies, universities, and medical facilities. It codifies the special review process for innovative devices and encourages coordinated development across health care, insurance, and pharmaceutical sectors to support adoption.

Increased penalties

Penalties for violations are significantly increased, with higher fines and the introduction of administrative detention for severe offenses, such as unauthorized manufacturing of Class II or III devices.

The Draft MDL reflects China's commitment to "high-quality development" in its medical device sector. While the changes present compliance challenges and costs, they also offer opportunities for companies that proactively adapt, as it may remove from the market those who cannot or will not meet the new requirements.

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China issues new rules on domestic responsible persons

On 13 November 2024, China's National Medical Products Administration (NMPA) issued the "Management of Domestic Responsible Persons Designated by Overseas Drug Marketing Authorization Holders Interim Provisions" (the "Interim Provisions"), which will come into effect on 1 July 2025. The Interim Provisions are designed to enhance regulatory oversight of overseas marketing authorization holders (MAHs) and their designated domestic agents, ensuring accountability across the life cycle of imported drugs.

A domestic responsible person (DRP) is a legal entity registered in China required to be designated by the overseas MAH to assume joint responsibility for performing drug marketing authorization obligations within China. Broadly speaking, the DRP shares responsibility with the MAH for ensuring compliance with local laws, regulations, and rules in China.

To qualify as a DRP, an entity must:

- Be a Chinese-registered legal entity;
- Have in place a quality management system aligned with the MAH's obligations;
- Maintain dedicated personnel for drug quality oversight; and
- Have suitable office facilities;

Failure to meet these conditions will result in the suspension of the sale or import of the overseas drug, with provincial-level NMPA responsible for enforcing these compliance requirements.

The DRP must be designated prior to importation of the drug into China. Each drug can only have one designated DRP in China, although the same DRP may represent multiple overseas MAHs or drug products.

The DRP will be responsible for performing several key obligations, including:

- Ensuring drug quality and safety and establishing postmarket quality assurance systems;
- Implementing traceability systems and submitting annual reports on sales, postmarket research, and risk management;
- Managing drug registration changes, renewals, and recalls; and,
- Monitoring adverse drug reactions and coordinating with NMPA for inspection and enforcement.

Starting from 1 July 2025, the DRP's name, address, and contact details, must be included in the drug's packaging insert. This means that DRPs are likely to have a much more consumer-facing role than previously.

The Interim Provisions underscore China's growing commitment to ensuring the safety and regulatory compliance of imported drugs. Overseas MAHs must carefully assess their compliance strategies and designate a qualified DRP in China that can meet these new requirements. For MAHs that already have DPRs, they should audit their existing stable and verify their compliance with the new criteria. This may result in a shake-out of current DPRs. The incumbent DPRs may also seek different commercial terms based on the costs of complying with the new requirements.

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Volume-based procurement: Is the reward worth the risk?

To control health care costs and ensure affordable access to medications and medical devices, the Chinese government has developed a volume-based procurement (VBP) program covering medicines, high-value medical devices, and medical consumables. The procurement process, led by the National Health care Security Administration (NHSA), involves competitive bidding, with the lowest bidders securing contracts to supply large volumes of products in exchange for significant price reductions.

Supply Commitments

For drug procurement, NHSA normally organizes procurement on behalf of public and military medical institutions across various provinces and other provincial administrative regions, including the Xinjiang Production and Construction Corps.

Once a pharmaceutical company wins the bid, it must enter into supply and sales contracts with designated medical institutions, committing to deliver the agreed quantities.

Caught in U.S. China Crosshairs

However, some purchasing entities in the VBP program may be subject to U.S. sanctions imposed by the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC). If an entity is placed on the Specially Designated Nationals and Blocked Persons List by OFAC (such entity, the "SDN"), U.S. persons will be prohibited from engaging in transactions with the SDN, as well as any entities owned 50% or more (directly or indirectly) by the SDN. This means that participation in the VBP program could constitute a violation of OFAC rules unless a license or waiver is secured beforehand.

On the other hand, if a winning pharmaceutical company opts to withdraw from the VBP program to avoid potential sanctions violations, it could face consequences under Chinese law, including:

- *Breach of Contract:* Failing to fulfill contractual obligations.
- *China's Countermeasures:* Potentially being viewed as taking discriminatory actions against Chinese parties, which is a violation of China's *Anti-Foreign Sanctions Law* and regulations such as the *Provisions on Unreliable Entity List*.

Item (b) will attract punitive measures against the winning bidder, which we previously detailed in our articles: "China Passes the Anti-Foreign Sanctions Law, Adding More Legal Tools to Countermeasure Foreign Sanctions and Interference," and "China reveals the Provisions on Unreliability Entity List."

Given the current geopolitical and macroeconomic climate, a thoughtful analysis of the political and regulatory considerations should be conducted before any proposal to participate in the VBP program.

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Key reforms in the United Arab Emirates

The United Arab Emirates (UAE) recently introduced a number of significant reforms at both the federal and Emirate level. These changes highlight the UAE's commitment to the continuous improvement of its regulatory framework to keep pace with the rapid growth of the health care sector:

- **New Pharmacy Law:** Federal Decree-Law No. 38 of 2024 (the "New Pharmacy Law") came into force, repealing its predecessor and reforming the regulation of medical products and pharmaceutical practices in the UAE. Notably, the New Pharmacy Law highlights the movement of regulatory responsibilities from the Ministry of Health and Prevention (MoHAP) to the newly established Emirates Drug Establishment (EDE), marking a significant evolution in the federal UAE health care framework. The EDE will regulate pharmacological research, register medical products, and manage marketing approvals.
- **New Federal Genomics Law:** Effective 1 December 2023, Federal Law No. 49 of 2023 established a comprehensive framework to regulate genomic data use across the UAE. Among other things, it regulates consent requirements and bans genome alteration and human cloning.
- **New Mental Health Law:** Coming into force in 2024, Federal Law No. 10 of 2023 regulates the relationship between psychiatric patients and health care providers, and outlines licensing requirements for mental health services.
- **National Standards for Home Health care Services:** MOHAP Resolution No. 40 of 2024 established national standards for home health care services and regulates registration requirements, staffing, safety and rights, and the use of remote monitoring equipment.
- **New and Updated Department of Health Abu Dhabi (DOH) Policies and Standards:** Including version 2 of the DOH Standard for Provision of Home Health Care Services, version 2 of Abu Dhabi Health Care Information and Cyber Security Standard (ADHICS), new Accreditation Standards for Health Care Facilities (Hospitals), new Policy on Biobanking, new Guidelines for Clinical & Translational Research in Genomics, new Guidelines for Clinical & Translational Research in Stem Cells, and a new Standard for Continuing Professional Development for Health Care Workforce.
- **New and Updated Dubai Health Authority (DHA) Policies and Standards:** Including a new Policy on Do Not Resuscitate, and a new Policy for Health Data and Information Sharing.

Looking to 2025 and beyond, we expect continued rapid growth in the health care sector, with a particular focus on the growth of digital health supported by regulatory frameworks that encourage telehealth and the expansion of electronic health records. We also expect the EDE, which is currently transitioning responsibilities from MOHAP, to become fully operational as the primary regulator of pharmaceuticals, medical devices, and clinical trials in the UAE, with new guidelines expected to be published soon.

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Cross-Jurisdictional.

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The hospital as a global institution

Hospitals continue to expand their global footprint. Demand for high-quality health care combined with innovative technology have generated worldwide opportunities for health care providers. This trend shows little signs of slowing in 2025, as hospitals race to establish collaborations that boost their global footprint and revenue.

Global advisory and consulting projects: Governments and companies continue to make deep investments in health systems infrastructure, especially in the Middle East. Respected hospitals are tapped to advise and consult internationally on best practices in clinical operation, care models, and quality initiatives, and to help guide establishment of new health care institutions.

Global telemedicine: Remote second opinions, virtual services, and hospital-to-hospital telemedicine collaborations continue to flourish across borders, even five years after the pandemic accelerated virtual caregiving.

Global patient services: Revenue is mounting from international patients, particularly from individuals who seek to travel for specialist "western" clinical services. Hospitals increasingly engage cross-border employees, independent contractors, and marketing firms to socialize their in-patient specialties and liaise with current and prospective patients.

Global data initiatives: Multi-country transactions are underway to consolidate and monetize rich repositories of patient data. As global data privacy regimes proliferate, data-oriented transactions are complex, but they hold great promise for the future of digital health.

Global research: Global medical research and clinical trials are imperative in the modern health care ecosystem. Tracking regulatory regimes across clinical research, insurance, pharmaceuticals, devices, and more is a full time affair. Research security and inappropriate "foreign influence" also will receive mounting attention under the new U.S. presidential administration.

Global clinical services: Physicians are daily traveling abroad for stints as "visiting physicians" at foreign institutions or to backfill staffing at foreign locations. These programs often stem from revenue-generating cooperations between hospitals and foreign governments.

Global education and training programs: Observerships, capacity building, and workshops for health care professionals are being conducted at home and abroad to foster teambuilding and to elevate patient care.

As hospital budgets continue to come under pressure, the zeal for international activity remains strong. Hospitals operating across borders should be mindful of complex legal challenges of international projects. Navigating the laws and regulations of multiple jurisdictions – including employment, tax, research, privacy, IP, and contracts regimes – is imperative as hospitals evolve into truly global enterprises.

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EU MDR/IVDR and U.S. FDA harmonization & global regulatory alignment

Medical device companies operating in both the U.S. and Europe face increasing challenges due to significant regulatory differences between the U.S. Food and Drug Administration (FDA) and the European Union's Medical Device Regulation (MDR) & In Vitro Diagnostic Regulation (IVDR). While FDA has long maintained a structured and predictable framework for medical device approval, the EU's transition from the older Medical Device Directive (MDD) and In Vitro Diagnostic Directive (IVDD) to the MDR and IVDR has introduced stricter clinical evidence requirements, enhanced postmarket surveillance, and a more complex CE marking process. These changes have lengthened conformity assessment timelines and created hurdles for manufacturers looking to maintain market access in both regions, requiring greater strategic planning and regulatory expertise to navigate the evolving landscape.

To address these challenges, global regulatory bodies, including the International Medical Device Regulators Forum (IMDRF), are working toward harmonizing medical device regulations. The goal is to reduce redundant compliance efforts, streamline approval processes, and ensure that devices meeting high safety and performance standards in one region can more easily gain approval in another. However, despite progress, key differences remain in classification, clinical evaluation requirements, postmarket surveillance, and software regulations, making dual compliance a costly and time-consuming endeavor for manufacturers.

One of the biggest **obstacles to harmonization** is the fundamental difference in regulatory oversight. FDA operates as a centralized authority, reviewing and approving medical devices through well-established pathways such as 510(k) clearance, Premarket Approval (PMA), and De Novo classification. In contrast, the EU system is decentralized, with more than 50 different Notified Bodies (NBs) designated by the competent authorities of the EU Member States to conduct conformity assessments for the CE marking of medical devices and IVDs. The transition to these new regulations has tightened requirements but also introduced delays and bottlenecks, as Notified Bodies struggle with capacity constraints and varying interpretations of compliance standards. Additionally, because Notified Bodies are subject to surveillance by their designating authorities, they tend to be risk-adverse in certification decisions. Unlike FDA, they cannot provide strategic guidance to manufacturers, such as advising on clinical strategy, making their reviews less predictable. These factors contribute to inconsistencies, prolonged approval times, and regulatory uncertainty, further complicating market access for global manufacturers.

Additionally, risk classification varies between the two systems. While FDA categorizes devices into Class I, II, or III, the EU's MDR or IVDR has a more granular risk-based approach, dividing devices into Class I, IIa, IIb, and III or Class A, B, C and D for the IVDs. The EU has also imposed stricter clinical evidence requirements, requiring manufacturers to provide robust postmarket clinical follow-up (PMCF) data, which is a challenge for companies used to FDA's more flexible approach.

FDA has long imposed its own requirements related to quality management system requirements under 21 CFR 820 which are similar but not identical to the international requirements for ISO13485. Both 21 CFR 820 and ISO 13485 focus on ensuring the safety, effectiveness, and quality of medical devices throughout their life cycle, emphasizing requirements for documentation, risk management, design controls, and corrective actions. It is not uncommon for companies to maintain two systems across markets with some duplication of regulatory and compliance processes, bringing with it complexity and compliance risk.

As a result of these key differences, another major concern is cost. Compliance with two distinct regulatory frameworks means higher costs and complexity for documentation, clinical investigations, regulatory approval/CE marking, Quality Management System operation and compliance, and postmarket surveillance.

Recognizing the strain these discrepancies place on the industry, FDA and EU regulators are actively collaborating through various **harmonization efforts**. One key area of focus is greater mutual recognition of regulatory data, which could help reduce the need for duplicate clinical trials and redundant testing. This would be particularly beneficial for devices incorporating artificial intelligence (AI), Machine Learning (ML), and Software as a Medical Device, where regulatory frameworks are still evolving on both sides.

EU MDR/IVDR and U.S. FDA harmonization & global regulatory alignment (continued)

Another major initiative is the alignment of Unique Device Identification (UDI) systems, which aim to improve global tracking of medical devices. The EU's new EUDAMED database, which consolidates device registration, vigilance reporting, and market surveillance data, is being developed with interoperability in mind. Efforts are underway to harmonize it with FDA's Global Unique Device Identification Database (GUDID), allowing for a more seamless global tracking system.

FDA is moving toward harmonization is quality system requirements with ISO 13485, which will help manufacturers simplify compliance efforts across markets, reduce duplication of regulatory processes, and improve the overall quality of medical devices globally. This alignment promotes greater consistency in industry practices and eases market entry for medical devices across different jurisdictions.

Moreover, postmarket surveillance regulations are being reviewed with the aim of standardizing adverse event reporting. The Global Medical Device Nomenclature (GMDN) is being adopted by both regions to create a common language for device and event classification, improving communication and consistency in safety monitoring.

Looking ahead, industry experts anticipate further regulatory alignment through IMDRF initiatives. There is growing momentum for the use of Real-World Evidence (RWE) in regulatory decision-making, which could help streamline approval processes across jurisdictions. Additionally, discussions on potential Mutual Recognition Agreements (MRAs) could, in the future, lead to partial acceptance of FDA and EU regulatory approvals, easing the burden on manufacturers.

Another expected development is the participation of the EU to the MDSAP program, expansion of third-party review and remote audits, which could reduce the redundancy in regulatory inspections and compliance reviews. Companies will also need to closely monitor changes in AI/ML regulations, as both FDA and EU are developing frameworks for adaptive algorithms and digital health technologies.

While complete harmonization between FDA and EU MDR/IVDR remains a long-term goal, ongoing efforts signal a shift toward greater alignment, benefiting both regulators and manufacturers. For companies navigating this landscape, staying ahead of regulatory updates and adopting a proactive compliance strategy will be essential for global market success.

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Complex patchwork of rules govern GMO medicine trials in the EU

The clinical trials of medicinal products involving genetically modified organisms (GMOs) present unique regulatory challenges within the EU. GMOs, defined under EU legislation as organisms whose genetic material has been altered in a manner not occurring naturally, are increasingly used in innovative therapies, including advanced therapy medicinal products (ATMPs) and vaccine development. However, due to the potential risks associated with the deliberate or unintended release of GMOs into the environment, the EU has established a complex regulatory framework to govern their use.

The EU's GMO regulatory framework consists primarily of two Directives: the Contained Use Directive 2009/41/EC (the "EU Contained Use Directive") and the Deliberate Release Directive 2001/18/EC (the "EU Deliberate Release Directive"). These directives impose strict requirements to mitigate environmental and public health risks, including the need for detailed environmental risk assessments and authorizations. While these rules provide essential safeguards, their application to the clinical trials of medicinal products involving GMOs may present challenges for sponsors, particularly due to procedural complexities and variability across EU Member States.

In practice, the regulation of GMO medicinal products for clinical trials requires sponsors to navigate dual application processes: one for clinical trial authorization under the Clinical Trials Regulation (EU) 536/2014 (the "EU CTR") and another for GMO-related permissions under the national implementation of the relevant directives. This dual burden is made more challenging by differences in how EU Member States apply the GMO framework, resulting in varying requirements and timelines across the EU.

In April 2023, the European Commission has proposed reforms to simplify the regulatory process for clinical trials involving GMO medicinal products as part of the "EU Pharmaceutical Package," aiming to revise the EU pharmaceutical framework. A key element of these reforms is the introduction of a centralized application system, allowing sponsors to submit a single application for both clinical trial authorization and GMO-related approvals. This approach would replace the current system, which requires separate applications to different national authorities for clinical trial and GMO compliance. As of January 2025, the legislative process of the "EU Pharmaceutical Package" is still ongoing. Once an agreement is reached between the Council and the European Parliament, the legislation will be formally adopted and published. Its adoption is likely to occur in 2026, with implementation following thereafter.

The next few pages examine the existing EU regime for clinical trials involving GMO medicinal products, highlighting the regulatory differences among different Member States and the challenges they can pose to sponsors. We also explore the European Commission's recent efforts to streamline the processes.

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Complex patchwork of rules govern GMO medicine trials in the EU (continued)

Belgium

In Belgium, clinical trials involving investigational medicinal products containing or consisting of GMOs are subject to comprehensive regulatory requirements, as outlined in guidance provided by the Federal Agency for Medicines and Health Products (FAMHP) and Sciensano.

Sponsors and investigators must determine the GMO status of the investigational medical product and identify the appropriate regulatory path: the "contained use" procedure, the "deliberate release" procedure, or both. The decision is based on whether the GMO could be released into the environment and the associated risks.

For the “contained use” procedure, activities involving GMOs in controlled environments, such as laboratories or hospital settings, must follow regional rules (Brussels-Capital, Flanders, or Wallonia). The sponsor must conduct a risk assessment to classify the activity (risk classes 1–4) and establish appropriate containment measures. A biosafety dossier, prepared with input from a biosafety officer, must be submitted to the regional competent authority and Sciensano's Service Biosafety and Biotechnology (SBB). Approval may require updates to the facility's environmental permit.

If the clinical trial involves a potential GMO release into the environment, the “deliberate use” procedure applies. This includes submitting a biosafety dossier, conducting an environmental risk assessment (ERA), and following additional public consultation requirements. The FAMHP, in collaboration with the Biosafety Advisory Council, will evaluate the application. Most clinical trials involving deliberate use will also require compliance with contained use regulations.

In addition to the above requirements, the EU CTR procedure governs the clinical aspects of the trial. The EU CTR dossier must be submitted via the EU Clinical Trials Information System (CTIS), and approval from the FAMHP is required before starting the clinical trial. For GMO-related clinical trials, sponsors are encouraged to submit both biosafety and clinical trial dossiers simultaneously to facilitate the process.

Timelines may vary depending on the procedure. Contained use procedures may typically take 30 days for advice from the SBB, while deliberate use approvals may take up to 90 days, including a public consultation period.

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Complex patchwork of rules govern GMO medicine trials in the EU (continued)

Germany

The German legislator considers the use of a medicinal product containing or consisting of GMOs to be a "deliberate release" of such GMO pursuant to the EU Deliberate Release Directive. Such clinical trials, therefore, require authorizations under both the EU CTR and GMO legislation.

Consequently, the German Medicinal Products Act (*Arzneimittelgesetz*, "AMG") stipulates that the sponsor of a clinical trial involving a medicinal product containing or consisting of GMOs has to submit – in addition to the documentation to be submitted pursuant to the EU CTR – the documentation required under Annex II and III of the EU Deliberate Release Directive. This includes, without limitation, an ERA of potential adverse effects of the GMO on human health and the environment and preventive measures to be taken.

Sponsors must submit the documentation pursuant to the EU Deliberate Release Directive to the higher federal authority (Bundesoberbehörde, "BOB") that is competent for the decision on the clinical trial under the AMG and the EU CTR (the Bundesinstitut für Arzneimittel und Medizinprodukte, "BfArM"; or the Paul-Ehrlich-Institut, "PEI"). The BOB will then liaise and align with the federal authority for consumer protection and food safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) on the GMO-related aspects. The ultimate decision by the BOB on the sponsor's clinical trial application will comprise both the decision under the EU CTR and the GMO legislation. For the sponsor, this means that it does not have to deal with two different authorities, because the competent pharma authority obtains the opinion of the GMO authority in an internal procedure.

However, the procedures under pharmaceutical legislation and under GMO legislation are not completely aligned. For instance, the EU Portal for the EU-wide submission of clinical trial applications under the EU CTR does not allow the submission of the ERA. Therefore, the ERA has to be submitted separately on a national level. Also, there is no harmonization of the assessment periods under Art. 8 of the EU CTR and those under GMO legislation. As a result, the decision under GMO legislation may still be pending when the EU CTR decision is due. In such event, the BOB will take an isolated decision pursuant to the EU CTR when due; however, the sponsor must not commence the clinical trial until it has also received the authorization under GMO legislation.

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Complex patchwork of rules govern GMO medicine trials in the EU (continued)

Italy

In Italy, clinical trials involving investigational medicinal products containing or consisting of GMOs require authorizations under both the EU CTR and the GMO legislation.

Sponsors must first assess whether the IMP qualifies as a GMO under the Italian law and determine whether the clinical trial falls under the "contained use" (CU) or "deliberate release" (DR) procedure. If the clinical trials are classified under the contained use, sponsors must proceed with an assessment to avoid risks to human health and the environment that the contained use may cause.

Based on this assessment, sponsors are required to classify the contained use in one of the risk classes (1-4) listed by the GMO legislation.

Depending on the chosen risk class, specific notification and authorization requirements for both premises and activities shall apply. For example, in case of Class 1 (no or negligible risk), no notification for the facilities is required if the use takes place in a facility previously authorised by the Ministry of Health, except in cases of use within clinical trials with ATMPs that contain or are composed of GMOs.

Risk classes 2-4 (low to high risk) always trigger the need to notify both the use and the facility where the use takes place to get the authorization from the Italian Ministry of Health. Different notification forms dependent on the risk class are provided for by the Italian Ministry of Health. The authorization timelines may vary based on the risk class, but these timelines will not in any case exceed 90 days.

In addition, if the assessment shows that the medicinal product contains a GMO that can replicate, transmit, and disseminate into the environment, an authorization under Part B of the EU Deliberate Release Directive should also be obtained from the Italian Ministry for Environment and Energy Security. The overall timeframe for this authorization is 120 days.

All the authorizations must be issued prior to the beginning of the clinical trial.

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Complex patchwork of rules govern GMO medicine trials in the EU (continued)

The Netherlands

Clinical trials involving investigational medicinal products containing or consisting of GMOs in the Netherlands are mainly regulated by the Genetically Modified Organisms (Environmental Management) Decree 2013: (Besluit genetisch gemodificeerde organismen milieubeheer 2013, the Decree) and the Medical Research with Humans Act: (Wet medisch-wetenschappeijk onderzoek met mensen) and subordinate legislation.

These clinical trials must be assessed by various authorities:

- The Central Committee on Human Research (as competent review committee: Centrale commissie mensgebonden onderzoek or CCMO), in the context of clinical trials in general, and
- by the Ministry of Infrastructure and Water Management: (Ministerie van Infrastructuur en Waterstaat or Ministry of I&W) and its GMO Bureau, which is responsible for processing permit applications) in the context of risks to humans and the environment.[10]

In the Decree, a distinction is made between "contained use" or "deliberate release." Contained use in the context of the Decree is understood to mean any activity such as production, application or which contains the possessing of GMOs, if containment measures are used in that activity. Deliberate release means the intentional introduction into the environment of a GMO or a combination of GMOs in any way whatsoever without containment measures being present or applied. In any case, deliberate release also includes activities such as the manufacture and use of a GMO or a combination of GMOs.

Therefore, the permit of the I&W for deliberate use is likely required for most clinical trials involving investigational medicinal products containing or consisting of GMOs. However, it is possible that in the context of the manufacturing of the investigational medicinal products, the notification/license requirements for contained use may also be applicable.

The minister will decide on the application for the license of the Ministry of I&W within 120 days of receiving the application. The entity that actually performs the clinical trial (not the sponsor) is required to request the permit, such as the board of directors of the hospital involved. In addition, there is a simplified and shortened procedure for specific categories of GMOs of a maximum of 56 days. If a number of additional conditions are met, a period of a maximum of 28 days applies.

The assessments of medical ethical aspects by the CCMO and the biosafety aspects by the GMO Bureau both have their own legal basis with associated terms and requirements. In terms of content, it is possible to request the Ministry of I&W permit separately from the other permission because the research protocol is not part of the Ministry of I&W application.

A positive opinion from an Ethics Committee is required for all clinical trials and is a procedure independent of the procedures as described above.

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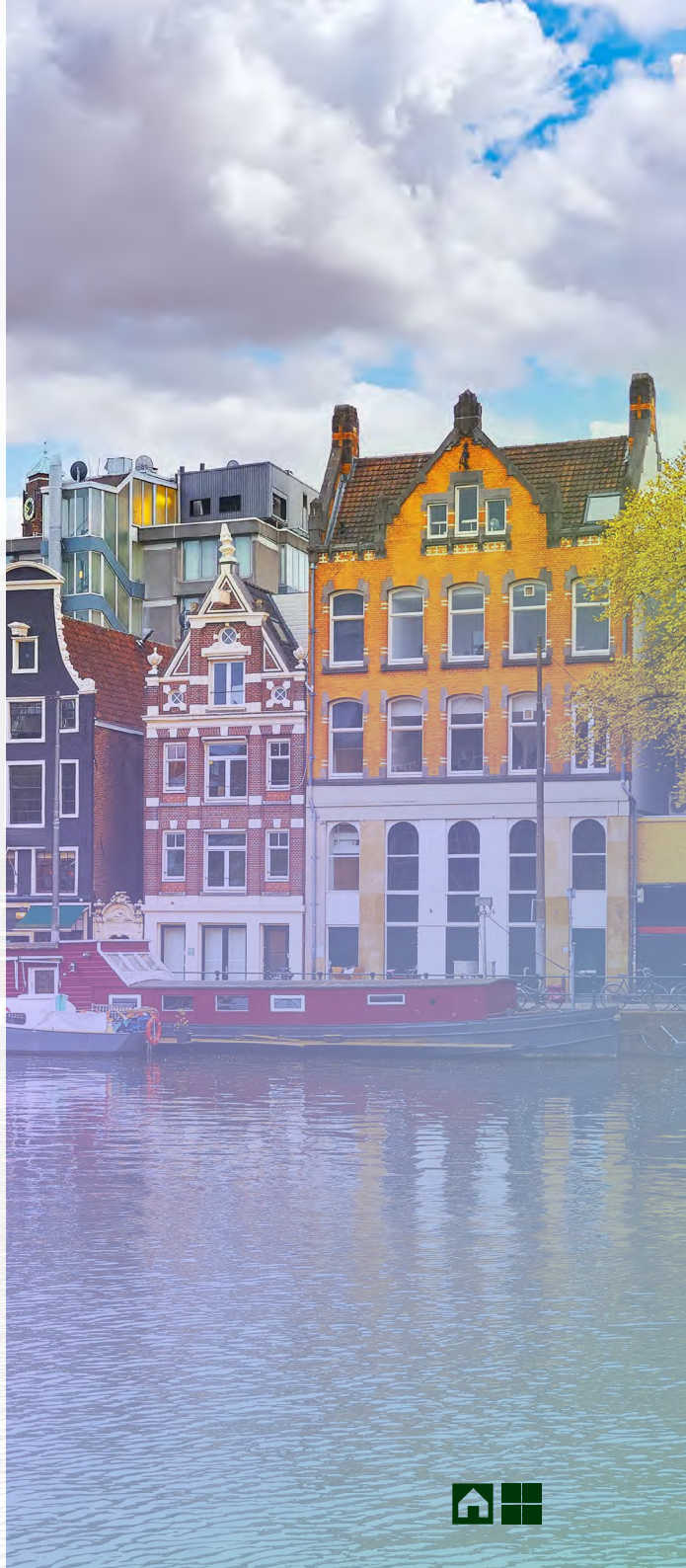

[10] Please note that for changes or relevant information from ongoing WMO medicine research (under old pre-CTR legislation) the Minister of Health, Welfare and Sport is the competent authority, which tasks are delegated to the agency of the Medicines Evaluation Board. Submissions for new medicine research files however fall under the CTR and do not have an additional assessment by the competent authority. In practice, therefore assessment by the agency of the Dutch Medicines Evaluation Board may occur less and less.

Complex patchwork of rules govern GMO medicine trials in the EU (continued)

Spain

In Spain, clinical trials involving investigational medicinal products containing or consisting of GMOs are understood as deliberate release activities and, as such, require authorization under the EU CTR and the GMO-legislation. Although both application-authorization procedures are separate from each other, it is standard practice to process both procedures in parallel.

For the purpose of the deliberate release authorization, the following authorities stand out:

- the Inter-ministerial Council on Genetically Modified Organisms ("CIOMG"), attached to the Ministry of Agriculture, Fisheries and Food ("MAPA"), as the body responsible for granting the authorization, and
- the National Biosafety Commission ("CNB"), attached to the Ministry for Ecological Transition and Demographic Challenge ("MITECO"), as the technical-scientific body responsible for the mandatory reporting in the context of the application-authorization procedure.

The CNB has issued a technical guide that details the deliberate release application-authorization procedure (generally, only one application per sponsor and clinical trial is required), as well as the documents to be attached to the application. It also includes detailed information about the application-authorization procedure for clinical trials involving specific GMOs (e.g., genetically modified human cells, viral vectors, or AAV vectors).

The (standard) application-authorization procedure takes the following steps:

- request for the notification number;
- online filing and submission of the application (form) and additional documents (technical dossier, SNIF, conclusions on the specific areas of risk of the ERA, and other documentation, where applicable) through this link;
- public consultation (30 days) of the application summary;
- risk assessment report by the CNB; and
- decision by the CIOMG within 90 days from the receipt of the application.

Interestingly, both the risk assessment reports by the CNB and the decisions on the application by the CIOMG are published on the MAPA's website here and here.

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Complex patchwork of rules govern GMO medicine trials in the EU (continued)

France

In France, clinical trials involving investigational medicinal products containing GMOs are subject to a complex set of various regulations involving European and French rules applicable to clinical trials and European and French rules applicable to GMOs. With regards to the national applicable regulations, the French Public Health Code is applicable, as well as the French Environment code.

The use of medicinal products containing GMOs in the context of a clinical trial in France is mainly considered as a contained use of GMOs. However, in some cases, notably in the context of early access stages, the use of investigational medicinal products containing GMOs can fall under the classification of deliberate release. In both cases, specific regimes apply to the rules applicable to GMOs to take into consideration the specific health context in which the investigational medicinal product is used.

A specific expert committee has been created within the Ministry of Research to provide assistance in the classification of the GMOs, to determine the level of risks for public health or environment. Even if the criteria are provided in the regulation, sponsors can reach out to this dedicated expert committee to receive assistance on the applicable classification and the related protection measures to be implemented.

Two procedures apply for the contained use of GMOs in the context of a clinical trial, depending on the level of risk for public health and environment:

- an authorization procedure for contained use with low or high risk must be submitted by the sponsor before the French National Agency for Healthcare Products and Medicines Safety (ANSM), which provides its decision upon the prior opinion of the expert committee. The authorization request must be based on a technical file including a risk assessment.
- a simplified declaration procedure for contained use with no or negligible risk, which has been available since 1 June 2022. The sponsor must submit a prior declaration to the ANSM, including a technical file containing a risk assessment. The ANSM may consult the experts committee if it has any doubts or questions on the level of risk entailed by the use of GMOs in the context of the clinical trial.

In some limited cases, the use of GMOs in the context of clinical trial may rather fall under the definition of deliberate release. In such case, the above procedures are not available to the sponsors, which should rather comply with legal obligations applicable to the deliberate release of GMOs. Under this regime, the sponsor must request an authorization before the French Ministry of Environment.

The ANSM has detailed the relevant procedures on its website, and has released simplified forms to accelerate the formalities which must be fulfilled by sponsors launching a new clinical trial in France involving medicinal products containing GMOs.

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How global antitrust compliance programs may help pharmaceutical companies

The increasingly stringent approach of the global antitrust regulators in overseeing the pharmaceutical industry is continuing to push companies towards efficient tools to secure antitrust compliance and mitigate antitrust risks. Although every jurisdiction is unique from legal and regulatory perspectives, there are general antitrust law restrictions and guidelines that can be broadly applicable.

Therefore, identifying those regulations, and crafting a global antitrust compliance training program – that addresses key "dos" and "do nots" – remains a manageable, and beneficial, exercise. Our key tips for a successful program are as follows:

- Antitrust legal training should be customized for its audience, for example, the global and regional leadership, and on a national level, may be customized with local law and enforcement practices. It is critical to raise awareness with all business divisions; it does not make much sense to train leadership but not train sales staff, because a sales representative's actions may create antitrust risks equally as serious as the actions of company's CEO.
- The primary goal of the training should be to raise awareness of the antitrust legal framework, practice, and risks of the company's business functions that do not deal with law enforcement on a daily basis. The training must be organized in the way such that the business teams feel comfortable to open up and to raise questions and concerns they may have, so that potential issues can be identified and duly addressed.
- To bolster the program, a global antitrust compliance training program may be used to introduce a global antitrust compliance policy, or amendments to such policy, or may be run in parallel with a company's internal antitrust compliance audit. A global compliance training program may also be complemented by dawn raid training, to also increase awareness regarding inspections.

Overall, a global antitrust compliance program may not only assist a business in mitigating risks of fines, criminal sanctions, exclusion from tenders, invalidity of contracts and damages – including for reputation and brand – but also in strengthening corporate compliance culture.

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How medical device companies should navigate the evolving AI regulatory landscape

The rapid advancement of artificial intelligence in health care has placed medical device companies at the forefront of innovation and regulatory scrutiny. Companies are also facing a patchwork of vastly different regulatory schemas in different regions; for example, the EU AI Act imposes stringent requirements on AI-powered medical devices, while the Trump Administration in the U.S. appears headed for a regulation-light approach to AI oversight. Given the evolving — and sometimes conflicting — global landscape for AI regulation, medical device companies must adopt proactive strategies to ensure compliance, mitigate risks, and maintain market competitiveness.

Align with the EU AI Act

The EU AI Act classifies AI systems based on risk levels, with high-risk applications — including AI-driven medical devices — facing strict compliance requirements. Medical device companies seeking to commercialize in the UK should align their AI systems with the Act's provisions, particularly in areas such as data transparency, risk management, and human oversight.

Given the EU's influence on global regulatory trends and being the first AI law with broad applicability, compliance with the AI Act framework help future-proof a company's AI model for upcoming regulations in other regions. In terms of regulatory oversight, the EU AI Act may represent one end of the spectrum globally, but its example as a rigorous oversight framework is being mimicked in other parts of the world, including in legislation pending in several U.S. states, such as California and Washington.

Monitor federal U.S. developments closely

In January 2025, U.S. President Trump rescinded a Biden-era Executive Order (EO) on AI, which had emphasized safety restrictions and increased oversight for potential discriminatory AI impacts. In its place, the Trump administration issued EO 14179, "Removing Barriers to American Leadership in Artificial Intelligence," which focuses on clearing a path for U.S. innovation that promotes economic competitiveness and directs the U.S. government to identify existing U.S. AI regulations for potential suspension, rescission, or revision.

Following the issuance of EO 14179, the White House published a solicitation for input on a new cross-industry AI Action Plan, which will likely include recommendations with downstream impacts for medical device manufacturers going forward. While federal agencies such as FDA have issued recent guidance on AI and machine learning (ML) in medical devices, those publications may be subject to change under the new American leadership. Companies should actively monitor emerging U.S. federal proposals that may impact their operations.

How medical device companies should navigate the evolving AI regulatory landscape (continued)

What steps can companies take now?

Given the lack of global conformity for AI oversight, medical device companies can voluntarily adopt best practices in a number of areas:

AI governance

A bedrock of AI development is solid governance processes. To do so, companies can:

- Establish AI ethics committees to oversee development and deployment;
- Implement robust documentation and audit trails for AI decision-making;
- Adopt risk management frameworks similar to those outlined in ISO14971 and the EU AI Act; and
- Ensure compliance with existing regulations such as HIPAA for data privacy and the FDA's software as a medical device (SaMD) guidelines.

Transparency and explainability

Regulators and health care professionals increasingly demand AI systems that are interpretable and accountable. Companies should prioritize explainability in AI models, ensuring clinicians and regulators understand how decisions are made. Implementing clear documentation, model validation, and postmarket performance monitoring will help build trust and regulatory readiness.

Foster industry collaboration and advocacy

Medical device companies should engage with industry groups, regulatory bodies, and AI standardization organizations to help shape policies and best practices. Participating in public-private initiatives and advocating for regulatory clarity will enable companies to influence the emerging AI framework and ensure practical, innovation-friendly regulations.

Future-proof AI strategies with adaptive compliance

With AI regulation still evolving, companies should build flexibility into their compliance strategies. Adopting an adaptive compliance model — where AI systems can be updated in response to regulatory changes — will be critical in ensuring long-term viability and global market access.

While the EU AI Act provides a clear regulatory direction, the U.S. is still in the process of defining its AI governance framework. In this transitional period, medical device companies must take proactive steps by aligning with existing international standards, strengthening internal AI governance, and engaging with policymakers. By doing so, they can navigate regulatory uncertainty while maintaining compliance, fostering innovation, and ensuring the safety and efficacy of AI-powered medical devices.

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FDA transition to QMSR marks a new era in device compliance

FDA has taken a significant step forward in modernizing its regulatory framework with the transition to the Quality Management System Regulation (QMSR), which essentially aligns FDA's regulatory requirements for medical devices with the internationally recognized ISO13485:2016 standard. By adopting this harmonized approach, FDA aims to streamline compliance, reduce regulatory burdens, and enhance global trade and innovation.

One of the most significant shifts is the harmonization with ISO13485:2016, which will make it easier for manufacturers to comply with both U.S. and international requirements, reducing duplicative efforts, particularly for companies that already follow ISO13485. Another crucial change is the adoption of a risk-based approach to quality management. The QMSR emphasizes identifying and mitigating risks throughout a product's life cycle, ensuring patient safety and product reliability.

Supplier controls have also been enhanced under the QMSR, which places greater emphasis on robust supplier management and risk-based strategies to ensure product quality. Manufacturers are now required to implement stronger oversight mechanisms, ensuring that their suppliers meet the necessary regulatory standards. Additionally, the transition to QMSR streamlines documentation and reporting requirements. The aim is to reduce unnecessary paperwork while maintaining strong regulatory oversight.

While FDA's transition to the QMSR aligns closely with ISO13485, some key differences will remain, requiring companies to manage both sets of requirements carefully. One major distinction is regulatory oversight, as FDA will continue to enforce specific legal obligations beyond ISO13485, including compliance with the FDCA and Unique Device Identification (UDI) requirements. Additionally, complaint handling and reporting requirements under the QMSR remain stricter, particularly in areas like Medical Device Reporting (MDR), which demands more rigorous adverse event tracking than ISO13485's general guidelines. FDA will also maintain its independent inspection process, which differs from the third-party certification audits used for ISO13485 compliance. Documentation requirements will continue to diverge as well, with FDA mandating additional records such as the Quality System Record (QSR), such as device history records (DHRs), device master records (DMRs), and quality system procedures.

Another key change in the transition to the QMSR is that FDA will have greater visibility into certain quality records. Under the QSR, FDA's policy is that it will not routinely inspect internal audit reports, Management Review materials, or supplier audits. This policy has been used to ensure the integrity of those processes so that companies can challenge their systems without the risk of an FDA investigator reviewing the materials. Under the QMSR, these materials will now be subject to review during an inspection or audit.

FDA's QMSR is set to become effective on 2 February 2026, following a one-year transition period after its final rule was published in February 2024. This gives medical device manufacturers time to adjust their quality management systems to comply with the new requirements. Industry experts and stakeholders have generally welcomed the change, viewing it as a positive step toward regulatory modernization and efficiency. As the industry moves forward, the harmonization with ISO 13485 is expected to drive innovation, efficiency, and improved health care outcomes worldwide.

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It was only a gift: Identifying and mitigating compliance risks

The life sciences industry tends to be a sector most replete with gifts and hospitality, and without people properly realizing the associated risks, and the severity of those risks. Modest salaries, rising medical costs, and increased competition are all factors that foster an environment where bribery and corruption can be a point of difference in the medical and health space. Adding to this concern is the fact that the majority of the life sciences sector operates in emerging markets where growth opportunities are rife and intense. In many of these markets, physicians can be considered as government officials, raising the compliance consequences.

At their extremes, gifts and hospitality policies can be easy to comply with. Our advice is principally for the behaviors existing in the liminal space. Branded paraphernalia for low-cost marketing and brand awareness is invariably OK; whereas expensive and extensive overseas travel for tourism and leisure is not.

The challenge can be in the form of **educational opportunities** (which if deployed correctly are important for scientific awareness and training), or **valuable free products** (that should not be used commercially). The industry relies on the sharing of new techniques and knowledge; but how is that monitored? Are you able to confirm **events, trainings**, and **conferences** happened, and sponsored attendees were present, and that the activities were actually relevant to the practice of the gift and to the hospitality recipients?

For devices or drugs offered as part of **demonstrations or for indigent patients**, can you marry inventory with sales, present records of proper use, and be prepared to distinguish from inducements for future purchases?

Another consideration often overlooked is **conflicts of interest and employment.** A "gift" can be an offer to employ or engage a family relation or close connection. It can also be the engagement of a related third party; they may not be offering the best price or service for the business, and could then be privy to confidential information.

To avoid regulatory risks associated with gifts, we advise:

- Create a concise gifts and hospitality policy, and separate register.
- Think of gifts and hospitality broadly.
- Know there are regulations that govern marketing, which vary across jurisdictions, and benchmark activities with trusted counsel against your operations and your peers.
- Audit your third parties' activities, and not just distributors or medical associations, but also service providers, like travel agents.
- Attend some of the events you sponsor.
- Be able to clearly identify health care (even if animal, plant, human) initiatives as a core principle of any sponsorship.
- Document and record decisions and receipts.
- Encourage transparency about requests, demands, and rejections.

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Use of AI in compliance and investigations: Expectations from regulators and enforcement agencies

The rise of AI has profoundly impacted various industries. Recent AI advances are not only redefining business processes, but also serving as the source for changes in how the government is responding to its use. The life sciences industry faces a noticeable shift in expectations from regulators and enforcement agencies. Key jurisdictions have adopted significant policy updates against the misuse of AI – and also with regard to setting expectations on where AI should be used.

Compliance expectations are tightening around the world. Back in September 2024, then-Principal Deputy Attorney General (PDAAG) for the U.S. Department of Justice (DOJ) Nicole Argentieri announced revisions to the Evaluation of Corporate Compliance Programs (ECCP) guidance. PDAAG Argentieri unveiled updates to the ECCP surrounding the use and assessment of risks associated with emerging technologies. The 2024 changes drew prosecutors' attention to the "deliberate or reckless misuse" of new and emerging technologies (especially AI). On the other hand, the updates also made clear that compliance programs need to use AI and technology where this is helpful to achieve compliance goals.

Just two months later, a new Guidance to Organisations on the Offence of Failure to Prevent Fraud was published in the United Kingdom. This recently published guidance accompanies the introduction of a new corporate offence of failure to prevent fraud through the Economic Crime and Corporate Transparency Act 2023. When describing the required elements of a compliance system, this guidance also expects the use of appropriate technology in managing fraud risks. In this context, it is also important to point out that the Serious Fraud Office (SFO) has increased its AI-trained staff considerably in recent years.

Similarly, against the backdrop of the enactment and implementation of the EU AI Act, German enforcement agencies are keeping an eye on the potential misuse of AI. For example, Germany's Federal Financial Supervisory Authority (BaFin) introduced principles for the use of algorithms in decision-making processes already back in 2021. Simultaneously, however, German enforcement agencies expect that companies use technology to make their compliance programs more robust and to complete investigations within a required time and depth. In addition, they increasingly work with vendors using AI to obtain large amounts of data and thereby increase their investigation speed.

These significant recent developments call for the following:

- **Company-wide AI governance frameworks.** These frameworks should define clear accountability and oversight mechanisms and align on AI initiatives and acceptable uses.
- **Implementation of AI and appropriate technology in compliance and investigation processes.** This includes, for example, AI in compliance monitoring, in compliance spot checks, and in investigations.
- **Periodic checks on the potential misuse of AI.** Regulators and enforcers are wary about the misuse of AI to circumvent compliance safeguards. They expect companies to adopt defensive strategies to safeguard against the misuse of advanced technologies by bad actors.

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"How do I terminate this agreement?": Top tips for terminating an agreement to achieve an optimal outcome in any subsequent dispute

Increased costs, complex supply chains, and the impact of the current uncertain business landscape may lead to companies in the life sciences and health care industry experiencing issues with a counterparty's performance and considering their options, including termination of contracts. Often, termination is hotly contested, particularly when high value and/or long-running contracts such as license, development, and distribution agreements are unilaterally ended, leading to arbitration or litigation where the termination comes under intense scrutiny. If a court or tribunal finds that a party has wrongfully terminated, the financial consequences could be severe, with the wrongfully terminating party potentially liable for substantial damages.

So, what questions should a party ask before terminating to ensure effectiveness?

- **Do I have a right (or rights) to terminate?** Termination rights may be set out in the parties' agreement, for example, where a party commits material breach(es) of contract, fails to pay sums owed, becomes insolvent, or becomes involved in compliance-related or illegal behaviors. Some agreements allow termination without cause. Termination rights might also exist outside the contract under the relevant applicable law. Careful consideration should be given to whether the specific facts give rise to any termination rights, and the evidence available to substantiate those facts in a dispute.
- **When should I terminate?** Consider any timing requirements. For example, the contract may include a "cure" period within which certain breaches may be remedied, failing which, the non-breaching party may have a right to terminate at the expiry of the cure period (but not before). Commercial considerations, such as the need to avoid supply disruptions, may affect the decision to terminate. However, a terminating party should exercise caution because the longer termination is delayed, the greater the risk of inadvertently waiving one's right to terminate. Consider if it is possible to buy time by expressly reserving the right to terminate.
- **How should I terminate?** Check the contract and comply with any relevant formalities. There may be provisions dictating information that must be included in the termination notice and how, where, and to whom, it is to be sent. At a minimum, the notice should clearly express an unequivocal intention to terminate the contract in its entirety and identify the right(s) relied upon.

Careful consideration of available termination right(s) and how they apply to the situation in question, the timing of termination, and adherence to any relevant formalities will maximize the chances of a termination withstanding scrutiny in a subsequent dispute.

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Parliament's opinion on European Commission's data exclusivity proposal

In April 2023, the European Commission published a proposal to reform the EU's pharmaceutical legislation, in an effort to make medicinal products in the EU more accessible, affordable, and innovative. In April 2024, the European Parliament adopted its position on the legislative text, with several amendments to the Commission's proposal. The Parliament's position is especially important with regard to regulatory data protection (RDP) and orphan market exclusivity (OME).

RDP: The current standard period of RDP of which is 8 years, would be reduced to 7.5 years, instead of 6 years as proposed by the Commission. Extensions would be possible if:

- the product addresses an unmet medical need (one year extension);
- comparative clinical trials are conducted (six months extension); and/or
- a significant share of the product's R&D takes place in the EU and at least partly in collaboration with EU research entities (six months extension).

The Parliament aims to cap the combined data protection period at 8.5 years. After the RDP, a one-time extension (one year) of the two-year market protection period could be granted if the sponsor obtains marketing authorization for an additional therapeutic indication that provides significant clinical benefits compared to existing therapies.

OME: The current baseline of 10 years would be reduced to 9 years for most orphan medicinal products. This exclusivity period can be extended by two years (11 years in total) if the product addresses a "high unmet medical need." The Parliament agrees with the Commission to abolish separate 10-year orphan market exclusivity periods for new orphan indications and to allow marketing authorization applications two years before expiry of OME.

In terms of reducing regulatory data exclusivity terms, the Parliament's text represents less of a change in status quo compared to the original Commission proposal; yet, it still shortens the overall data exclusivity periods.

The next step is for the EU Member States in the Council to take a position on the Parliament's text, after which the Commission, Parliament, and Council will start negotiations on the final form.

The new protection periods proposed for regulatory exclusivity terms could potentially affect the protection of products that are already in the pipeline. Therefore, when developing and investing in novel products, medical product sponsors should take into account the potential modifications in EU regulatory exclusivity rights.

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EU Health Technology Assessment takes effect for ATMPs, oncology medicines

Pricing and reimbursement are not harmonized in the EU; instead they are regulated on a country-by-country basis. Regulation (EU) 2021/2282, which took force in January 2022, introduced rules on the health technology assessment (HTA), introducing EU-wide collaboration. HTA is a scientific, evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing health technologies, prior to making decisions on pricing and reimbursement. The Regulation became applicable in mid-January 2025.

The rules apply to medicinal products, medical devices, in vitro diagnostic medical devices, and medical procedures, as well as measures for disease prevention, diagnosis, or treatment. The relative effectiveness is measured on the basis of clinical and non-clinical aspects, although the Regulation focuses on clinical aspects:

- the identification of a health problem and current health technology,
- the examination of the technical characteristics of the health technology under assessment,
- its relative safety, and
- its relative clinical effectiveness.

The Regulation aims to enhance the coordination of the HTA in order to avoid multiple assessments of the same product with diverging outcomes in the EU member states. The outcome of the HTA shall be used to support the EU member states' budgetary decisions. This includes decisions on pricing and reimbursement; however conclusions on the added value for health systems of health technologies remain under the EU member states' sole discretion.

The Member State Coordination Group on HTA ("Coordination Group"), as introduced in the Regulation, will help oversee "joint clinical assessments" (JCA): a mechanism that ensures that any information, data, analyses, and other evidence required for an HTA is submitted only once at the EU level by the health technology developer.

The JCA only applies to certain health technologies, including medicinal products for which an application for a centralized marketing authorization is submitted to the European Medicines Agency, but with step-wise implementation timelines. First, as of 12 January 2025, oncology medicinal products with a new active substance as well as advanced therapy medicinal products (ATMPs), including cell and gene therapies, are subject to JCA. As of 2028, orphan medicinal products will be subject to JCA. As of 2030, the HTA Regulation's full scope will apply.

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New EU antitrust standard for patent strategies and communication campaigns

The European Commission (EC) is intensifying its enforcement of abuse of dominance cases under Article 102 of the Treaty on the Functioning of the European Union and one focus is the pharma sector. Two recent cases have established stricter standards for patent strategies and communication campaigns that potentially affect rival products. One case (Teva Copaxone) ended with a substantial fine of €462.6 million, and the other case with a commitment by the company to alter its conduct. National competition authorities in the EU are already following in the EC's footsteps: in January 2025, the Romanian competition authority imposed fines of €26 million for a misleading communication campaign against rival generics. Below, we summarize the key aspects and provide practical takeaways, taking into account the Teva summary decision published in January.

The *Teva* case deals with potentially anti-competitive patent strategies. Teva had filed multiple divisional patents, enforced them, and withdrew selective patents when negative precedents were anticipated. As this obstructed an effective legal review, the EC found it to be an abuse of the patent system. The related press release and summary decision do not yet contain the full legal framework underlying the EC's considerations. We see three key elements of an "abuse" found in this case, noting that an abuse in this sense is not limited to divisional patents but also concerns other strategies such as filing SPCs or acquiring blocking patents:

- **The patent strategy cannot be deemed "competition on the merits";** for example, because it does not pursue legitimate objectives such as protecting innovation or ensuring further R&D versus plain anti-competitive objectives.
- **It is capable of producing exclusionary effects;** for example, it artificially creates legal uncertainty and thus effectively hinders market entry such as in the *Teva* case; and,
- **It is not justified,** as filing patents in line with European Patent Office rules does not constitute an objective justification.

In both cases, the EC also incriminated aggressive and misleading communication about rival products. If one attempts to derive the legal standard behind both cases, communication on rival products could be "abusive" if the following cumulative requirements are met:

- **Communication cannot be deemed competition on the merits;** for example, if it is objectively misleading due to inaccurate or incomplete information about the safety, efficacy, or therapeutic equivalence of rival products and spreads unfounded health risks. An EC official recently even suggested that only randomized head-to-head clinical trials would be accepted when making claims about a competing product; this was, however, only an informal statement.
- **Communication is capable of producing exclusionary effects;** for example, targeted messaging to demand drivers such as HCPs or systematic dissemination through various channels.
- **It is not justified;** for example, there are no evidence-based public health objectives.

Therefore, we observe the following key compliance takeaways:

- Keep potential antitrust implications of patent strategies and communication campaigns in mind.
- Document patent filings to demonstrate legitimate interests.
- Ensure communications are accurate, evidence-based, and not misleading.
- Use neutral, objective language in internal documents.

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New EU rules on human blood, tissues, and cells

In 2024, EU legislation on human blood, tissues, and cells saw a major change with the adoption of the new Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application ("SoHO Regulation"). This new Regulation will apply from 7 August 2027, replacing the rules that have governed the use of human blood, tissues, and cells in the EU for more than 20 years.

The SoHO Regulation will have a broader scope and cover all SoHO, defined as any substance (and preparations thereof) collected from the human body, whether or not it contains cells and whether those cells are living or not. This will capture substances such as intestinal microbiota and blood preparations not used for transfusion that were outside the scope of the current legislation, as well as other substances for which clinical use may emerge in the future.

The SoHO Regulation will also cover SoHO used to manufacture medicinal products and medical devices, making it a key piece of legislation for companies operating in these sectors.

Numerous other changes have been introduced. Amongst them is the new SoHO Coordination Board (SCB), which will provide opinions on the regulatory status of substances, products, or activities. The hope is that this new body will bring more legal clarity for developers of borderline and combination therapies, as well as remove some of the challenges to cross-border exchanges of SoHO.

Another main objective of the SoHO Regulation is to facilitate the development of innovative therapies. For this purpose, a new risk-based authorization model was introduced for SoHO preparations, requiring developers to provide clinical evidence proportional to their level of innovation and risk.

Guidelines issued by the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicine & Healthcare (EDQM), already widely applied in the sector, will now have a reinforced role and constitute the primary means to meet the SoHO Regulation standards. These guidelines incorporate the latest scientific evidence and are regularly updated, which shall allow the SoHO framework to stay aligned with technological advancements and evolving risks.

Learning lessons from the COVID-19 pandemic, there will also be new rules on supply continuity, including the establishment of emergency plans and certain obligations for entities dealing with critical SoHO, as we dissect deeper online here.

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CJEU mulls questions over pharmacy compounding

In 2024, the Dutch Supreme Court referred questions to the Court of Justice of the EU (CJEU) regarding the ability for EU member states to require pharmacies to obtain a marketing and manufacturing authorization for medicinal products that are prepared in pharmacies.

In the EU, regulations regarding the manufacturing and marketing authorization of medicinal products are harmonized in Directive 2001/83/EC (the "Directive") and Regulation (EC) No 726/2004 (the "Regulation"). Medicinal products may, with certain specific exceptions, only be placed on the market after having obtained a marketing authorization issued by the competent authority of the EU member state in accordance with the Directive, or by the European Commission in accordance with the Regulation. In order to obtain a marketing authorization, an appropriate data package must be submitted to the competent authorities, including the results of pre-clinical tests and clinical trials, regarding the quality, safety and efficacy of the medicinal product. Further, a manufacturing authorization is required for the manufacturing of medicinal products.

The requirement to obtain a marketing and manufacturing authorization applies to medicinal products either "*prepared industrially*" or "*manufactured by a method involving an industrial process.*" In 2015, the CJEU ruled that characteristics of "industrial preparation" include standardized production of significant quantities of a medicinal product stocked and sold wholesale, and large-scale or serial production of magistral formulae sold in batches.

Excluded from the scope of the Directive are, among others, medicinal products prepared in a pharmacy in accordance with the prescriptions of the pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ("*officinal formula*"). The Directive does not set any additional quantitative requirements. In the Netherlands, *officinal formula* preparations do not require a marketing and manufacturing authorization, but only insofar as the products are prepared on a "small scale," meaning they are prepared and supplied to a maximum of 50 unique patients per month for long-term use, and a maximum of 150 unique patients per month for short-term use.

The CJEU has now been asked to clarify whether an interpretation in conformity with the Directive allows EU member states to pose any quantitative requirement for *officinal formula* preparations. The outcome of the case could be of great importance for compounding pharmacies as well as holders of marketing authorizations in the EU.

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Read our Life Sciences Law Update for key developments for

Pharma & device companies in the EU

Italian Medicinal Agency (AIFA) reform and its impact on innovative medicines

In January 2024, the Italian Medicines Agency (AIFA) underwent a significant restructuring to streamline drug approval processes and facilitate faster access to innovative therapies. This reform, introduced by Ministry of Health Decree No. 3 of 8 January 2024, represents a pivotal step in modernizing Italy's pharmaceutical landscape.

The cornerstone of the reform is the unification of AIFA's two main decision-making bodies: the Technical Scientific Committee (CTS) and the Price and Reimbursement Commission (CPR). Historically, CTS conducted scientific evaluations, while CPR managed pricing and economic assessments. This bifurcated structure often led to significant delays in drug approvals due to divergent perspectives and the need for iterative discussions between the two bodies.

To address these inefficiencies, the reform merged CTS and CPR into a single entity: the Scientific and Economic Commission for Medicines (CSE), which is now tasked with conducting comprehensive, 360-degree evaluations of medicinal products, combining clinical and economic perspectives. Additionally, for the first time, the new CSE Regulation allows patient associations and scientific societies to be involved in decision-making processes to provide broader insights. We have identified the following key impacts on the pharmaceutical market:

Faster access to innovative medicines. By consolidating evaluations into a single streamlined framework, the reform aims at reducing significantly approval timelines, particularly for advanced therapies addressing complex conditions or unmet medical needs. Indeed, according to AIFA's President, in the short time since the reform was implemented, the reformed AIFA cleared over 150 backlogged dossiers and expedited approval times for new medicines.

Comprehensive evaluations. The CSE's integrated framework enables a holistic assessment of innovative therapies by considering clinical efficacy, safety, cost-effectiveness, and socioeconomic impacts simultaneously. This approach ensures that the long-term benefits of high-cost treatments are balanced against their immediate financial impact, thus ensuring that the innovative nature of these products is fully recognized while considering their broader impact on health care systems.

Italy already demonstrated strong performance in efficiency and accessibility before the reform. According to the EFPIA "*Patients W.A.I.T. Indicator 2023 Survey*," the average timeline for making new medicines available – measured as the time between European marketing authorization and inclusion on the public reimbursement list – was 424 days, below the European average of 531 days. For oncology drugs, the timeline was 417 days compared to the European benchmark of 559 days. Additionally, 77% of centrally approved medicines from 2019 to 2022 were made available in Italy, surpassing the European average of 72%, with 62% enjoying full NHS coverage.

By building on an already strong foundation, the reform has the potential to make Italy more and more competitive and a leading player in Europe's pharmaceutical sector.

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Regulation of health centers in France: Stricter oversight and new compliance hurdles

The French health care sector has changed significantly in recent years, attracting growing interest from financial investors due to its high profitability. While these investments can help improve technology and processes, the regulatory framework remains complex, leading to alternative models, such as health centers.

As a result, private health care services in France have been under closer scrutiny from regulatory and administrative authorities, especially after several public health scandals. Many of these scandals involved health centers, which are regulated by the French Public Health Code. To address these issues, a new law was adopted on 19 May 2023, specifically targeting health centers offering dental, ophthalmological, and orthoptic services. The law aims to prevent profit-driven partnerships with private companies.

To avoid potential abuses in patient care – especially since treatments are often reimbursed by public health insurance – the 2023 law introduced several key measures:

- Mandatory prior approval from administrative authorities;
- Stricter conflict-of-interest rules for health center managers;
- Requirements for staff qualifications and human resources; and
- Increased penalties for non-compliant health centers.

Most of the necessary regulations to enforce this law were adopted in 2024. A key decree No. 2024-568, 20 June 2024, clarified the approval process and listed required documents. Another law dated 27 December 2024 allowed financial authorities to audit health centers, while other decrees adjusted health center funding and established rules for excluding certain centers from public health insurance reimbursements. This exclusion applies when authorities identify abuses, such as unnecessary medical treatments.

At the same time, 2024 saw a rise in reimbursement exclusions for health centers, showing increased government oversight and stricter enforcement. Many of these sanctions have been challenged, but they reflect a tightening of controls.

A few final regulations are still expected, but authorities are already actively monitoring compliance with the new legal framework. As investors, particular attention must be given to the structuring of investments in health centers to ensure compliance with the new legal and regulatory requirements.

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The use of influencers in France to promote health products and services online

The online practices of influencers are now specifically regulated in France since a new legal framework has been set up with the law of 9 June 2023, amended on 6 November 2024 (the "Law"). The Law aims at regulating commercial influence practices in various sectors, including the health sector, and non-compliance with its requirements may entail criminal sanctions. It is the first time such practices have been regulated in the EU, and that may inspire other jurisdictions to adopt a similar framework in the near future.

What is an influencer?

Within the meaning of the Law, an influencer is any person (natural or legal) who, for consideration (in kind or in cash), uses their notoriety towards their audience to communicate online information aiming at promoting, directly or indirectly, products, services or any cause whatsoever.

Other sets of rules applying to the promotion of health products use a wider definition (e.g., Transparency regulations) which, for the purposes of compliance with those other rules, should be kept in mind when interacting with influencers.

Major new requirements and prohibitions

- **Compliance with sector-specific rules:** Influencers must comply with the specific rules governing the promotion of various products, such as medicinal products, medical devices, food products with health claims, tobacco and vaping.
- **Commercial transparency:** Any collaboration or promotional intent must be disclosed using explicit references (such as "promotion" or "paid commercial collaboration").
- **Mention of retouching and AI-generated content:** Images that have been retouched or generated by AI must be clearly identified as such with a specific compulsory mention.
- **Specific prohibitions:** Promotion by influencers of the following is prohibited:
  - aesthetic acts, processes, techniques and methods that may present health risks; and
  - non-therapeutic products, acts, processes, techniques and methods presented as comparable, preferable or substitutable to therapeutic acts, protocols or prescriptions.

How companies should adapt

- Identify potential direct and indirect interactions with influencers.
- Put in place agreements with them and adapt current contractual arrangements.
- Set up internal guidance to help company's personnel and business partners in navigating French rules governing the promotion of health products and services online.
- Monitor influencers' content (including comments) to assess compliance with (a) legal requirements, (b) their contractual obligations and (c) company's standards.
- Track any transfer of value that may need to be reported.

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A new regulatory frontier for precision diagnostics in the Trump administration

The past decade has seen significant advances in precision medicine with novel diagnostics for prevention and treatment of chronic and life-threatening illness in oncology, neurology, transplantation, and cardiovascular disease, among other areas. Key to advances in precision medicine are regulatory and reimbursement decisions by FDA and CMS. In the first Trump Administration, numerous policy changes were considered to facilitate advances in precision medicine, and it is likely that many of these issues will be revisited in the next several years.

In the precision diagnostics space, one of the most significant issues we've been monitoring is FDA's regulation of laboratory developed tests (LDTs). After three decades of efforts, in May 2024, FDA finalized a wide ranging rule requiring LDTs to undergo premarket review as medical devices. Then, in March 2025, a federal court vacated the rule, determining LDTs are "services" and not "articles of commerce" regulated under the FD A medical device authorities. Stakeholders could continue to push for legislative action to unlock cutting-edge tests through a consistent framework to improve test accuracy and greater predictability for investment in precision medicine.

Similarly at CMS, a number of reimbursement policies could significantly impact precision diagnostics. A key barrier to the adoption of precision diagnostics has been the coverage process for assessing clinical utility of new diagnostics, including those cleared or approved by FDA. In January 2021, the first Trump Administration finalized a rule on Medicare Coverage of Innovative Technology, which would have provided transitional coverage for FDA cleared or approved breakthrough devices. This rule was withdrawn by the Biden Administration in 2021, but it is expected that some version of this rule will be rolled out again by the Trump Administration and could benefit certain novel diagnostics.

Additionally, in the first Trump Administration, CMS and Congress made modifications to billing and payment rules for diagnostics. In 2017, CMS updated archaic "Date of Service" rules that impacted billing for clinical laboratory tests performed at an independent laboratory on a specimen collected at a hospital. The ongoing issue of implementation of the market-based pricing system for clinical laboratory tests is another area ripe for regulatory improvements. Beginning in 2020, Congress has delayed reporting requirements for private payor rates under Section 216 of the Protecting Access to Medicare Act of 2014, which took effect in 2018.

Lastly, the Trump administration may set regulatory policy for how new targeted precision medicine technologies are commercialized, such as multi-cancer early detection tests, and algorithmic tests that use AI-assisted detection of biomarkers. These new tests call for new approach by FDA in terms of assay validation data requirements. They also present novel regulatory issues for an incoming CMS to define what constitutes a cancer screening test for purposes of Medicare, and whether algorithmic tests using AI pathology biomarkers constitute "lab tests," or software as a medical device (SaMD).

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New scrutiny for pharmaceutical market access innovations

Identifying patients for appropriate on-label use of pharmaceutical products is critical from both a business perspective and a public health perspective. The rise of precision medicine and growth in rare disease treatments have heightened the importance of identifying appropriate patients for emerging treatments through sponsored testing programs.

At the same time, telehealth platforms allow interested patients to connect with virtual health care services, which has expanded access to treatments but also introduced new risks and regulatory considerations when manufacturers of available treatments facilitate those connections.

Both types of market access innovations — sponsored testing programs and telehealth arrangements — have recently attracted governmental scrutiny in the U.S.

Sponsored testing programs generally involve pharmaceutical manufacturers providing no-cost testing, typically for rare genetic conditions, to potential patients. While these programs are beneficial for patient diagnosis and education, they have been scrutinized by regulators under the federal anti-kickback statute (AKS). In two separate Advisory Opinions — 22-06 and 24-12 — the U.S. Department of Health and Human Services Office of Inspector General (OIG) emphasized the potential risks of these programs, particularly when data is used for sales and marketing purposes. In December 2023, Ultragenyx paid $6 million to resolve allegations that their genetic testing program violated the AKS because it involved the use of data for sales and marketing purposes. And, in November 2024, QOL Medical paid $47 million to resolve allegations that their testing program related to Sucraid violated the AKS for similar reasons, plus the company allegedly misled health care professionals about the efficacy of the sponsored test.

Telehealth arrangements that link patients directly from manufacturer websites to health care professionals have also come under scrutiny due to concerns about potential kickbacks to telehealth providers and the promotion of medically unnecessary medications. These types of arrangements are often used by manufacturers with products that treat lifestyle or common maladies, such as obesity and migraines, but manufacturers in other disease states have explored similar arrangements. The continued growth of these arrangements has attracted attention, and, in October 2024, Congress requested information from Pfizer and Eli Lilly regarding their telehealth platforms and relationships with prescribers, reflecting growing regulatory interest in this topic.

Identification of appropriate patients for treatment with medications leads to better health outcomes, reduces misuse of medications, and improves adherence, but must also be done in careful consideration of complex regulatory requirements and emerging enforcement scrutiny.

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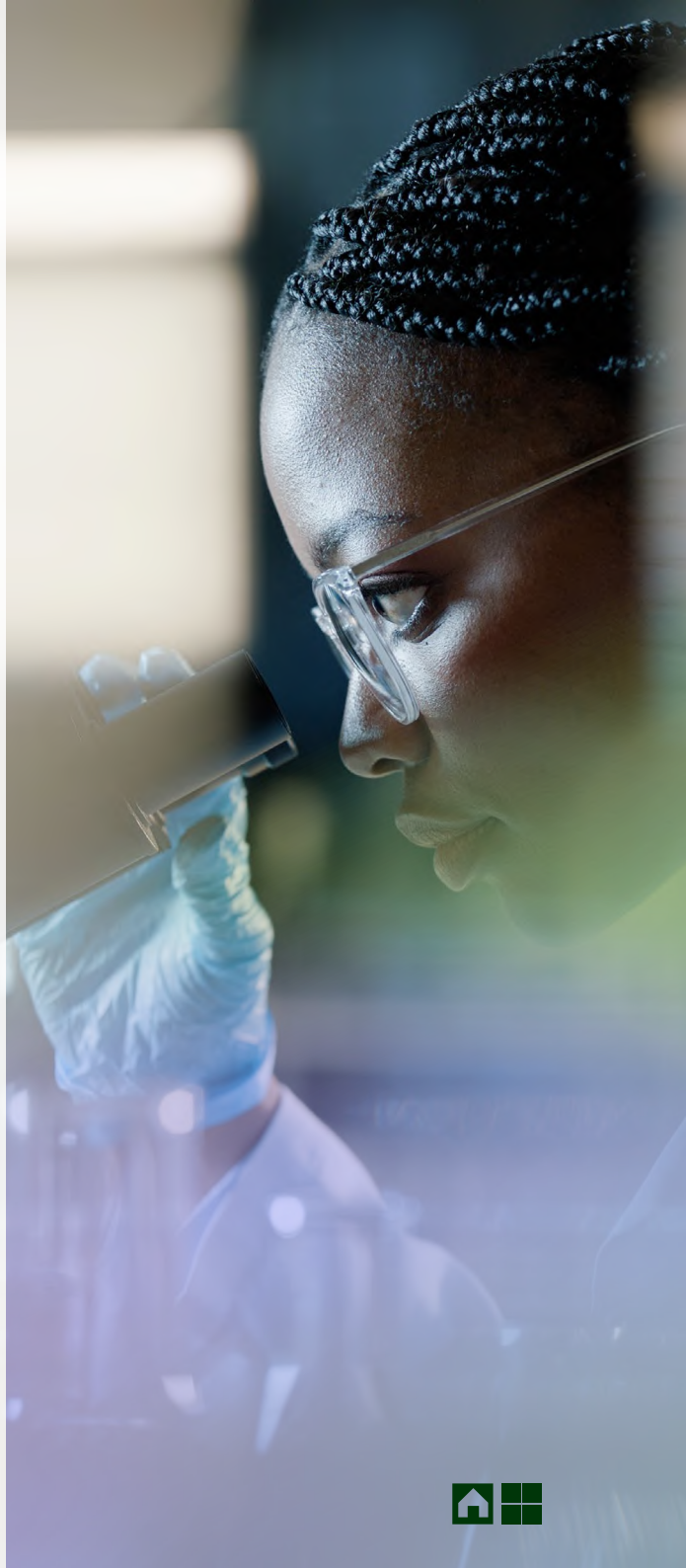

The evolving biosimilar framework: Moving toward interchangeability and less clinical data

The Biologics Price Competition and Innovation Act (BPCIA) established a two-tiered abbreviated approval pathway for biological products, with separate designations and standards for "biosimilar" and "interchangeable" biological products. Significantly, many state laws only allow biosimilar substitution at the pharmacy level if FDA has made a finding of interchangeability. In recent years, however, FDA has signaled a move away from differentiating between non-interchangeable and interchangeable biosimilars.

In 2023, FDA began taking steps to combat "confusion" that the safety and efficacy standards differed for non-interchangeable and interchangeable biosimilars by recommending interchangeable sponsors no longer specify in labeling that the product is interchangeable (rather than biosimilar). Most recently, in June 2024, FDA reversed course by no longer recommending switching studies to establish interchangeability. In a guidance update, FDA explained that sponsors may instead provide an assessment of why comparative analytical and other clinical data support an interchangeability determination, reducing the regulatory burden on potential interchangeable applicants. This change followed on the heels of a meta-analysis published by FDA officials of studies with a "switch" treatment period, which reported no difference in safety profiles and immunogenicity rates between participants who switched between the reference product and the biosimilar and participants who did not switch.

The result of these developments may be an uptick in interchangeable biosimilars on the market, an important potential consequence of which is an increase in substitution of biosimilars at the pharmacy level. The prior administration and Congress have supported removal of the statutory distinction between non-interchangeable and interchangeable biosimilars, signaling their understandings that new legislation would be required before the distinction can be eliminated entirely. Absent new legislation, we expect FDA to continue making individual interchangeability determinations but anticipate licensure of more interchangeables generally and earlier in a biosimilar's life cycle.

Additionally, for all biosimilars – both non-interchangeable and interchangeable – FDA appears to be moving away from requiring comparative efficacy studies to establish biosimilarity. The agency has made public statements reflecting an increased focus and reliance on comparative analytical data and belief that clinical data might be unnecessary given the analytical tools now available.

As FDA and industry gain more experience with biosimilars, we expect a continued trend toward streamlining of the data packages establishing biosimilarity and interchangeability. We continue to monitor FDA's action in this area and are keeping a close eye on proposed legislation in this evolving landscape.

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Accelerated approval: FDA defines whether a confirmatory trial is “underway”

The accelerated approval (AA) pathway allows FDA to approve drugs for serious conditions that address an unmet need based on surrogate or intermediate clinical endpoints that are reasonably likely to predict clinical benefit or an effect on irreversible morbidity or mortality. This pathway expedites the availability of treatments for serious conditions while obligating sponsors to conduct confirmatory trials post-approval to verify clinical benefit.

Congress amended the AA statute in 2022 to provide FDA new authorities. Among other things, the amended statute permits FDA to require, as appropriate, confirmatory trial(s) to be “underway” prior to approval or “within a specified time period after the date of approval.”

In January 2025, FDA published a draft guidance, ”Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway.” The draft guidance states that FDA generally intends to require that confirmatory trial(s) be “underway” prior to AA, although FDA explicitly recognizes that drugs intended to treat some rare diseases may be excepted.

Per the draft guidance, a trial is considered "underway" if:

- it has a target completion date “consistent with diligent and timely conduct of the trial,”
- the sponsor’s plans “provide sufficient assurance to expect timely completion of the trial,” and
- enrollment has been initiated (patients are actively being enrolled).

As sponsors consider the timing of submitting applications for AA, we recommend engaging with FDA about study design, practical limitations, and challenges in confirmatory trials as early as possible. In addition to timely agreement on the protocol, these discussions should include:

- Expected timelines for enrollment and study completion.
- Factors that may impact timeliness, including the accrual rate and enrollment timeline, number of active trial sites, and rate of additional site activation.
- Objective benchmarks for measuring progress, e.g., recruitment goals or endpoint event accrual.

FDA may be concerned that commercial availability may hinder recruitment. A sponsor unable to enroll a significant portion of the anticipated patient population before approval should proactively engage with FDA on enrollment plans and why timelines can be met after commercial availability.

FDA has recently issued other draft guidance documents on AA as well, including regarding withdrawal procedures where clinical benefit was not confirmed and determining whether a surrogate endpoint is reasonably likely to predict clinical benefit.

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Scaling back: Changes to FDA's pediatric drug development incentives

The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA)

BPCA and PREA have played pivotal roles in pediatric drug development. The BPCA, enacted in 2002, extends the period during which competitor products cannot be approved due to certain exclusivities and patents by six months for conducting pediatric studies based on a written request (WR). PREA, enacted in 2003, mandates pediatric studies for certain pharmaceuticals and biologics. The two statutes are often referred to as the "carrot" (BPCA) and "stick" (PREA). While the two programs have historically overlapped in many ways, in 2023, FDA issued a draft guidance proposing to limit the issuance of WRs only to sponsors who conduct additional pediatric studies beyond what is required under PREA, a change to FDA's longtime practice. In other words, sponsors would no longer qualify for pediatric exclusivity based solely on PREA-required studies. Many commenters criticized the proposal, and it remains to be seen how or if it will be finalized. Nonetheless, we have already observed in recent years a trend toward increasing difficulty for obtaining a WR.

The agency will be holding a public meeting on 15 May 2025 to gather input from stakeholders on pediatric drug development and labeling. The meeting will involve discussions on the public health impact of BPCA and PREA, challenges in conducting pediatric studies, and the impact of scientific advancements on pediatric drug development. The agency has invited public comments, and we encourage interested parties to share with FDA their perspectives to help shape the pediatric drug regulatory framework.

Rare Pediatric Disease Priority Review Voucher Program

Under the rare pediatric disease PRV program, companies that receive approval for a rare pediatric disease drug may qualify for a voucher granting priority review for a future drug application. These vouchers may be used by the company, transferred, or sold, and vouchers have sold on the market for over a hundred million dollars. Currently, a drug must have received rare pediatric disease designation by 20 December 2024 and must be approved by 30 September 2026 to be eligible for a voucher. While the bill extending the December 2024 sunset date ultimately did not pass, FDA continues to review designation requests in the event the program is reauthorized in future legislation.

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The promise of RWD/RWE to continue to fine tune REMS

In the past few years, FDA has doubled-down on its commitment to find ways to leverage real-world data (RWD) / real-world evidence (RWE), which is data collected outside of traditional clinical trials, such as information from electronic health records, patient registries, etc. This increased focus on and appreciation of the benefits and insights from RWD/RWE can and should be used to help enhance and adapt Risk Evaluation and Mitigation Strategy (REMS) programs.

In fact, the application of RWD/RWE is uniquely suited to the REMS context, because

- the goal of a REMS program is to ensure that drugs are safe in everyday clinical practice without impeding patient access or unduly burdening the health care system, and
- FDA requires sponsors to conduct periodic assessments of REMS in the postmarket ("real world") setting.

Improved risk monitoring with RWD can help arm sponsors with insights on how a REMS is operating in clinical practice. RWD can provide continuous, real-time monitoring of a drug's safety profile once it is in widespread use. This could enable the sponsor to identify new risks promptly or demonstrate that expected risks are not as frequent or severe as predicted or that known risks have been effectively managed.

In turn, these insights can lead to better sponsor and regulatory decision-making. REMS programs often include elements such as educational materials and clinical requirements that were not necessarily included in clinical investigations for the drug. RWD/RWE can help inform whether these elements are being effectively implemented and whether they are achieving their intended outcomes.

Although a REMS program is an essential tool for managing risks associated with certain medications, they can be burdensome and difficult to evaluate. Leveraging RWD can help create more dynamic, responsive, and patient-centered strategies to monitor and mitigate risks.

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Increasing state board enforcement against device firms, and the role of the DSCSA

In recent years, U.S. state Boards of Pharmacy have significantly ramped up enforcement actions against prescription medical device manufacturers and distributors, and the Drug Supply Chain Security Act (DSCSA) — although not applicable to medical device firms — has indirectly fueled this existing trend.

Historically, the Boards of Pharmacy have been tasked with protecting public health by concentrating regulatory efforts on the manufacture of drugs and the pharmaceutical supply chain, with their authority extending to manufacturers, pharmacists, pharmacies, and pharmaceutical distributors. However, the growing recognition of the risks posed by prescription medical devices — such as long-term implantables, software as a medical device, radiation emitting products, sophisticated insulin pumps, and metered-dose inhalers — has prompted state boards to assert more oversight in this space.

In particular, regulatory requirements that have exclusively pertained to drugs are increasingly enforced against medical device firms. Although some of these changes can be found in updated state laws and regulations, a surprising number of requirements have been imposed through state boards' interpretations of their enabling statutes and related regulations. Specifically, many states not only require licenses or permits for prescription medical device manufacturers and distributors, but application requirements and associated compliance measures are increasingly analogous to what has historically been limited to pharmaceutical entities. This shift can be partly attributed to concerns about patient safety, counterfeit products, and supply chain transparency; but it can occasionally be inadvertent (e.g., licensing requirements applicable to those who "dispense" prescription-only software products).

In most cases, regulatory expectations can be discerned and are relatively predictable; however, in other cases, state boards have pursued legal action or imposed fines or other discipline on device manufacturers for failing to comply with distribution and licensing requirements that were previously unenforced.

The DSCSA, enacted in 2013, was designed to enhance the security of the pharmaceutical supply chain by establishing national track-and-trace requirements for prescription drugs. The law mandates, in part, that pharmaceutical manufacturers, distributors, and dispensers implement electronic systems to verify and trace prescription drugs throughout the supply chain. However, the DSCSA explicitly excludes medical devices from its requirements, leaving a regulatory gap that has spurred individual states to take action. Without a unified federal standard governing medical device distribution in the same manner as pharmaceuticals, state Boards of Pharmacy have increasingly imposed some of the complex obligations inspired by or arising out of the DSCSA on medical device firms.

Accordingly, this patchwork of regulations frequently creates compliance challenges for medical device manufacturers and distributors, as they must navigate varying, and often confusing, state-by-state requirements. While there may be an intuition on the part of industry about how certain states *should* regulate different types of medical device firms and activities, it is common for this not to completely align with a states' interpretation or requirements in practice.

Increasing state board enforcement against device firms, and the role of the DSCSA (continued)

The increased scrutiny from state Boards of Pharmacy has led to a number of unique challenges for prescription medical device companies, including:

- **Complex compliance burdens:** Unlike the pharmaceutical industry, where state-based requirements are generally in line with the DSCSA's unified framework such that licensing expectations are relatively predictable, medical device manufacturers and distributors must discern and comply with a diverse set of state-level regulations. For example, companies operating in multiple states may face varying licensing fees, inspection requirements, and reporting obligations; and while some states require applicants to provide a large amount of documentation to accompany an application, other states require none.
- **Increased legal risks:** Failure to comply with state regulations can result in penalties, license revocation, or other legal action. Some states have pursued aggressive enforcement measures, leading to reputational damage and costly fines for non-compliant companies, which have in some cases reached six-figure penalties.
- **Market access and distribution challenges:** Companies that fail to anticipate and satisfy state-specific licensing requirements risk being unable to distribute their products in certain states, disrupting supply chains and limiting patient access to essential prescription medical devices. Moreover, a firm that is disciplined in a single state is likely to receive discipline and potentially suffer business disruptions in other states due to Board of Pharmacy reporting requirements.
- **Uncertainty in regulatory oversight:** A lack of federal guidance (comparable to the DSCSA for medical devices) imposes unique burdens on manufacturers and distributors as they attempt to discern the requirements that are applicable to their business. Adding to this uncertainty, state Boards of Pharmacy commonly establish enforcement policies and regulatory interpretations that may differ from the text of governing state laws. Medical device companies must therefore constantly monitor regulatory developments at the state level to ensure they remain in compliance.

Given the increasing enforcement activity by state Boards of Pharmacy, industry stakeholders are yearning for a standardized regulatory framework for prescription medical device distribution. Some trade associations and lobbying groups have pushed for federal legislation to establish a national system akin to DSCSA for medical devices, thereby reducing the regulatory burden caused by highly variable, and ever-changing state-based regulatory regimes. However, it is likely that states will continue along the current trend of incrementally applying pharmaceutical requirements to medical device firms, coupled with heightened enforcement efforts.

To succeed in this environment, medical device manufacturers and distributors are proactively assessing state-based requirements, implementing rigorous internal compliance programs, and closely monitoring state-based regulatory changes and enforcement trends to navigate the evolving landscape.

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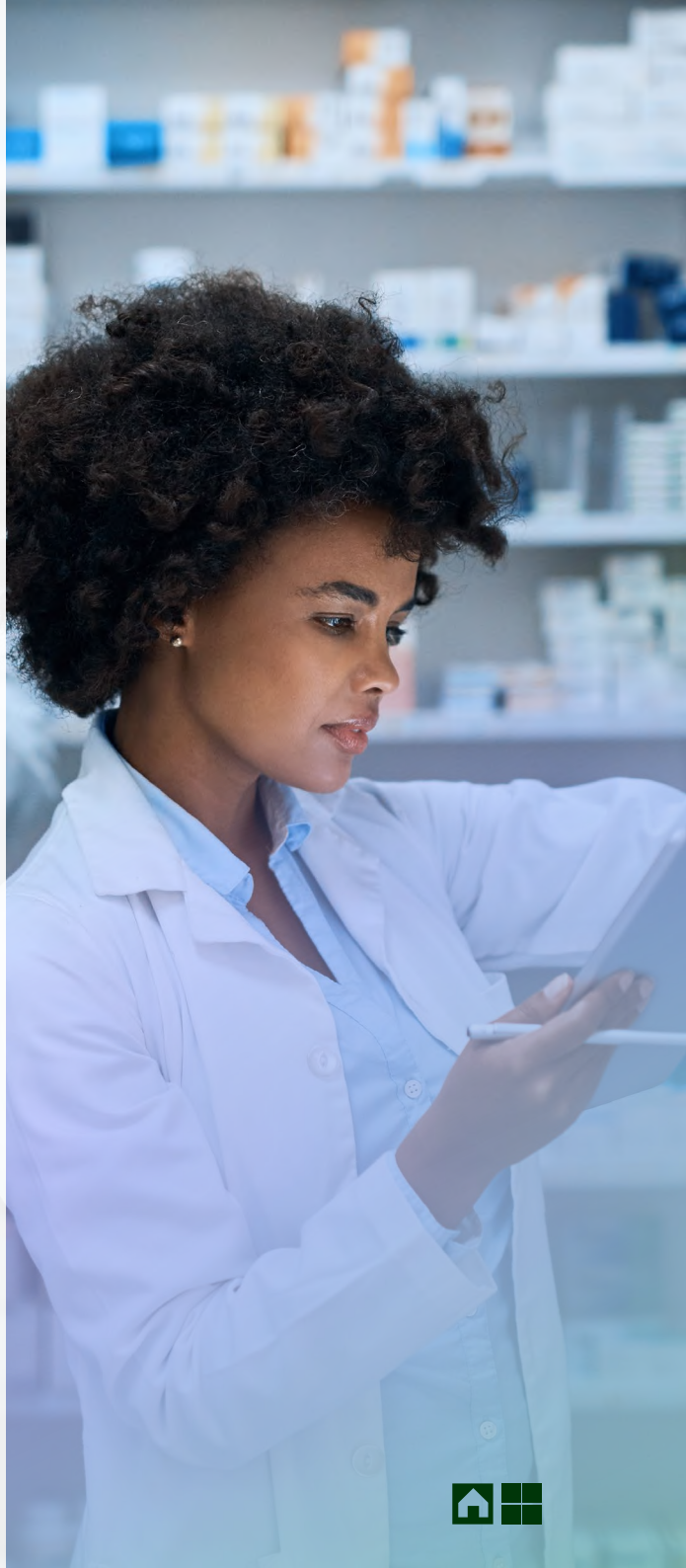

Psychedelics: Has FDA missed its opportunity and allowed the states to open the door?

The waiting game continues. Despite growing momentum and demands for access to psychedelic treatment, FDA has not approved psilocybin, midomafetamine (MDMA), or any other novel psychedelic for medical use; FDA has previously approved ketamine and esketamine, which have some hallucinogenic effects, for limited clinical use. Though some of these Schedule I drugs have shown promising results for treating mental health conditions such as depression, PTSD, and anxiety, no treatment has yet to meet the high evidentiary bar for FDA approval, as the agency attempts to apply its existing framework for these conditions which does not seem to be fit for purpose in evaluating these novel treatments.

While FDA has been restrained by application of its drug approval standards to these novel treatments, states have been pressing ahead. In 2020, the Oregon Psilocybin Services Act permitted the state to begin regulating the production of psilocybin products and the administration of psilocybin therapy, despite the substance's status as a Schedule I substance under the federal Controlled Substances Act (CSA). And, in 2023, the state licensed its first "psilocybin service centers." At these centers, patients (21+) can consume state-regulated psilocybin products while being monitored by licensed facilitators. State materials tout the "benefits" of psilocybin including research suggesting the drug may help with "depression, anxiety, trauma, and addiction" and "increase spiritual well-being."

This year, Colorado will begin to offer similar services, and is allowing separate licenses for centers that store relatively small amounts of psilocybin products (not more than 750 mg of psilocin), ideal for current mental health or wellness practitioners seeking to tack psilocybin services on to their existing practice.

Advocates for psychedelic therapy and patients seeking new effective treatments for difficult to treat conditions continue to request FDA-approved treatment options, and we expect the first few psychedelic approvals to trickle in over the next few years. Even so, it is unclear if FDA will be able to reel in this emerging industry, which is currently operating under state initiatives and permitting the use of non-FDA approved drugs that are not stifled by prior authorizations, REMS programs, etc. — especially if more states follow suit.

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Unpredictability persists in DEA quota system

The federal Controlled Substances Act (CSA) requires the Drug Enforcement Administration (DEA) to use quotas to manage the amount of Schedule I and II controlled substances and List I chemicals available for use in the U.S. for the upcoming year. On an annual basis, DEA determines the total quantity – aggregate production quota (APQ) – of each basic class of Schedule I and II controlled substances and certain List I chemicals that can be manufactured or procured for use, and manufacturers request slices from this aggregate pie to satisfy their individual manufacturing and procurement needs. However, it is a delicate balance for DEA to determine the supply adequate to meet medical, scientific, research, and industrial needs, while also mitigating opportunities for diversion and illicit use.

Congress and industry stakeholders have criticized the quota system for its contribution to drug shortages. According to DEA, 21% of drugs in shortage in 2024 were controlled substances, up 68% from 2023. Drugs subject to quota limitations accounted for 73% of this number. Once manufacturers determine a drug shortage is imminent due to a quota-related reason, they can request assistance from FDA to engage with DEA to address the issue. Yet, drug shortages continue to persist in spite of this mechanism.

DEA has made recent attempts to improve the quota allocation system, including rolling out a quarterly approach to quotas in 2024 that appeared to cause more disruptions than it solved, causing DEA to backtrack. DEA has also sought to rely more on ARCOS monthly reporting data to obtain real-time sales and purchase data to understand patient and industry demand. Still, uncertainties remain in the process. DEA can increase a substance's APQ during the year, but there is no way to tell beforehand whether DEA will do so, or what the increase will be if it does. Manufacturers may also request supplementary quota during the year, but the success of the request hinges on the manufacturer's rationale for needing additional quota, as well as how much of the aggregate quota of the substance remains, but DEA typically does not explain its reasoning if a quota request is not granted in full.

We have found that timely and well-supported quota requests and supplemental requests increase the chance that adequate quota will be provided. DEA continues to examine potential areas for improvement in the quota system.

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FDA offers new way for nonprescription drugs to be marketed

This past year saw some noteworthy updates to FDA's regulation of nonprescription drugs, including a new option for companies to bring nonprescription drugs to market with an additional condition for nonprescription use (ACNU), and FDA using the administrative order process to propose two significant changes to over-the-counter (OTC) monograph drugs containing acetaminophen and phenylephrine.

Last December, FDA issued a final rule allowing companies to bring nonprescription drugs to market with an ACNU. An ACNU is a condition that must be affirmatively fulfilled by a consumer which ensures that a drug can be appropriately selected and used safely and effectively without the supervision of a practitioner. An example of an ACNU is a requirement for consumers to complete a questionnaire to evaluate the consumer's safety risk before allowing the drug to be purchased.

FDA is requiring that the label of a nonprescription drug with an ACNU contain instructions about the ACNU, such as directing consumers to go to a particular website or retail location to complete a questionnaire to check if the drug is safe for the consumer. FDA said it hopes that allowing companies to market nonprescription drug products with an ACNU will increase consumer access to some drugs that are currently available only by prescription, such as those that treat certain chronic diseases or conditions. Some OTC drug manufactures have expressed concern that this final rule will allow FDA to simultaneously maintain prescription and OTC versions of the same drug product, discouraging full switches for prescription drugs to OTC drugs.

Over the past year, FDA also used the OTC monograph order request process to propose significant changes to OTC monograph drugs containing acetaminophen and phenylephrine. Last June, FDA issued a proposed order to amend the OTC monograph for internal analgesic, antipyretic, and antirheumatic drugs to add an allergy alert warning that drugs marketed under the monograph containing acetaminophen may cause severe skin reactions, including skin reddening, blisters, and rash. And last November, FDA issued a proposed order to amend the OTC monograph for cold, cough, allergy, bronchodilator, and antiasthmatic drug products to remove oral phenylephrine as a nasal decongestant. FDA has solicited public comments on both proposed orders, but has not yet finalized either.

Although the effective date of the ACNU final rule was originally 27 January 2025, it was delayed to 27 May 2025, due to a regulatory freeze. This will provide time for the new Trump Administration to consider whether to revise the ACNU rule, which would require further notice-and-comment rulemaking.

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BIOSECURE stalled in 2024, but may resurface

Certain Chinese contract manufacturing and development organizations (CDMOs) named as "companies of concern" in the proposed 2024 "BIOSECURE Act," and their business partners let out a collective sigh of relief late last year when BIOSECURE did not make it into end-of-year legislation. With the Trump administration already flexing its muscles to put pressure on China, and with Republicans in control of both houses of Congress, the BIOSECURE Act could well be taken up again this year.

The bill was touted as a national security measure intended to curtail the sharing of genomic data with CDMOs that were considered to present a risk of sharing the data with foreign adversary governments. In practice, the most current version of BIOSECURE would have prohibited Federal agencies from contracting with biopharmaceutical and other manufacturers who would supply biotechnology products or services obtained from these identified companies of concern in the performance of their Federal contracts. Given the nature of this prohibition, subcontractors and suppliers linked with these Federal contracts would have been impacted, as well. However, companies that enter contracts providing for reimbursement or payment under Federal health programs were specifically excluded from BIOSECURE's coverage.

BIOSECURE specifically named five companies as "companies of concern," and applied the contracting restriction to them as well as all subsidiary, parent, affiliate, and any successor entities. Additional companies could be added based on a determination of national security risk.

BIOSECURE garnered strong bipartisan support last year despite the inability of its sponsors to add it to a legislative package before year-end. Some legislators opposed to the bill expressed concerns that the BIOSECURE restrictions could impact access to needed biotherapies within the embedded Veterans Administration and Department of Defense TRICARE Federal health programs. Others expressed concerns regarding the bill's "automatic" application of the Federal contracting prohibition to the set of five named companies without any due process or opportunity for them to respond to perceived national security concerns.

We are continuing to monitor BIOSECURE developments closely in 2025.

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Life Sciences and Health Care Horizons provides only a snapshot of some issues the industry will face in the coming months and years ahead. Our team is focused on tackling these issues to provide our clients around the globe with valuable and innovative solutions to their most complex challenges – present and future.

To learn more about our team or any of the issues covered, please contact any of the authors in this publication, or one of the partners with whom you regularly work.

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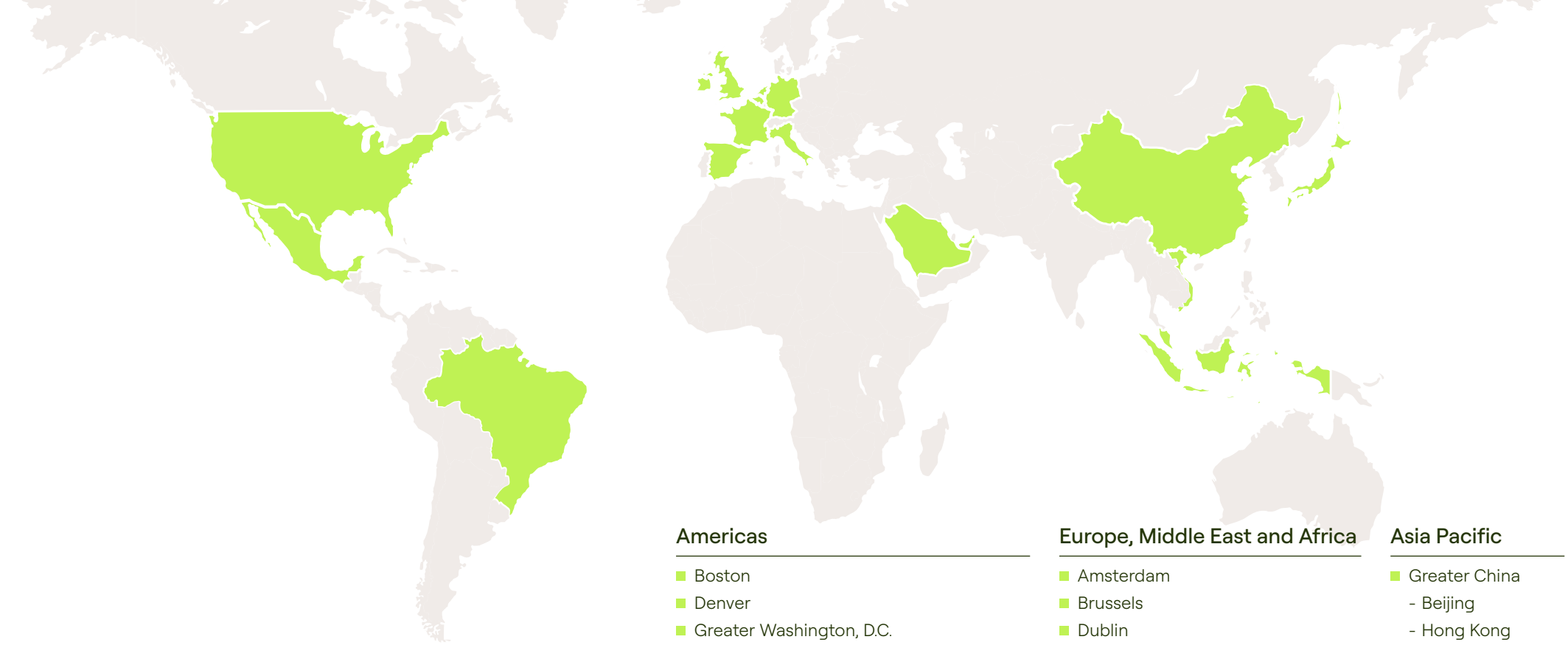

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