Hogan Lovells

Life Sciences and Health Care Horizons

2018

Welcome

Innovation in the life sciences and health care industries is occurring at a dizzying pace. Five years ago, anti-PD-1 antibodies from Merck and BMS had yet to be approved, CAR-T therapies were still in small-scale clinical trials, and digital health was seen as electronic step counters and little else. Today, cures are being found for diseases and conditions once considered life threatening or permanently debilitating.

All of this is happening within a regulatory environment characterized by constant turmoil, and the reality that for better or worse, innovations in medicine and health care lead to legal uncertainty. The market is striving to keep pace with novel technologies while also grappling with changes in the macro- and micro-political climate, including Brexit, GDPR and responses to a nationwide opioid crisis.

Our global Life Sciences and Health Care team—comprising more than 500 lawyers around the world who support more than 1,000 clients — helps chart safe passage through the uncertainties that exist at the intersection of business and government.

In the following pages, our team identifies a number of current and evolving trends that are shaping the future of the industry. We hope that you find our view of the horizon thought-provoking. We also want to thank you for your continued innovation for the purpose of improving human health. In many cases, it is your efforts to make the world healthier, and our work alongside you that allows us to better navigate the uncertain, but exciting future.

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Asia

Unlocking China's expanding life sciences market

Driven by rapid economic growth and the world's largest rapidly aging population, China should be one of the most important markets for global life sciences companies. But with less than a third of new drugs approved in western countries between 2001 and 2016 currently marketed in the region, China has proven to be a difficult market to enter.

During 2017, the China Food and Drug Administration (CFDA) introduced a series of regulatory and policy changes designed to streamline the approval process for new imported drugs. For example, CFDA enacted rules that allow for multi-jurisdictional clinical trials. This lifts the prior requirement for a new drug to first be approved (or have entered Phase II or III clinical trials) in the country where it was initially developed. This change in policy is expected to shorten the timeline for new, imported drugs to be available in the Chinese market. The CFDA has also been accepted as a member of the International Council for Harmonization (ICH), signaling an important step forward in the country's regulatory modernization.

In January 2018, the CFDA proposed two important new mechanisms: conditional marketing approvals and the expansion of compassionate use. The conditional approval mechanism allows innovative drugs to be granted conditional marketing approval when no other effective therapy is available. These innovative drugs, which would treat severe and life-threatening diseases or orphan diseases, would then be evaluated through post-approval clinical trials or studies. The compassionate use system allows patients who are in urgent need of clinical trial drugs but unable to join the in-progress trials to gain access to these crucial medicines. Though still in their early stages, we expect these two mechanisms to be formally adopted soon.

Another encouraging development is the strengthened intellectual property environment for new drugs. For the first time, the CFDA plans to adopt a patent linkage system (similar to the Hatch-Waxman system in the U.S.), under which every new drug applicant will be required to make a declaration on patent rights infringement.

2018 provides tremendous opportunities for fostering new innovations and improving access within China. As global companies continue to develop new positioning strategies for doing business in the marketplace, they'll also find new opportunities to leverage the sweeping regulatory and policy changes that continue to evolve.

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New Hong Kong listing regime proposals for biotech companies

HKEx recently (23 February 2018) published a consultation paper proposing to expand the current listing regime to attract more companies from emerging and innovative sectors to list in Hong Kong. The new regime would allow some biotechnology companies which would otherwise not be eligible to list under the current regime (eg those without profit or revenue) to be listed on the Main Board of HKEx.

To qualify under the proposed new regime, the biotech applicant should have:

- been in its current line of business (under substantially same management) for at least 2 financial years
- been primarily engaged in R&D of its core products for at least 12 months
- durable patent(s), registered patent(s), patent application(s) and/or intellectual property over its core product(s)
- obtained meaningful investment from at least one sophisticated investor 6 months prior to listing
- upon listing, a market capitalization of at least HK$1.5bn (approx. US$190m and €150m)

And regarding its core products,

- they can be pharmaceuticals, biologics, medical devices (including diagnostics) or other products which might be considered on a case-by-case basis
- they are regulated by one of FDA, CFDA, or EMA, or a competent authority acceptable to the HKEx and Hong Kong Securities and Futures Commission
- the R&D of at least one is "beyond concept stage"

HKEx is expected to publish the consultation conclusions in late April. Companies may submit a formal listing application under the new regime after the new rules come into effect.

We expect that these changes will make the HKEx more attractive to life sciences and health care companies and facilitate more early-stage capital raising and retail investor participation.

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Biologics and biosimilars in Japan

Japan is the world's third largest pharmaceutical market. With an average life expectancy of 85 years, the rapidly aging nation is experiencing health care cost pressure that is pushing the increasing use of biosimilars, both through domestic development and increased investment by international companies.

Beginning with the approval of Sandoz's growth hormone treatment Somatropin BS in June 2009, the Japanese regulator has approved nine biosimilars, including granulocyte colony-stimulating factor, erythtropoesis stimulating agent, and insulin and tumour necrosis factor-inhibitor. Two of the most recent approvals are Nichi-Iko Pharmaceutical's Infliximab BS treatment for Crohn's disease, rheumatoid arthritis, and ulcerative colitis in September 2017; and Mochida Pharmaceutical's Etanercept BS treatment for rheumatoid arthritis in January 2018.

Historically, Japanese pharmaceutical companies have focused their R&D efforts on small chemical molecules. But due to increased government pressure, attention is now shifting towards more biosimilars. Recent press reports suggest that in addition to partnering with international companies, Japanese biosimilars manufacturers are also seeking to acquire relevant secondary patents. This strategy may help strengthen Japanese companies' negotiation position—especially with respect to potential cross-licensing arrangements—and enable them to be more nimble when entering the fast-growing biologics market. As the push for increased biosimilar availability in Japan continues, more competition, collaboration and challenges are expected to follow.

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Ranked Band 1 for Life Sciences – Japan
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Europe

GDPR: the future of unified data requirements

In 2018, the EU General Data Protection Regulation (GDPR) will transform the way data is processed, resulting in an increase in data subjects' control over their data and compliance requirements. The accountability principle introduced by the GDPR means that not only do companies need to comply with new requirements but must also be able to demonstrate that they have adopted the most adequate measures to do so. Players across the health care and life sciences sector including pharmaceutical, insurance, and research companies will be subject to this obligation.

The appointment of a data protection officer (DPO)—tasked with independent and objective supervision of data protection compliance—will become mandatory for companies processing sensitive data on a large scale.

The GDPR will also impose direct liability on data processors. Sponsors and contract research organizations engaged in clinical trials will begin considering privacy as a priority in their internal relationships—and in their choice of commercial partners. Specific safeguards like pseudonymization and anonymization, will be adopted when processing data for scientific purposes.

As the GDPR begins rolling out these new compliance requirements, early preparation will become a critical competitive factor for life sciences and health care companies. The challenge is to leverage this legislation into new opportunities.

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MDR and IVDR

In 2017, after much discussion, Medical Devices Regulation and In Vitro Diagnostics Regulation were adopted at the EU level. These regulations, which include changes in classification of medical devices—as well as the conformity of assessment processes that will precede their CE marking, marketing in the EU and related clinical data requirements—are likely to result in major changes to EU regulation of medical devices.

Although the Medical Devices Regulation will not officially come into effect until May 2020 and the In Vitro Diagnostics Regulation will not begin until May 2022, manufacturers are already facing the impact of the upcoming changes, including in their interactions with authorities and notified bodies.

A number of notified bodies have decided either not to seek licences to the MDR and IVDR or to limit the scope of these licences. Consequently, these notified bodies will either cease to exist or have a reduced capacity to issue CE Certificates of Conformity. As a result, manufacturers are facing the prospective of losing their notified body and, as a result, losing the CE Certificates of Conformity that is essential to marketing of their medical devices in the EU.

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Brexit

Brexit is continuing to create significant uncertainty for the life sciences industry. While 2018 opened on an optimistic note with the start of negotiations for a transition period to allow businesses to prepare for the new EU-UK relationship post-Brexit, the details of that relationship—and the resulting impact on the life sciences industry—will not be clear for some time yet.

Industry bodies and their members in both the EU and UK are aligned on the priority issues for life sciences companies—regulation, trade, innovation and the free movement of people—and the overarching need to ensure patient safety and supply continuity. The industry is pressing for close cooperation and alignment of the future UK and EU regulatory regimes for medicines and devices, a position which has been publicly supported by the UK government. Whether close alignment will prove to be politically achievable remains to be seen.

Life sciences companies with operations, suppliers, or customers in the UK need to assess the potential legal and business risks resulting from Brexit and develop plans to mitigate those risks. This is not an easy task as the nature and timing of many of the risks will depend on the outcome of the EU-UK negotiations.

The UK is not set to leave the EU until March 2019 but companies need to start making decisions now about restructuring and investment to safeguard their ability to develop, manufacture and supply post-Brexit.

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Regulatory exclusivities in the EU

Regulatory exclusivity rights in the EU were originally developed to incentivize the industry to continue development of innovative medicinal products, including for the treatment of rare diseases and for use by children. In an effort to further promote development of these innovative treatments, the European Commission continues to consider the legal environment and its effects on innovation, as well as, now, pricing.

In the EU, innovative medicinal products can be protected by several regulatory exclusivities including regulatory data protections that safeguard data contained within marketing authorization dossiers and market exclusivity protections for orphan drugs. Pediatric extension of SPCs or of orphan exclusivity is also available in return for conducting pediatric studies.

With continued emphasis on innovative drugs, governments in the EU have been considering to what extent the legal framework for regulatory exclusivities is successful and how regulatory exclusivities relate to pricing and affordability of medicinal products.

The European Commission has recently launched several projects to evaluate the legislation on regulatory exclusivities. In 2017, reports on the Pediatric Regulation were issued and report on the impact of SPCs, pharmaceutical incentives and rewards is expected in 2018, along with an evaluation of the legislation on medicines for children and rare diseases.

In 2018 we anticipate new reports will help shed light on the impact of exclusivity rights in the EU. As potential new proposals for amendments in legislation on regulatory exclusivities continue, more debate around their efficacy is sure to follow.

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Digital Health

Overview

Technology is rapidly changing the way the health care industry operates, introducing unique solutions for challenging issues and creating potentially enormous business opportunities. From mobile applications and novel wearable sensors to complex predictive analytics and advanced digital therapeutics, digital health products encompass a broad range of different designs and technological solutions.

Continued technological advances, ever-increasing adoption of wearables, and growing health insurer interest in digital health intervention helped fuel digital health M&A in 2017. 2018 promises new opportunities in AI, robotics, and development of technologies in areas ranging from mental health, diabetes, and support for aging adults.

These technological disruptions require critical adjustments to today's complex legal and regulatory frameworks, and regulatory systems are rapidly evolving to address new technologies. From privacy and reimbursement considerations to changing product liability and medical device regulatory frameworks, optimal business planning requires understanding the issues as they exist today and anticipating how they are likely to evolve in the future.

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Data breaches

With the media regularly reporting on cyberattacks and data breach investigations, and calls for increased regulation growing louder, the existence of cyber threats to digital health businesses cannot be ignored. Legislators and regulators around the world are enacting data breach notification laws and the trend toward imposing industry-specific cybersecurity standards is expected to continue. The EU's General Data Protection Regulation (GDPR) includes key provisions requiring data breach reporting and imposing security obligations.

Hackers view health systems and medical devices as high value targets. Liability for class action and shareholder suits, regulatory penalties from enforcement actions, and reputational damage associated with health data breaches continues to grow. Digital health organizations must account for the unique risks associated with health information and implement programs for cyber risk identification, management, and protection that go beyond "check-the-box" compliance efforts.

Every digital health organization should have an Incident Response Plan (IRP) ready and rehearsed. Effective preparation for managing a data breach helps ensure a swift and coordinated response that can minimize harm to patients and consumers and reduce reputational impact and potential legal liability. As the threat of cyberattacks continues, nearly every digital health organization will be faced with a cybersecurity incident. Organizations that have plans in place to mitigate the risks will be better positioned to survive and thrive.

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"They are a fantastic, go-to firm for privacy counseling. They will drop everything when something is pressing and their work product is top-notch."

Client, Privacy and Data Security, Chambers USA, 2017

Health technology assessment in the EU

In many European member states, reimbursement of new health technologies—namely medicinal and pharma products and, increasingly, medical devices—is linked to a health technology assessment (HTA) which is the payer's prior assessment of additional patient value compared to other existing technologies. In the past, various HTA bodies have cooperated to some extent, but this has proven largely inefficient. A proposal for a new regulation submitted by the European Commission to streamline the HTA process may help change this.

Each member state typically conducts its own HTA. The result is multiple assessments, often with divergent outcomes. Moreover, HTAs are not well aligned with the regulatory requirements for product approval, which means uncertainty for pharma and device companies as well as significant financial and administrative burdens.

The new regulation (Regulation on health technology assessment, 2018/0018 (COD), 31 Jan. 2018) stipulates that the clinical part of the HTA exercise be conducted just once and steered by a newly established coordination group of HTA bodies. The outcome of this type of joint clinical assessment would then form the basis for reimbursement and pricing decisions by the respective member states. They are not to repeat the joint HTA assessment or to deviate from its clinical outcome.

It is also proposed that manufacturers be entitled to joint scientific consultation. There, the parameters and requirements for the respective technology will be determined uniformly for the upcoming joint HTA and can even align with the scientific meeting at EMA. These measures, along with the cooperation of individual HTA bodies, are likely to result in a more streamlined process, and further alignment for reimbursement across the EU as new and novel technologies continue to expand.

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Artificial intelligence: primary care and beyond

Continued advances in artificial intelligence (AI) are leading to new levels of automation in primary care, with several developments contributing to the transformation of outdated health care services and platforms. For example, public health services like NHS in the UK are partnering with app providers to trial the effectiveness of AI-powered chatbots and symptom checkers to triage patients. Early reports of patient engagement and satisfaction are evidence that the industry—and the public—are ready to embrace these new levels of automation.

The integration of AI and big data—a synergy that supports and improves clinical decision-making around diagnosis and treatment—will continue to advance. And companies across the health care continuum are taking the first steps in securing their own big data technologies. Digital health company Medopad's recent deal with Chinese tech giant Tencent to develop AI decision support software (giving Medopad access to the nearly 1 billion users of Tencent's WeChat messaging service), is just one example of the future landscape of R&D and AI partnerships.

In 2018 we will see more mainstream use of AI. Increasingly, companies will rely on AI to improve returns on the huge investment they make to bring new drugs to market. Leveraging new systems will ultimately boost the efficiency of clinical trials, enhance the quality of evidence, streamline processes and ensure accuracy.

As these new technologies develop, so will the potential risks for both health care companies and the data they will need to leverage. How regulators will wrestle with encouraging innovation, while simultaneously protecting the rights of patients and their data, remains to be seen.

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Digitization of the supply chain

The digital revolution is poised to create sweeping changes for life sciences companies—helping them better understand patients, but also transforming their manufacturing and supply chain operations. Machine learning and autonomous machines will change views on regulatory responsibility and liability in contracts, particularly given the absence of guidance documents from European or national authorities on the implications of digitization.

Pharma and med tech companies face growing challenges: globalization, personalized medicine, increasing supply chain complexity and price and cost pressure. Digitization of the supply chain holds enormous potential in helping companies cope with these challenges and gain competitive advantage. Integrated digital supply chains will allow companies to improve planning accuracy, manufacturing efficiency and productivity, inventory levels and service levels.

Sharing digital data throughout the entire supply chain (starting with the patient and ending with the supplier) may allow continuous manufacturing instead of "siloed" batch manufacturing. However, these new data streams raise critical legal questions: How do you create a GMP digital supply chain if there is not yet regulatory guidance? Who is responsible if machines are making autonomous decisions? How do companies separate and define responsibilities in contracts?

As automation in the supply chains becomes critical for remaining competitive, these questions, and many other surrounding the future of regulation, will come into focus.

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For more on digital health-related issues, download our recently published 2018 Digital Health Issues Guide

Liability for cyberattacks on products

Cyberattacks continue to be an ongoing issue within the life sciences industry, and any company using or producing digitally connected products is at risk. Many of these cases—all covered extensively by the media—have involved risk exposure related to remote-controlled medical devices, cyber vulnerabilities of products, and software hacking. Damage caused by these cyberattacks has been extensive and is expected to increase in 2018.

To respond to these threats, product compliance must take cyber vulnerabilities into account throughout a product's life cycle. In a worst case scenario, non-compliance results in claims for civil damages and/or severe penalties. Companies and their representatives may even face criminal charges for bodily harm or involuntary manslaughter.

In regard to potential product liability, supply chains can also be vulnerable to cyberattacks. As the systems that distribute and process medical products become more complex, the potential for exploitation also increases. Although manufacturers may in turn be able to claim redress against suppliers or service providers, risk allocation and liability are becoming increasingly important considerations.

Moving forward, manufacturers must be attuned to state-of-the-art compliance measures that will ensure their products remain protected. Adequate safety measures—including warnings, notifications, updates or recalls—must be timely, which means also having appropriate risk management measures in place. Carefully monitoring the market and staying current on cybersecurity threats will help ensure that companies are prepared—and ready to react.

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M&A

Pharma and biotech M&A

2017 was a relatively slow year for activity in the M&A markets for pharma and biotech companies. Uncertainty around the impact of the new presidential administration in the U.S. created significant headwinds for transactions, as deal makers waited to see the outcome of initiatives around health care and tax reform, and whether action would be taken on drug pricing.

Despite these uncertainties, many of the factors driving transactions remain in effect: big pharma and biotech's need for new products and technologies on the buy side and a desire to rationalize portfolios around "best-in-class" assets on the sell side. Furthermore, the strong venture capital market of the past several years has provided funding for early stage biotechs that are well positioned for an exit.

Conditions look very favorable for a robust M&A market in 2018. With tax reform enacted, the continuation of relatively low interest rates, and many companies holding significant amounts of cash to put to work, a number of significant transactions have already been announced. The main threat to this early momentum is potential volatility in the equity markets, and the risk that it could create uncertainty in what otherwise looks to be a busy year.

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Private equity: healthy competition

Following a quiet 2017, all signs point to an uptick for life sciences M&A in 2018. With asset valuations near historic highs, private equity sponsors will be taking creative approaches to compete and find value in the new year.

One way forward is the "club deal" where two or more private equity groups come together to improve their chances in high-priced, high-profile auctions. The model was successfully adopted by Bain Capital and Cinven in 2017 in their €4.1bn 2017 acquisition of Stada—the German maker of generic Viagra. We expect this collaborative approach will continue to proliferate.

As biopharma and med-tech companies continue to jettison underperforming, overlapping or non-core divisions, we may also see increasing numbers of private equity groups bidding for business spin-offs. Already this year, a number of private equity groups have entered the bidding for Sanofi's European generics business, which is valued at US$2bn.

Private equity groups are well-positioned to add value to these divisional spin-offs through effective management changes—and by helping their acquisitions switch from capital retention to funding ambitious growth and long-term strategic bets.

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> "I find them extremely collaborative. What I've always found and still get a sense of is that the partners all collaborate and work together as one."
>
> *Client, Life Sciences, Chambers Europe-wide, 2018*

Transfer Pricing

As the life sciences sector continues to evolve, adopt new technologies, and seek new growth opportunities, Transfer Pricing (TP) and tax and supply chain planning will continue to play a very important role in 2018.

The use of technology and the fragmentation of IP make it increasingly difficult to determine where value creation is. What's more, companies aren't able to operate in many jurisdictions without people on the ground, stripping them of their value creation under the more classic supply chain model (e.g. distribution and manufacturing activities).

Tax authorities are becoming more aggressive, and businesses should expect new legislation on IP and an increased number of TP audits.

M&A, JVs, and collaborations are often common in life sciences as a way to grow product lines, market products, or divest from mature markets and products to focus on new opportunities. Assessing risk and identifying opportunities through supply chain planning can generate significant financial benefits for businesses in this sector and mitigate tax and TP risk.

If carefully planned and aligned with commercial strategy, TP can enable businesses to achieve their strategic goals and become more efficient. But if ignored, it can result in significant cost and reputational damage.

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Hospital M&A

Hospitals and health care providers are continually asked to do more with less: improve efficiency and quality of care delivery (while bearing some or all of the financial risk), and at the same time contend with decreases in U.S. government reimbursement. To respond to this challenge, health systems must acknowledge a need for better management of health within the populations they serve—driven by access to services across the continuum of care.

In 2018, health systems will continue the search for partners that can assist with these goals. New relationships will take on a host of forms with increasingly complex legal and regulatory issues that that set them apart from transactions in other industries. And because most U.S. health systems operate as not for profit corporations, governance, culture and community-dynamics provide an additional level of complexity.

In the coming year, we expect to see:

- a host of transaction structures, including joint ventures, joint operating agreements, member substitutions, co-management agreements, and all-out acquisitions;
- a range of targets and combinations spanning the continuum of care;
- increased attention to the tax and finance implications of these structures;
- continued, heightened attention from antitrust enforcement agencies to competitive effects of these deals.

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Emerging markets

Africa

South Africa's proposed National Health Insurance scheme (NHI), once implemented, will represent a new paradigm in how health care is funded and procured in South Africa. The Government intends to formulate a comprehensive legislative framework for the full implementation of the NHI by 2026.

Despite the perceived benefits of NHI adoption, many questions remain, and there is uncertainty regarding matters such as funding, administration, legislative reforms and the future of private health care. Government has not provided any concrete indication regarding projected costs of the NHI or the manner in which it will be funded. Current funding options include payroll taxes, surcharges on taxable income and/or increases in VAT.

The future of private medical schemes once the NHI has been implemented is also uncertain. It is conceivable that medical schemes may be rendered redundant by the NHI or that they may be prohibited from funding health services covered by the NHI. There is also concern that implementation of the NHI may adversely impact private medical schemes.

In light of these uncertainties, the 2026 implementation timeline is widely regarded to be ambitious.

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Health care innovation: the view for Latin America

Transnational companies from the sector will continue to view Latin America and its emerging markets as attractive for expanding their businesses. Some of the factors key to Latin America's appeal include:

- increasing growth and expansion of health infrastructure and services aimed to better cover the population's needs
- innovative but not yet fully explored business and regulatory models aimed to improve access to innovative technologies, therapies and products
- regulatory frameworks which in some jurisdictions aim to simplify the launching of drugs and devices
- jurisdictions where various factors – including location, costs, population, and health infrastructure – are highly conducive to conducting clinical trials"
- adoption of specific recognition agreements between certain Latin American countries aimed to expedite regulatory processes.

New regulations and trends related to regulatory enforcement, competition and consumer protection are also emerging in several Latin American territories. Key issues in the region in 2018 include general compliance, data privacy, competition, and health regulation (which includes innovative therapies, digital health and clinical trials). Strategic investments and divestitures adopted globally are delineating new business trends and models for the further expansion of the life science industry sector throughout the region

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Russia: permanent injunction and generic drug sales

Generic producers continue to pose a challenge for innovative pharma in Russia. Generic producers use various strategies in order to launch products before expiration of innovator's patents, including registration of dependent patents, patent invalidity actions, and compulsory licensing claims. Yet through it all, our Moscow team represented Novartis in a precedent case for pharma business, proving that one can obtain an injunction using patent rights against a generic in Russia before the generic starts sales.

In the past, Russian courts granted permanent injunctions in patent disputes only upon actual commercialization of the infringing generic product. In the case of Novartis, when a generic producer began taking steps toward obtaining a marketing authorization for its generic product—seven years before Novartis' patent expiration—we chose to base the case on a concept of threat of patent infringement—without waiting for generic sales to happen. The Russian courts proved the threat of patent infringement in our favor and justified a permanent injunction.

This case confirms that successful patent enforcement is possible in Russia. It also proves that the Russian court system is able to demonstrate international standards for injunctive relief in pharma patent litigation.

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"The team's 'cross-border capabilities plus the deep knowledge and experience in the markets – we need someone who really understands the legal environment in these countries.'

Client, Life Sciences, Chambers Global-wide, 2018"

Regulatory outlook

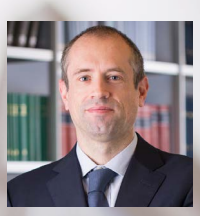
Pricing and reimbursement in the EU

Reimbursement of medicinal products in the EU is handled on a country-by-country basis. But because in many EU nations health care is provided and financed directly by the government through tax payments, challenges tend to be similar from country to country. Innovative medicines, such as gene therapies, now pose new questions around the future of reimbursement.

Seeking budgetary relief through a spending review is no longer sufficient. Increasingly, the focus is shifting to health technology assessment (HTA) and new pricing strategies. The concept of "pay per value" continues to be relevant, the idea being that reimbursement is not one-size-fits-all. As a result, payments for results, as well as mechanisms for sharing the costs and the risks with payors, are becoming popular.

What should innovators do? Real-world evidence is the key and cannot be limited to considering a therapeutic comparator that is considered as a reference for assessing the added value that a medicinal product may provide as against available alternatives. In the case of universal health care coverage systems like those the EU, many authorities may also consider the indirect cost-saving and social benefits associated with new therapies.

Unexpected or out-of-control costs are the main concern. How to address them is not only a matter of price: in some instances, precision medicine and new tools (e.g. diagnostic companions) may help to define the target and may become part of the answer.



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Pricing and reimbursement in the U.S.

Drug prices and how patients—as well as public and private payers—are able to afford them will continue to dominate the policy landscape in 2018. The Centers for Medicare & Medicaid Services' (CMS) 2017 approval of an innovative pricing arrangement for Novartis' new cell therapy KYMRIAH is encouraging other manufacturers to be more aggressive in pursuing such arrangements in 2018.

The president's 2019 budget proposes new demonstration project authority with respect to state Medicaid programs. This would enable adoption of private plan best practices regarding outcomes-based pricing, as well as bring a focus on restructuring the Medicare Part D benefit to lower patient out-of-pocket obligations. Where appropriate, the budget would also move Part B drugs to Part D in order to enable greater price competition. Congress's consideration of these proposed reforms may create opportunities for stakeholder input and may also trigger additional Congressional oversight efforts.

With the court challenge to California's new transparency law filed in December 2017—and with drug price transparency bills expected in Connecticut, Michigan, Oregon, and Washington—states show no sign of slowing their legislative and ballot initiative efforts to bring transparency and constraints to drug prices.

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Complex generics

Scott Gottlieb, Commissioner of FDA, is rallying his staff to "crack the code" on complex brand-name drugs that have frustrated the generic drug industry. Gottlieb speaks frequently on using FDA's scientific and gate-keeping roles to lower drug prices. Widening the array of products available as generics is one way to do that.

These complex products fall into three categories:

- active ingredients, e.g., drugs derived from natural sources, peptides, and drugs that incorporate novel chemistry (complexes, shared salts, and encapsulated compounds)
- drug delivery, e.g., products that incorporate device components such as auto-injectors and inhalers
- bioequivalence, e.g., implants and long acting depots with months-long dosing intervals.

FDA recently hosted three public meetings on solving the "problem" of complex products and is applying user fee funds (per agreement with the generic industry) to develop alternative methods for demonstrating equivalence. One area of research focuses on advanced metrics for characterizing factors that govern drug release and correlating those factors with in vivo pharmacokinetics. The idea is to use in vitro release measures as a proxy for in vivo testing.

On the drug-device side, FDA is focusing on whether products with different designs may nevertheless be used with no greater error rate than the pioneer. We are monitoring this area for our pioneer clients who are concerned about the validity of these methods to determine whether a generic is safe, effective, and functionally sound.

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OTC drugs

Starting in 2018, we expect major changes to unfold in the way over-the-counter (OTC) drugs are regulated by FDA. The regulatory scheme that governs the marketing of OTC drugs is now widely recognized as outdated and inadequate. As a result, Congress is likely to pass legislation soon that will overhaul the 45-year old OTC drug monograph system.

FDA has complained publicly that the monograph system is cumbersome and impedes prompt agency action on safety issues. The draft legislation is designed to expedite agency action on evolving science and safety issues and to create new incentives for innovation, including a new exclusivity provision. The new system is expected to result in opportunities for marketing OTC drugs with new ingredients and dosage forms, including some that were previously only available overseas or by prescription.

FDA is also developing a regulation—under its Non-Prescription Safe Use Regulatory Expansion (NSURE) program—to expand the types of drug products that may be considered OTC. Such OTC conditions of safe use might include consultation with a pharmacist on the use of a self-selection algorithm in the retail pharmacy setting, or even a mobile medical app. Using these new technologies and other conditions, certain products now available only by prescription will become more widely available as OTC drugs.

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>
> *Client, Life Sciences, Chambers USA, 2017*

Medical products with military application

In 2018, FDA launched a new program to expedite development and review of products designed to address unmet medical needs. The program—which expands upon recently enacted legislation that helps accelerate availability of medical products for the U.S. military—follows earlier enactment of a new priority review voucher for material threat medical countermeasures.

Beginning immediately with blood products designated as high priority by Department of Defense (DoD), the program will significantly increase collaboration between FDA and DoD. It will eventually expand to include other DoD priorities, including vaccines, regenerative medicine and other medical products. The program includes involvement of senior FDA leadership, enhanced communication with FDA and extensive manufacturing and clinical advice—all aimed to encourage FDA to treat DoD priority products at least as favorably as "breakthrough" therapies.

We anticipate that FDA will take this new program beyond its current military context in 2018. Based on FDA's initial work plan, FDA aims to expand the program beyond the battlefield to include other products for "austere environments" and other "front-line conditions" that may provide collateral benefits for military personnel, and in turn, the general population.

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Right to try

In his 2018 State of the Union Address, President Trump urged Congress to pass "right to try" legislation that allows patients with life-threatening diseases to gain access to unapproved experimental drugs. The President's comments followed the Senate's passage of a right to try bill on August 3, 2017. Key elements of the Senate bill include the following:

- Companies can make unapproved drugs available to patients with life-threatening diseases without FDA's authorization.
- Drugs must only complete one Phase I trial before becoming eligible for right to try use.
- As a general rule, FDA may not use clinical outcomes from "right to try" patients during the new drug review processes.
- Manufacturers cannot be held liable for making their drugs available on a right to try basis.
- Companies may be able to charge patients for certain costs of drugs provided under right to try.

If a federal right to try law is ultimately enacted, pharmaceutical and biotechnology companies will need to carefully consider whether they should make their investigational therapies more widely available. Doing so could pose significant risks, but may also lead to substantial benefits, including obtaining broader patient experience outside of the framework of clinical trials.

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Government enforcement

Controlled substances

Prescription drug abuse continues to be a key focus of DOJ, DEA, and the states. As a result, new developments regarding obligations to detect and report suspicious orders of controlled substances have come to light. The most recent examples include the D.C. Circuit decision in Masters Pharmaceuticals, Inc. v. DEA, a settlement agreement between DOJ and Mallinckrodt regarding the manufacturer's suspicious order monitoring (SOM) system, and a January 2018, announcement by DOJ regarding data mining.

In Masters, the D.C. Circuit found fault with the company's treatment of flagged orders as held orders that would not be reported as suspicious until after an investigation. The court's decision made clear that the indicia of suspicious orders set out in the regulation (unusual size, pattern, or frequency) were not the only factors that had to be considered.

In the Mallinckrodt settlement, DOJ pursued an enforcement action that the company was obligated to detect and report suspicious orders that placed by downstream customers (e.g. pharmacies, hospitals) of Mallinckrodt's distributor. Further indicating that SOM systems will be a focus of DEA activity, DOJ announced that DEA agents will be mining data to identify large opioid prescribers and dispensers. The review of this data, and additional enforcement actions, can be expected to result in a continued focus on manufacturers' and distributors' SOM systems.

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IWCF developments in life sciences

The Department of Justice (DOJ) is conducting an industry-focused investigation into allegations that pharmaceutical companies violated the False Claims Act by paying kickbacks to Medicare patients through charitable foundation disease funds. United Therapeutics recently entered into a $210m settlement to resolve such allegations, including one claiming that UT engaged in misconduct to eliminate price sensitivity to the relevant drugs. We anticipate continued DOJ focus in this area in 2018.

As discussed in the previous section, DOJ has announced opioids as its highest enforcement priority. In 2017, it settled Controlled Substances Act civil penalties with distributors Cardinal & Kinray ($44m) and McKesson ($150m) for alleged failure to report suspicious orders. McKesson agreed to an independent monitor and DEA compliance program, the first of its kind with a distributor. Opioid manufacturer Mallinckrodt paid US$35m to settle alleged failures to report suspicious orders. It agreed to monitor and report to DEA suspicious chargeback volume in its distribution chain, the first time a manufacturer has been asked to monitor and report such chargebacks at a lower level in its distribution chain.

DOJ is scrutinizing electronic medical records software used in medical practices when physicians receive HiTech Act incentives for adopting electronic recordkeeping and communication with hospitals, labs, and other health care providers. The $155m eClinicalWorks civil False Claims Act settlement and HHS-OIG Corporate Integrity Agreement in 2017 demonstrate that software companies are expected to comply with the Anti-Kickback Statute, and ensure that their testing, certifications, and functionality meet HHS Office of National Coordinator regulations. These require software to meet "meaningful use" standards for their HCP customers. We expect more scrutiny in this arena by DOJ, HHS-OIG and the ONC.

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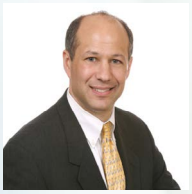

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Yates memo

The Yates Memo—a directive from 2015 that provides guidelines focused on prosecuting culpable individuals within entities, rather than just the entities themselves—remains unchanged. Despite reported comments from Deputy Attorney General Rod Rosenstein that suggested future changes to the Yates Memo, the Department of Justice has remained silent on the issue into 2018.

The DOJ reported through a press release that it recovered US$3.7m in civil settlements and judgments in 2017. The department specifically touted holding individuals accountable in several of those settlements where individual owners of companies agreed to joint and several liability with their company. For example, the DOJ highlighted the US$155m settlement with eClinicalWorks (eCW) settlement and a US$145m settlement with Life Care Centers of America, where individual owners agreed to such joint and several liability. The DOJ also claimed that it had recovered $60m in settlements with individuals separate and apart from any corporate settlements.

The eCW settlement is unique in that the DOJ, in addition to requiring the company owners to admit joint and several liability for the settlement payment, required three lower-level employees to pay relatively minor sums (US$50k for one individual and US$15k for the other two) to resolve their liability in separate settlement agreements apart from the company. This appears to be a departure from previous experience where the DOJ only pursued high level employees, officers or owners of companies who directly benefitted from the alleged conduct.

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Precision medicine

Gene therapies

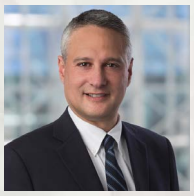
In 2017, the FDA approved the first gene therapies, marking a new era in precision medicine. Gene therapies are beginning to deliver on their promise of eradicating the underlying causes of diseases, and we anticipate continued progress throughout the coming year.

The FDA has approved Luxturna, a treatment for a rare, blindness-causing genetic mutation, and Yescarta and Kymriah, two gene-based blood-cancer treatments which are CAR-T immunotherapies. Gene therapy is also being developed for more prevalent diseases, such as hemophilia, Parkinson's disease, Huntington's disease, and cystic fibrosis.

Despite new opportunities bolstered by FDA announcing that gene therapies may qualify as Regenerative Medicine Advanced Therapies, challenges remain. Thoughtful clinical trial design continues to be a critical component. Small patient populations and serious and progressive symptoms in diseases targeted by gene therapies create barriers to generating the robust clinical evidence needed for both FDA approval and reimbursement decisions by payers.

There is also uncertainty and concern around long-term outcome durability, dangerous immunogenicity reactions and unique manufacturing challenges. Government policy continues to evolve on issues like reimbursement and the regulation of diagnostic devices often needed to personalize therapies.

Gene therapies will play a growing role in medicine in the decades to come, but important challenges will need to be addressed before their full potential can be realized.



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Regenerative medicine

Regenerative medicine—which includes breakthroughs like stem-cell-regenerated organs and personalized gene therapies—has been recognized by the FDA Commissioner as one of the "most promising fields of science." To support innovation, the FDA has issued four guidance documents designed to clarify how it will apply the existing regulatory framework to these therapies. This framework includes the Regenerative Medicine Advance Therapy (RMAT) designation program, which offers sponsors more frequent interactions with FDA during product development.

These guidelines attempt to clarify which human cellular and tissue products (HCT/Ps) require approval versus which may continue to be marketed without prior FDA approval. To provide time for HCT/P manufacturers to come into compliance, the FDA will not enforce its stricter interpretations for 36 months. An uptick in FDA enforcement action against certain currently-marketed HCT/Ps has demonstrated that those HCT/Ps promoted for serious or life-threatening diseases (e.g., cancer) or with high risk routes of administration (e.g., intra-ocular injections) will not be insulated by this enforcement moratorium.

For regenerative medicines that will require FDA pre-approval, the FDA may consider innovative approaches adapted to the revolutionary nature of these products. Sponsors may also benefit from enhanced collaboration with the FDA and expedited review in obtaining pre-market approval.

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"I have found them to be excellent strategic thinkers who propose courses of action to streamline processes and deliver the results we need."

Client, Life Sciences, Chambers USA, 2017

Personalized medicine

Personalized medicine seeks to precisely target therapies to the specific characteristics of individual patients. Rapid advancements in genetic and molecular testing, along with other diagnostic technologies such as cell-free DNA assays, have improved the ability to select the right therapy at the right dose for the right patient. Other forms of personalized medicine, such as 3D printing of individually matched implants, also promise to improve targeted treatments.

Personalized medicine is also changing the way therapies are developed. For example, collaboration between pharmaceutical and diagnostic companies allows for the design of companion diagnostic assays early in the development of novel therapies.

While these medical approaches are revolutionizing certain areas of medicine, they also require adjustment of traditional legal and regulatory frameworks. Companion diagnostics and their associated pharmaceutical products must be approved by the U.S. FDA in parallel, requiring close collaboration between multiple companies.

Similarly, a complex framework of reimbursement is slowly being developed and traditional models of laboratory regulation are melding with diagnostic product regulatory requirements. The novel regulatory and reimbursement issues require forward thinking collaboration agreements between the companies working in this space. As these technologies grow in prevalence, questions surrounding the legal issues will continue to evolve as well. As these technologies grow in prevalence, questions surrounding the legal issues will continue to evolve as well.

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On the horizon

Punctuated equilibrium? Convergence and non-traditional entrants in the health care industry

In the not-so-distant past, the health care industry comprised a familiar cast of characters: pharmaceutical and medical device companies, hospitals and other health care providers, and payors for these products and services. These players generally operated as discrete sectors of the industry, each adapting to distinct business dynamics and legal/regulatory frameworks.

This ecosystem is in the midst of upheaval. Last December, CVS announced a merger with Aetna and in March, Cigna announced its acquisition of Express Scripts. In January, a consortium of several hundred hospitals announced they would form a generic drug company. And new types of entrants have been streaming into the industry. Google and Apple entered the health care market a few years ago. In January, Amazon, Berkshire Hathaway, and JP Morgan announced they were forming a health care company. In February, Amazon launched a private label line of OTC products, and many believe these steps are part of a larger push by Amazon to move into the health care sector.

These developments present new business challenges (and potential opportunities) for traditional industry actors, and new legal and regulatory questions are sure to emerge in the rapidly evolving health care landscape.

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Closed loop systems

So-called "closed loop" systems, which sit at the forefront of cutting edge technology, combine novel sensors, therapy delivery tools and control algorithms to automatically deliver therapy based on a patient's specific needs. Artificial pancreas systems, which combine glucose sensing technology, insulin delivery pumps and automated control algorithms, are one of the more advanced examples of a closed loop system. These tools leverage automation to help manage complex diseases, alleviating some of the self-management burden on patients and potentially improving outcomes.

Complex systems like artificial pancreas products require innovative regulatory approaches, nuanced privacy strategies and long-term reimbursement plans. They are also an area to watch because development often involves strategic partnerships between multiple companies. This requires that deals be structured to provide long-term benefit to all of the players.

While some initial technologies have already been released to the market, innovation promises to bring continued improvements.

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3D printing in the EU

3D printing is quickly taking hold in the **medical devices market** and poised to change how we think about health products, manufacturers, and the legal issues they create. While medical devices like implants, prostheses, and even bones are already being produced by 3D printers, Medical Device Regulation, which has not yet even come into force, is outdated in this area.

Until now, 3D printing has largely been unregulated, despite multiple legal issues. For example, if an implant is 3D printed by a hospital, who is responsible? The supplier of the printer, the supplier of the CAD files providing the blueprint for the implant, or the hospital itself? Is the implant a customized device? Which manufacturing standards and regulatory requirements apply? Do exemptions apply for devices made in health care institutions or are they manufactured on an industry scale?

The answers to all these questions have to be found by interpreting laws which do not explicitly regulate this new area of technical developments. Additional questions also arise from the direction of the machinery directive, the REACH Regulation, data privacy, intellectual property and product liability.

These issues also impact the **pharmaceutical industry**, as 3D printers may soon be used to manufacture drugs. For traditional manufacturers, utilizing 3D printers compliance with GCP is in focus. However, 3D printers may soon be used by hospitals to print their own medicinal products or to do patient-individual compounding. Questions arise as to whether a hospital/pharmacy is allowed to manufacture outside the scope of pharma laws, and what traditional manufacturers can do about it.

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New scientific technologies on the horizon

This year, there is great anticipation for the results of the first clinical trials to use CRISPR-Cas9 technology to "fix" defective genes. Across the life sciences industry research efforts are focus on deconstructing the established understanding of medical conditions and treatments. The use of innovative technologies such as nanoparticles targeted to specific bacterial markers are being used more widely to reimagine the way in which diseases are treated.

Many of these developments are being informed by systems in nature. Biomaterial technologies have taken inspiration from electric eels for developing hydrogels as power sources for active implantable medical devices. Venus-fly traps have inspired construction of nanowire claws capable of capturing over 90% of bacteria in blood passing through dialysis machines.

The current scrutiny over the misuse of painkillers will be of particular interest to those developing an aromatherapy-based analgesic, where cells have been genetically engineered to produce a painkiller in response to a volatile component of spearmint.

Digital technology continues to revolutionize development of treatments for patients and enables clinicians to better understand the world as experienced by the people being treated. But technology's largest contribution will likely be the analysis of big data by artificial intelligence systems in the design, testing, and delivery of new health care solutions.

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Blockchain and life sciences

As numerous companies explore use cases that may deliver innovative cost-cutting solutions, blockchain is forecast by many to have a profound impact on the life sciences industry in 2018.

Among its many potential benefits, blockchain may be able to reduce the risk of counterfeit medicines, offering the ability to track medicine batches in real time—from manufacture to supply. A unique blockchain record would be assigned to each batch as it begins its life in the supply chain, and additional information would be uploaded as the batch progresses through its lifecycle. This level of tracking would allow businesses and consumers to trace the full history of each batch, a level of oversight that will prove invaluable to life sciences and other sectors, such as retail and logistics.

Blockchain may also increase transparency and improve patient experiences by granting unprecedented access to medical records for both medical professionals and patients. The decentralized nature of blockchain would enable patients and doctors to interact and share data on a peer-to-peer basis, eliminating the need for a centralized database or intermediary.

While the regulatory, data privacy and security areas still cause concern across all industries, blockchain looks set to accelerate during the course of 2018.

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Client, Life Sciences, Chambers Global-wide, 2018

For more information

Life Sciences and Health Care Horizons provides only a snapshot of some issues the industry will face in 2018. 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 Asher Rubin, any of the authors in this publication, or one of the partners you regularly work with at Hogan Lovells.

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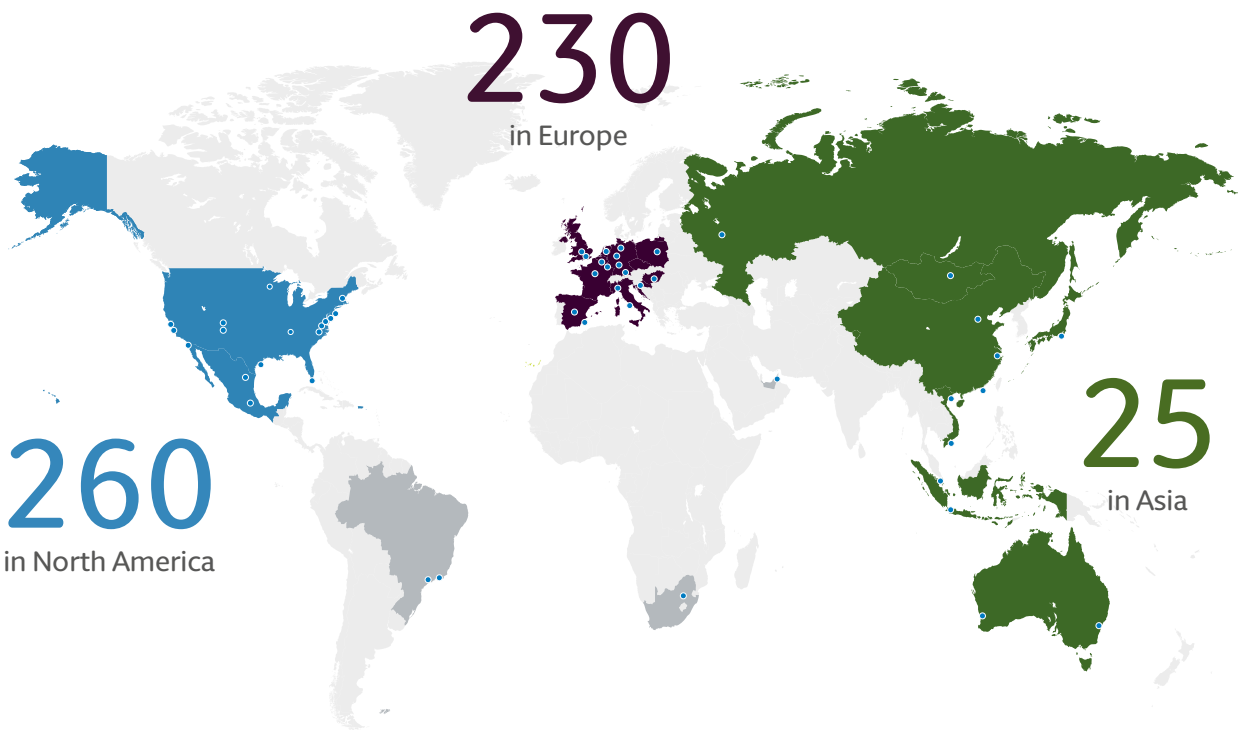

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