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Bird & Bird

Bird & Bird's *Bio & Beyond*

Keeping you up to date on Life Sciences & Healthcare Regulatory developments in the European and Asia-Pacific regions

Welcome to the first edition of our quarterly Life Sciences & Healthcare Regulatory Newsletter – Bio & Beyond – tailored specifically for our US-colleagues and friends.

With this newsletter, we aim to support you when assisting your clients with businesses in the European Union, the United Kingdom and the Asia-Pacific region by providing key developments you need to be aware of.

In this issue, we highlight the latest international regulatory developments relevant to US businesses. You can expect concise, practice-focused insights on emerging regulations, compliance challenges, and new market opportunities.

We hope these key takeaways will keep you ahead of shifting regulatory demands across global markets and ready to support your clients in navigating the evolving regulatory landscape - wherever they do business.

Always feel free to reach out to us to discuss any of the below updates or any other regulatory issues of interest. We would be very happy to stay in contact.

European Union

New EU Pharmaceutical Reform

Why is this relevant to US businesses?

The proposed changes under the EU pharmaceutical reform will directly affect US life sciences businesses operating in the EU. Staying ahead of these developments is essential for safeguarding market access and ensuring regulatory compliance.

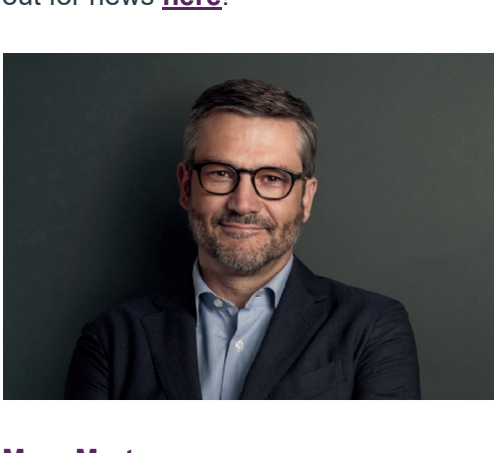
EU Pharma Reform

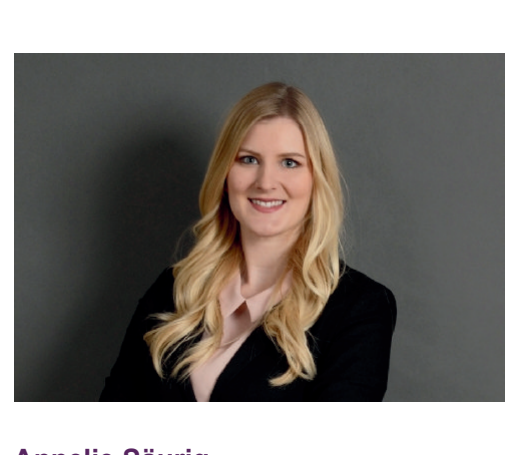
European institutions have identified the need to overhaul key pharmaceutical legislation, especially as last major amendments were from 2004. The European Commission published its reform proposals in spring 2023, and on 10 April 2024, the European Parliament adopted the EU Pharmaceutical Package consisting of a new directive and regulation. On 4 June 2025, the EU Council agreed on its position on the proposal and will now negotiate with the Parliament to reach a final version of the new EU pharmaceutical legislation. The current drafts and status of the legislative procedure can be found on the EU Parliament's website (here and here). The Council's mandate for negotiations was published on the Council's website (here).

The package addresses key areas with important implications for the industry – which we have summarised in brief updates.

- Proposals to revise the procedures for obtaining and maintaining marketing authorisations in the EU. Find our full assessment here (5 min read).
- Updates of the (incentive) framework for orphan medicinal products, aiming to better support treatments for rare diseases. Find our insights of the key changes here (3 min read).
- For paediatric medicines, the reform also presents new requirements and incentives. Read our take on the impact here (4 min read).
- A new focus on combating antimicrobial resistance. Find our update here (3 min read).
- Introduction of new rules on parallel imports of pharmaceuticals altering the landscape for trademark holders. Read our assessment on what this means here (4 min read).

We will be publishing a further series of updated articles on the EU Council's position. Watch out for news here!





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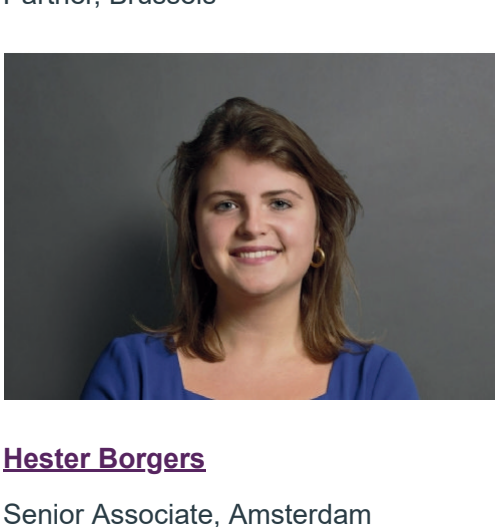


Hester Borgers
Senior Associate, Amsterdam

European Health Data Space

Why is this relevant to US businesses?

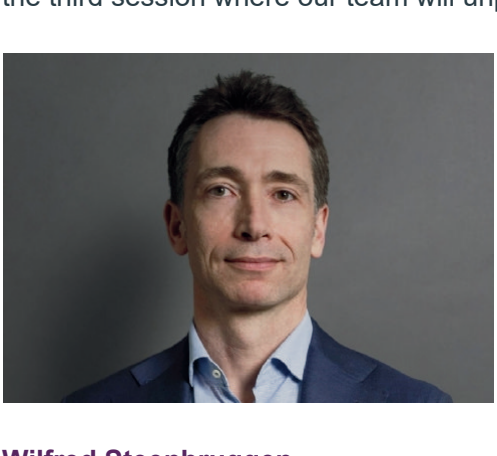
This new legislation changes the whole legal framework for health and research data in the EU. It is important for all companies with business (including clinical trials and research) in the EU to fully understand their obligations under the EHDS, assess when these rules will apply to them, and prepare accordingly.

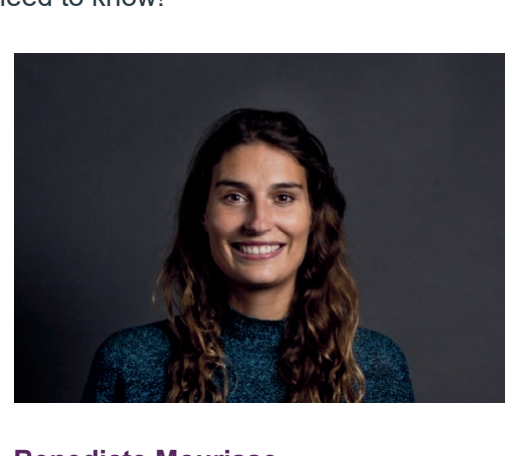
A new landscape for health data

On 26 March 2025, the EHDS Regulation entered into force and will gradually start to apply (find here). The EHDS introduces new opportunities for life sciences companies, particularly in the area of secondary use of electronic health data (EHD). At the same time, it imposes a range of new obligations on Health Data Holders, including requirements to share, document, and manage access to EHD. Read our overview of what you need to know here.

Webinar series EHDS

We have introduced an on-demand webinar series on the EHDS. The first session can be found here and the second deep dive on secondary use of health data can be found here. Curious how the EHDS will impact your IP and trade secret strategy? Register here to watch the third session where our team will unpack all you need to know!





Wilfred Steenbruggen
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AI Policy of the European Medicines Agency

Why is this relevant to US businesses?

The EMA is moving toward a broader regulatory framework for AI in life sciences, with more guidance expected in the coming years. For US life sciences companies operating in the EU, staying aligned with these regulatory developments is essential to ensure regulatory compliance and future market access, and to use this opportunity to stay ahead of the crowd.

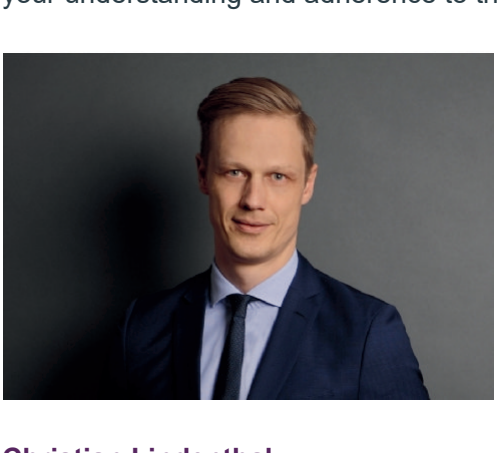
EMA's AI policy

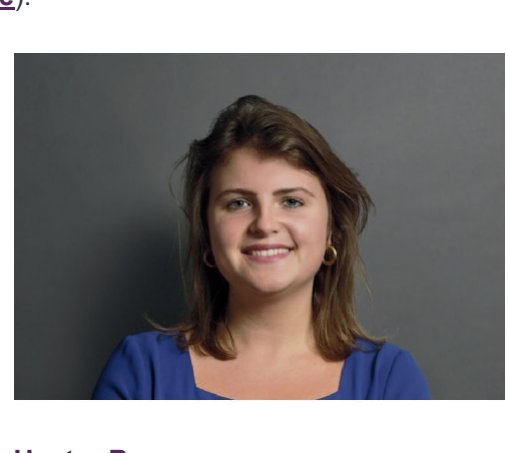
EMA's policy signals the EU's approach to regulating AI in the EU life sciences sector. The EMA has retained a strong focus on AI, with its reflection paper at the end of last year setting out its current vision on the use of AI in the lifecycle of medicinal products (find here). Read our assessment on what this means for the industry here.

The reflection paper is part of EMA's multi-annual workplan (2023-2028) (find here), outlining the key focus areas and areas where further guidance is needed. Read our break down of this workplan here.

AI Act

Bird & Bird's AI team has created an AI Act guide, walking you through the key aspects of this new regulation highlighting the most important actions organisations should take to ensure compliance and provides navigational signposts to relevant regulatory sources to enhance your understanding and adherence to the AI Act (here).





Christian Lindenthal
Partner, Munich

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EU Proposes Critical Medicines Act.

Why is this relevant to US businesses?

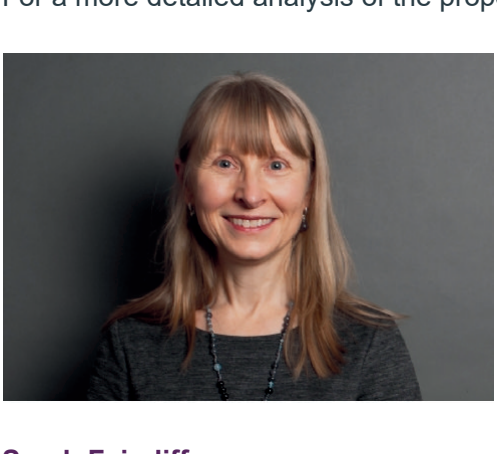
The proposed Critical Medicines Act (CMA) consists of a range of industrial policy measures which aim to strengthen supply chain vulnerabilities and boost EU-based manufacturing of medicines and active pharmaceutical ingredients. Given the global nature of the pharmaceutical industry, this will have direct or indirect consequences for any manufacturer or distributer of medicines. The proposed fundamental restructuring of critical medicines procurement frameworks will also need to be on the radar of all companies selling medicines within the EU.

Proposed new measures to address shortages of key medicines and supply chain vulnerabilities

In proposing a new Critical Medicines Act (CMA), the EU is taking action to address the long-standing problem of serious disruptions to supplies of certain medicines in EU Member States. By encouraging more EU-based manufacturing and the diversification of supply chains, the aim is to guard against potential public health crises due to product shortages. The draft legislation aims to boost investment in EU manufacturing capacity, so reducing the EU's dependence on third party manufacturing and diversifying supply chains. It also proposes the introduction of procurement-related measures to strengthen supply chains and leverage aggregated demand for products. It is based on the following key elements:

- Support for "strategic projects" (those that create, increase or modernise EU manufacturing capacity for critical medicines and active substances)
- Significant changes concerning public procurement to incentivise supply chain diversification and resilience
- Collaborative & joint procurement as an option for Member States
- Strategic partnerships to support supply chain diversification

For a more detailed analysis of the proposals here.



Sarah Faircliffe
Legal Director, London

Clarissa Junge-Gierse
Senior Counsel, Munich

United Kingdom

The Windsor Framework: new rules from 1 January 2025

Why is this relevant to US businesses?

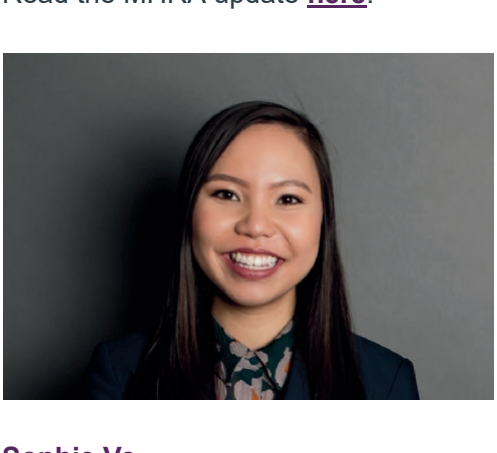
The new rules are applicable to US businesses that place medicinal products on the UK market, including Great Britain (England, Scotland and Wales) and Northern Ireland, which may differ to EU requirements.

Regulatory changes for medicines

From 1 January 2025 the Windsor Framework introduces new rules in the UK for:

- product licensing
- packaging and labelling
- the EU Falsified Medicines Directive (FMD)

Read the MHRA update here.



Sophie Vo
Senior Associate, London

UK Clinical Trials Regulation Reform

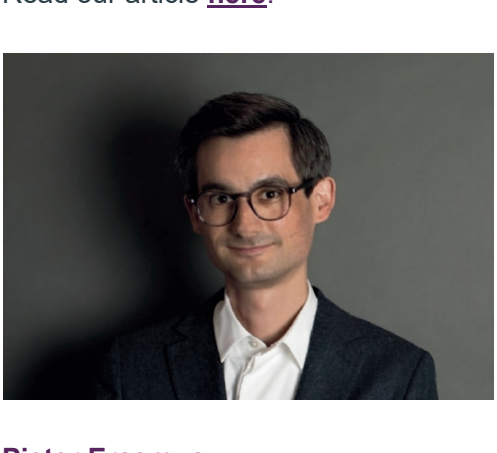
Why is this relevant to US businesses?

As this is said to be the most significant reform of UK clinical trials regulation in more than 20 years, the changes are relevant to research functions at US institutions and businesses considering the UK for commercial clinical trials.

Keeping up with the changing landscape

In line with the UK's ambition to become a world-leading place for health and care research, on 11 April 2025, the new Clinical Trials Regulations were made into law with the aim of bringing harmonisation with EU regulation and international legislation standards, streamlining the process for sponsors, increasing flexibility and ensuring safety and transparency for patients. The new regulations introduce changes to the application and review process, publication and reporting requirements and updates to Good Clinical Practice provisions.

Read our article here.



Pieter Erasmus
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UK Medical Devices Reform

Why is this relevant to US businesses?

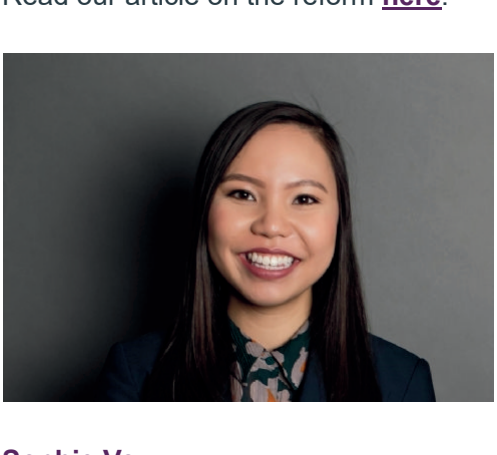
The significant change to the Post-market Surveillance ("PMS") requirements in the UK, now with strict and specific obligations, will directly affect US manufacturers which place medical devices on the Great Britain market. As of 16 June 2025, the new measures have come into force, requiring new systems and processes to be put in place.

Current and future reform

On 11 December 2024, the MHRA published an updated roadmap for the future of the regulatory framework for medical devices in the UK, indicating that it would be delivered via four Statutory Instruments. The first of the four, being the PMS Statutory Instrument was made into law and came into effect on 16 June 2025.

The new PMS Regulations address the lack of specificity in the prior regulations, providing for enhanced data collection, shorter timelines for incident reporting, and clearer obligations for risk mitigation and communication to protect patients and users.

Read our article on the reform here.



Sophie Vo
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Australia

AI regulations and the Australian life sciences sector

Why is this relevant to US businesses?

In contrast to the European AI Act, Australia has not yet implemented AI-specific laws and regulations. However, evolving Australian laws and regulations continue to impact the use of AI by US life sciences business in Australia. For example, existing medical device regulations established under the Therapeutic Goods Act will capture the use of AI in software deployed as a medical device.

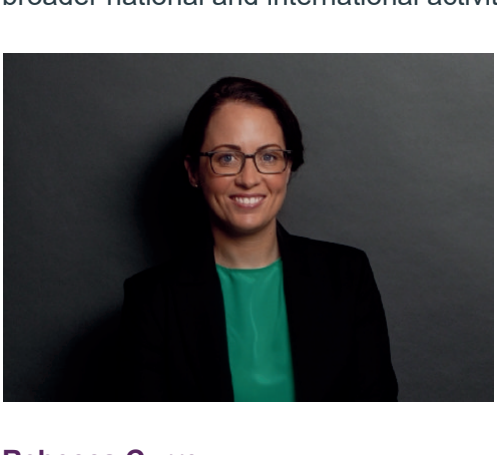
Australian AI regulations

Australia's existing patchwork regulations can create uncertainty for US life sciences companies operating in Australia. We address the key issues for AI in Australia in 2025 here, particularly the risks arising from the deployment of AI in Australia and the importance of businesses maintaining oversight of the use of AI technology.

Approach adopted by the Therapeutic Goods Administration (TGA)

The TGA has issued revised guidance on its approach to the regulation of software and AI based medical devices (available here). Significantly, the guidance reiterates that the use of text-based AI models, including large language models (**LLM**), in medical services offered to Australian patients may require approval by the TGA. A software developer who incorporates a LLM into products offered to Australian patients may also be at risk of being deemed to be the manufacturer of the product and may be exposed to liability under the Therapeutic Goods Act.

The TGA is continuing to undertake consultation on the regulations applicable to the use of AI systems within, or as, therapeutic goods. In February 2025 the TGA published feedback received in response to its 'Clarifying and strengthening the regulation of Artificial Intelligence' consultation paper (available here). In particular, the TGA noted that the ongoing review of AI regulations relevant to the life sciences sector should be undertaken in harmonisation with broader national and international activities to ensure clarity for businesses.



Rebecca Currey
Partner, Sydney

Additional incentives to conduct clinical trials in Australia

Why is this relevant to US businesses?

The Australian Government has committed to investing AUD$750 million between 2024–25 and 2033–34 to increase clinical trial activity in Australia, particularly by bringing investigator-led international clinical trials to Australia (see further details here). US life sciences businesses may wish to consider conducting early phase clinical trials in Australia to take advantage of relatively lower costs (when compared with trials undertaken in the US), while also benefiting from Australia's robust regulatory framework and intellectual property laws.

Established clinical trials regulations

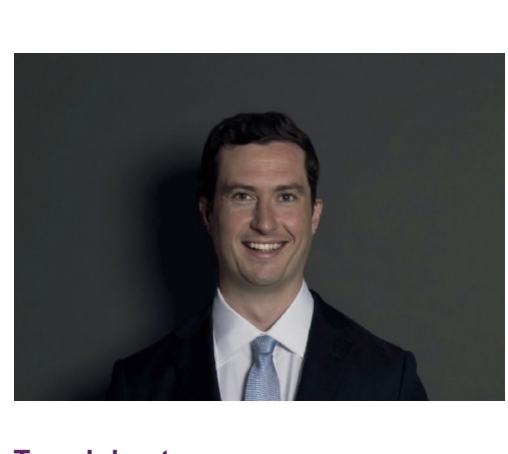
Australia has adopted reliable regulations that assist with obtaining efficient approvals for clinical trials. The health and life sciences sector also continues to be a significant focus for the Australian Government in encouraging foreign investment. Additional information regarding funding initiatives relating to health and medical research, along with incentives that may be available to US life sciences companies is available here.

Streamlined foreign investment regulations

In 2024 the Australian Government announced changes to streamline Australia's foreign investment regulations in order to deliver a risk-based, faster and more transparent approach to assessing foreign investment proposals, including those in the life sciences sector (see our review of these changes here). We explore the impact that these changes have had on enabling foreign investment in 2025 while also protecting Australia's national interests here.

Investments in incubators and accelerators

The Australian Government and various state governments have announced investments in biotech incubators and accelerators, including the Sydney Biomedical Accelerator (a partnership between the University of Sydney and the New South Wales Government) and the CSIRO's (Australia's national science agency) ON Accelerate 9 cohort. These initiatives continue to foster a diverse start-up ecosystem that will be attractive to US life sciences businesses.



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Tom Johnston
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Asia

China releases long-anticipated Data Exclusivity Rules

Why is this relevant to US businesses?

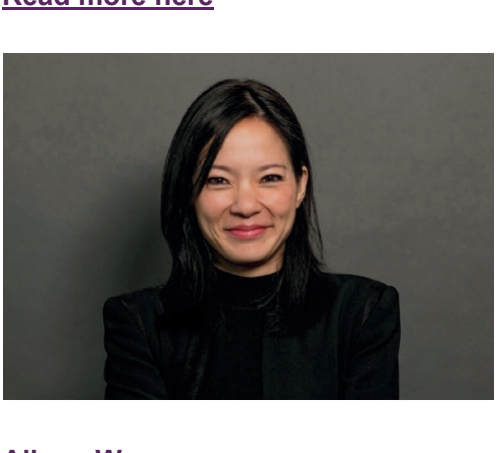
The draft Data Exclusivity Rules are highly relevant to U.S. pharmaceutical and biotechnology businesses seeking to enter China. The proposed system would provide up to six years of exclusivity for new chemical entities and innovative biologics. Under China's first-approved, first-protected approach, U.S. drug developers with global assets should proactively align their China regulatory timelines and market entry strategies to ensure they secure maximum exclusivity.

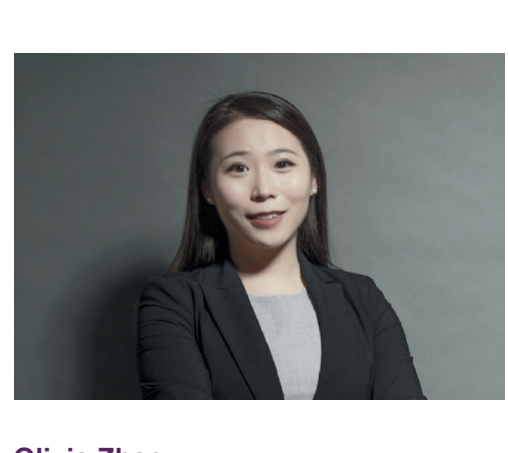
Data Exclusivity Protection

On 19 March 2025, the National Medical Products Administration (NMPA) published two draft documents for consultation: the "Interim Implementation Regulations for Drug Trial Data Exclusivity (Draft for Comments)" and the "Work Procedures for Drug Trial Data Exclusivity (Draft for Comments)."

The proposed framework extends data exclusivity protection to new chemical drugs, biologics, improved chemical drugs and biologics, drugs approved abroad but not yet in China, and first approved generic drugs or biologics.

Read more here





Alison Wong
Partner, Hong Kong

Olivia Zhao
Associate, Shanghai

China's 2025 Pharmaceutical Regulatory Roadmap

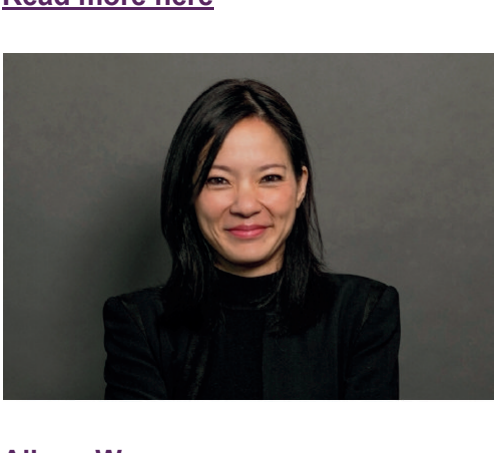
Why is this relevant to US businesses?

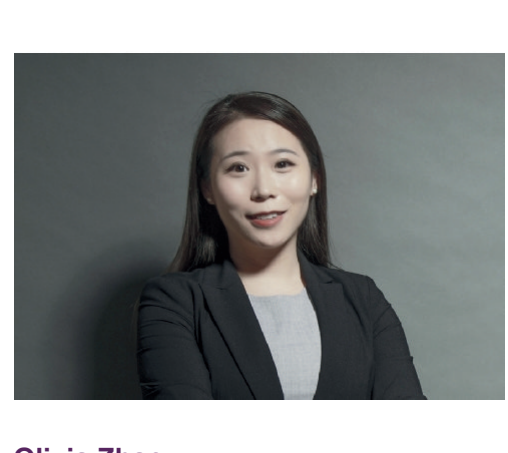
These reforms are especially pertinent to U.S. businesses, reflecting a clear effort to attract foreign innovative drugs and biologics through streamlined, expedited review and approval pathways. In tandem with growing alignment to ICH standards, broader support for global multi-center trials, and segmented biologics manufacturing models, these measures encourage U.S. companies to expand their presence in China.

The reform measures

On 3 January 2025, the General Office of the State Council issued the Opinions on Comprehensively Deepening the Reform of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry (Circular 53) (2025 Opinions). The 2025 Opinions comprise 24 reform measures across five key areas, designed to strengthen China's pharmaceutical regulatory framework, expand the domestic market, and bolster innovation incentives, all with the goal of achieving full regulatory modernisation by 2035.

Read more here





Alison Wong
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Expedited process for approval of new drugs in Hong Kong

Why is this relevant to US business?

Subject to fulfilling other criteria set out by the Hong Kong Department of Health, US businesses looking to launch their pharmaceutical products in Hong Kong will now only be required to submit approval from the FDA (or another reference authority) for their MA application in Hong Kong.

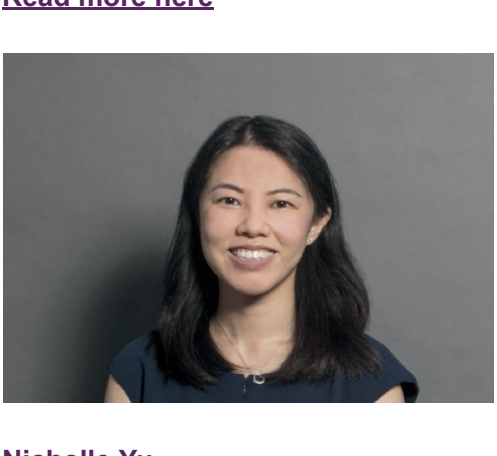
This accelerates the process for obtaining approval of new drugs in Hong Kong.

Marketing authorisation procedure

Previously, marketing authorisation applicants for new drugs intended to treat life-threatening or severely debilitating diseases were required, amongst other criteria, to submit approval from two reference drug regulatory authorities (e.g., the FDA, MHRA, or NMPA). Under the "1+" mechanism introduced in November 2023, this requirement was reduced to just one approval from a reference drug regulatory authority.

In November 2024, the scheme was further extended to include all new drugs, including any new chemical or biological entities, along with vaccines and advanced therapy products.

Read more here



Nicholle Yu
Associate, Hong Kong

Legislation Update - Changes to patent linkage system in Singapore

Why is this relevant to US businesses?

A number of amendments have been made to the regulations relating to Singapore's patent linkage system, which are found in Regulation 23 of the Health Products (Therapeutic Products) Regulations 2016 (the "Regulations"). These amendments to the Regulations came into effect on 1 August 2024.

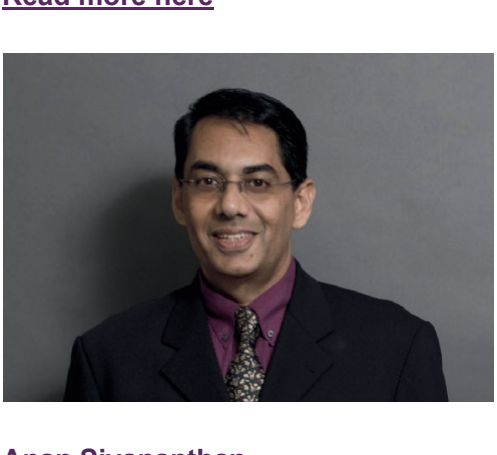
The amendments lend much needed clarity to the Regulations and are of particular importance to US businesses that intend to market their therapeutic products in Singapore.

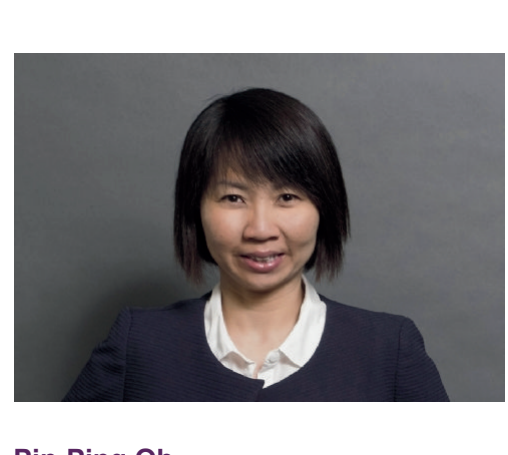
Patent linkage

One of the key amendments clarifies the types of patents that must be declared when applying for registration of a therapeutic product in Singapore, e.g., confirming that a process patent, amongst others, is not subject to the declaration requirement.

Additionally, changes have also been made to the steps which the patent owner must take to trigger the 30-month stay on the grant of an MA application.

Read more here





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Pin-Ping Oh
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Webinars

Our webinar series on the European Health Data Space

On 26 March 2025 the long-anticipated European Health Data Space (EHDS) regulation came into force, signifying a pivotal moment for digital health in the European Union.

The EHDS regulation aims to create a harmonised framework for the use and exchange of electronic health data across the EU. It enhances individuals' access to and control over their personal electronic health data, while also improving access for healthcare and enabling reuse for better policy making, and scientific research and innovation purposes.

Register for our next webinar focused on the potential implications of the new EHDS for your IP & Trade Secret strategy. The team will explore:

- IP provisions and procedures in the EHDS
- Type of rights concerned (i.e. copyrights/database rights, trade secrets and third-party IP?)
- Influence on IP strategies
- Strategic relevance for IP litigation

RSVP here

Watch part 1 of our webinar which provides an introduction to the new EHDS and part 2 which explores the practical and legal implications of the secondary data regime under the EHDS through the links below.

Watch part 1 here | Watch part 2 here

Looking for more?