Bird & Bird

Bird & Bird's *Bio & Beyond*

Keeping you up to date on Life Sciences & Healthcare Regulatory developments in Europe/UK and the Asia-Pacific

Welcome to the second 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 Europe, 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, including the EU Pharma Pack, updates on AI and medical devices and the UK's strategy for US businesses.

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.

In Focus

European Union

New EU Pharmaceutical Reform

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.

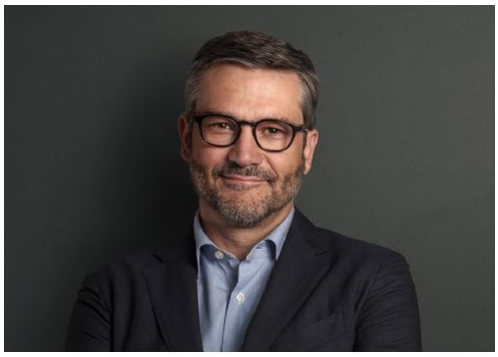
EU Pharma Reform

The EU legislative institutions continue to advance the most significant overhaul of the EU pharmaceutical legislation since 2004. Following the European Parliament's adoption of the Pharmaceutical Package in April 2024, the EU Council agreed on its position in June 2025. Trilogue negotiations are now underway to finalise the new directive and regulation.

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).

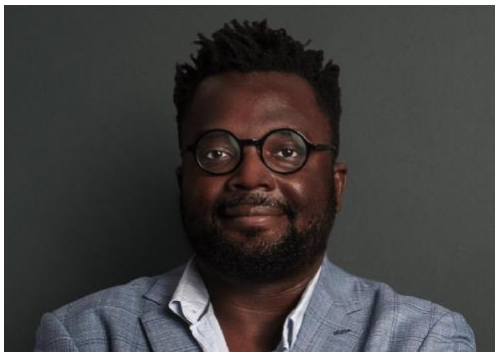
The reform package addresses a wide range of regulatory, commercial, and scientific issues – and we've summarised the latest developments in brief updates.

- Find an overview on the EU Council's Position and the legislative process timeline here (3 min read)
- Key Changes on Advertising of Medicinal Products. Find our insights here (5 min read)
- Council advances paediatric medicine reform with more flexible investigation plan proposals. Find out more here (5 min read)
- A stronger focus on antimicrobials and transferable data exclusivity vouchers. Find our update here (4 min read)
- A new framework for combination products. Find our insights here (4 min read)



Marc Martens

Partner, Brussels



Kevin Munungu

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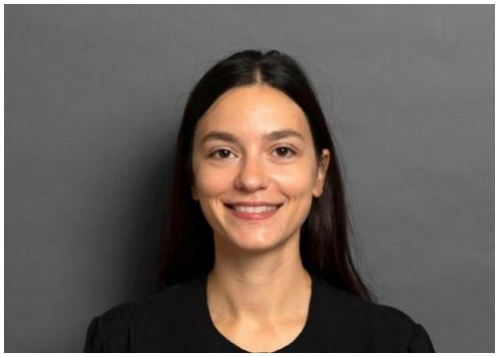

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Counsel, Paris

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Biotech Act

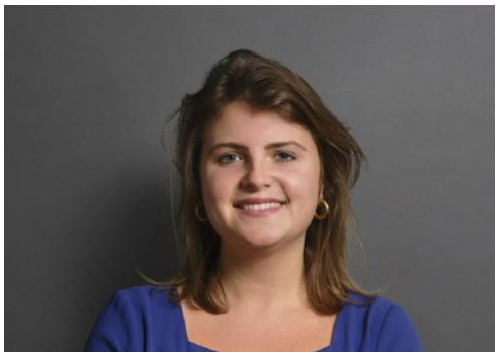
Why is this relevant to US businesses?

The EU legislator is laying the groundwork for a new Biotech Act aimed at streamlining regulatory processes and boosting innovation across the EU biotech sector. For US life sciences and biotech companies operating in or partnering with EU entities, this initiative could significantly impact market access, regulatory compliance, and funding opportunities. Now is the chance to engage early and help shape a more innovation-friendly regulatory environment.

Biotech Act - Proposal and Public Consultation

The Act is part of the EU's broader Strategy for Life Sciences and is expected to cover a wide range of biotech applications – from healthcare and pharmaceuticals to agriculture, energy, and climate technologies. The Biotech Act Initiative aims to simplify biotech regulations, accelerate time-to-market, improve access to capital, support biomanufacturing infrastructure, and integrate AI and biosecurity measures.
The legislative proposal is expected by the end of 2025, with adoption planned for Q3 of 2026. The European Commission is currently seeking input from stakeholders on the future Biotech Act, focusing on regulatory simplification, biomanufacturing, and the integration of digital technologies. Any comments within this public consultation process are due until 10 November 2025.

Stakeholder can participate in the consultation and read more about the initiative here.



Hester Borgers

Senior Associate, Amsterdam

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AI & Medical Devices

Why is this relevant to US businesses?

For US medical devices companies operating in the EU, staying aligned with the regulatory framework is essential to ensure regulatory compliance and future market access.

MDCG Guidance on Medical Device AI

For our summary of the MDCG Guidance, see here. The regulatory landscape for AI-enabled medical devices (MDAI) has become significantly more complex with the introduction of the EU AI Act. The Medical Device Coordination Group (MDCG) and the Joint Artificial Intelligence Board (AIB) have published new guidance to help manufacturers navigate the interplay between the Medical Devices Regulation (MDR)/In vitro Diagnostic Medical Devices Regulation (IVDR) and the AI Act.

The guidance clarifies how these two frameworks interact and what additional obligations apply to MDAI. With the AI Act introducing new requirements for risk management, data governance, and transparency, manufacturers must ensure simultaneous compliance with both regimes. In practice, many more EU regulations will often apply to these devices.

This dual regulatory framework requires forward planning – something many manufacturers have likely already been doing so for a long while. Generally, and in light of the guidance,

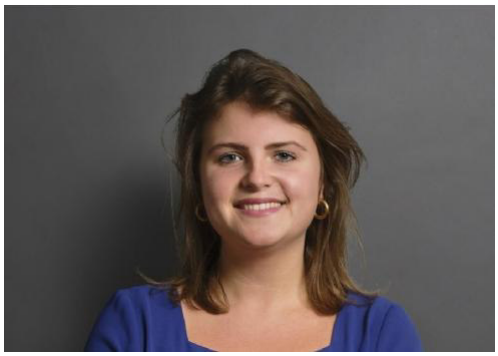
manufacturers active in the EU should keep the following in mind to get a better understanding of where their medical device fits within this changing landscape:

- Conduct an AI Act risk assessment
- Review and align the quality management system (QMS)
- Evaluate data governance practices
- Plan for substantial modifications

Read the full guidance document 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.



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United Kingdom

Fit for the Future: England's 10 Year Health Plan and Implications for US Companies

England's National Health Service (NHS) is seen as one of the world's most ambitious and comprehensive healthcare systems, but has been in desperate need for an overhaul in order to adapt to adapt to demographic changes, technological advances, ongoing fiscal pressures, and evolving public expectations. The UK Government has shared its plans for the future here.

Why is this relevant to US businesses?

For US companies operating within or close to the healthcare sector, understanding the pillars and ambitions of this plan is essential in order to identify both opportunities and the potential shifts in the wider international health economy.

Strategic Themes of the Plan

- Prevention and Population Health
- Transformation Through Technology
- Integrating Health and Social Care
- Workforce and Skills Renewal
- Sustainability
- Patient Empowerment and Personalisation

Read our full article, which covers the implications for businesses, including US companies.

Sally Shorthose

Partner, London

UK Decentralised Medicine Manufacturing Regulations

Why is this relevant to US businesses?

A new model for the decentralised manufacturing is now in place in the UK. Any pharmaceutical company producing or developing medical products where point of care delivery or modular manufacturing are advantageous should explore the opportunities presented by this framework.

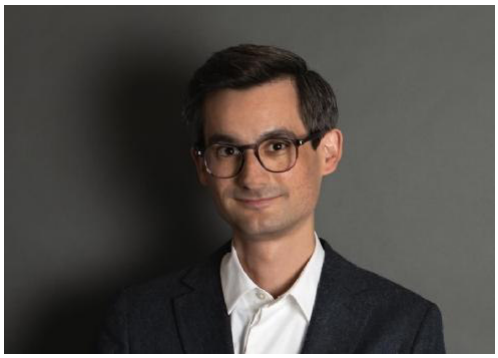
Decentralised manufacturing enables the adoption of personalised medicine. Given that personalised medicine is expected to become a routine part of healthcare, most pharmaceutical companies will likely need to adapt to some form of decentralised manufacturing regulations in the future. Early familiarity with the UK's decentralised model provides a strategic advantage.

In the USA, the FDA is currently exploring its own comparable model of 'distributed manufacturing'. The UK's world-first legal framework (and its successes or failures) may influence the FDA's approach. The need for regulatory harmonisation is particularly important given the highly globalised nature of pharmaceutical trade and supply chains.

Understanding the new regime

On 23 July 2025, the UK's world-first regulatory framework for the decentralised manufacturing of medicines came into effect. The new regulations introduce two new licences for point of care and modular manufacturing. This framework seeks to address the limitations of conventional, centralised manufacturing, especially for emerging classes of innovative medicines which must be manufactured close to patients. The regime aims to make the UK a global centre for novel medicines, such as CAR-T cells and gene therapies, supporting the UK's ambition to become Europe's leading life sciences economy by the end of the decade.

Read our article here.



Pieter Erasmus

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Australia

National Health and Medical Research Strategy

Why is this relevant to US businesses?

The Australian Government has published a draft National Health and Medical Research Strategy. This is a ten year plan that intends to facilitate medical research in Australia and to continue to increase the attractiveness of Australia as a destination for clinical trials.

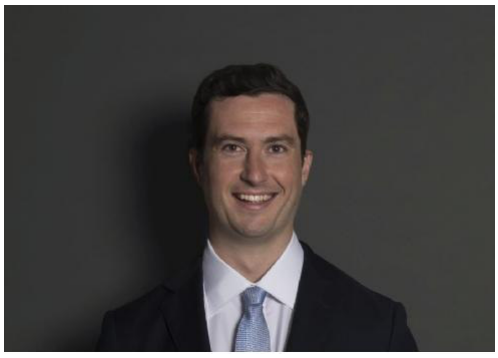
The Strategy prioritises the importance of international collaboration and foreign investment, including from the United States, in expanding the Australian life sciences industry.

Data and advanced technology enabling initiative

The strategy encourages international and cross-jurisdictional agreements for health data sharing in order to improve the interoperability of regulatory systems across jurisdictions. This is directed towards improving access to reliable and responsibly sourced de-identified health data to accelerate research conducted in Australia and the United States.

Rebecca Currey

Partner, Sydney



Tom Johnston

Senior Associate, Sydney

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 regulations continue to impact the use of AI by US life sciences business in Australia.

Keeping up with the changing landscape

Australia's existing patchwork regulations can create uncertainty for US life sciences companies operating in Australia, particularly suppliers of medical devices. The TGA recently published its 'Clarifying and strengthening the regulation of Medical Device Software including Artificial Intelligence (AI)' report.

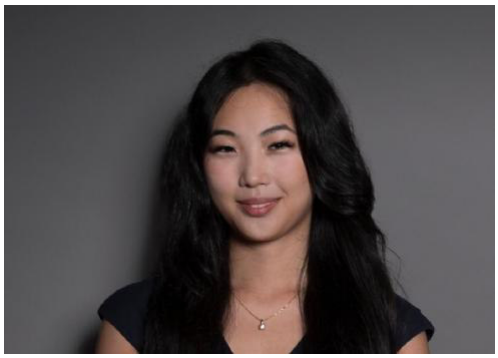
The Report identifies the TGA's regulatory priorities for medical devices that incorporate AI, including:

- the regulation of medical devices that incorporate generative AI, such that the function of the device can evolve over time;
- the use of patient data in AI models; and
- transparency requirements regarding use of AI in medical devices.

For US life sciences companies, a risk-based approach to the adoption of AI tools will be critical to ensuring compliance with Australian regulations.

Rebecca Currey

Partner, Sydney



Evelyn Park

Associate, Sydney

Increased regulatory scrutiny for therapeutic goods

Why is this relevant to US businesses?

Recent action taken by the TGA against sponsors of sunscreens in Australia suggests that they will more rigorously scrutinise testing data provided by manufacturers of therapeutic goods in order to determine the safety and efficacy of therapeutic goods (not only sunscreens), including products sold by US businesses in Australia.

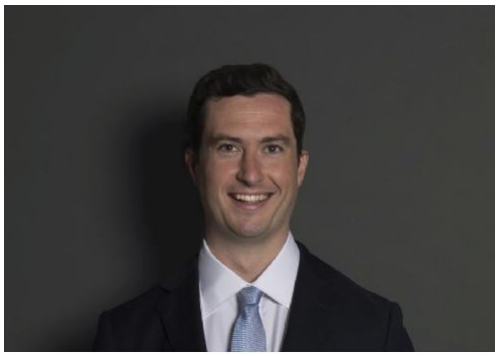
Sunscreens and SPF testing

The TGA regulates sunscreens that are therapeutic goods (i.e. where the product is used for protection from UV radiation) and these products must be registered on the Australian Register of Therapeutic Goods (ARTG).

Testing published by a consumer advocate group has identified that certain sunscreens registered on the ARTG do not meet their claimed sun protection factor (SPF) 50+ ratings.

In this case, the discrepancies arose from testing prepared in accordance the applicable ISO standard. This data was then used to support regulatory submissions.

The TGA has taken regulatory action against sponsors of these products. This has resulted in recalls and some products being removed from the ARTG.



Rebecca Currey

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Asia

Hong Kong: A New Chapter in Medical Products Regulations - Bird & Bird

Why is this relevant to US businesses?

These regulatory changes present significant opportunities and considerations for US life sciences companies operating or targeting the Hong Kong market.

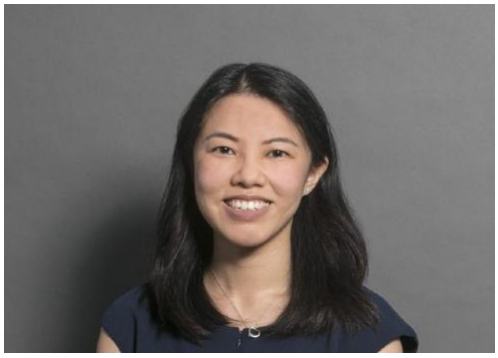
The “primary evaluation” approach for drugs will reduce approval timelines, enabling quicker launch of new therapies. Companies should prepare for the transition by aligning clinical data submissions with the CMPR’s requirements and prepare for adjustments to application processes, fees and registration pathways.

“Primary evaluation” system to be introduced in Hong Kong

On 26 June 2025, the Department of Health (DH) announced the timetable for establishing the Hong Kong Centre for Medical Products Regulation (CMPR) and the roadmap for implementing a new “primary evaluation” system. This system will allow direct evaluation of applications based on local clinical trial data, rather than requiring prior regulatory approval from reference authorities.

This is a major update following the establishment of the Preparatory Office for the CMPR about a year ago. The CMPR will be established by the end of 2026, with the “primary evaluation” approach to be introduced in phases from 2026 to 2030.

In addition to implementing the “primary evaluation” system for new drug registration, the CMPR will also consolidate regulatory oversight of pharmaceutical products, traditional Chinese medicine, and medical devices.



Alison Wong

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Upcoming Events

Data, Drugs & Devices: Digital Health Law Update - Thursday 6 November 2025

As digital technologies continue to reshape healthcare delivery and innovation, the legal and regulatory landscape is evolving just as rapidly. Join our Life Sciences and Tech specialists, alongside industry experts, for an afternoon of insights, practical guidance, and future-focused discussion at our Digital Health Law Update.

We're especially excited to welcome Dr Frank O'Donnell and Brian Monaghan as our guest speakers.

- What it's like to build a digital health business
- What's new in Regulation – The EU AI Act, the EU Data Act, European Health Data Space, NIS/Cyber and Medical Device Regulations
- Contracting for AI
- Direct-to-Consumer issues in Telemedicine and Patient Engagement
- Dealmaking & Transactions in Digital Health

Forward to a colleague Register here

Webinars

Women in Tech Driving Innovation in Healthcare AI

Dana Ghosn, AI Program Senior Lead at Doctolib and founder of Typeless, joins our *Women in Tech* series to share how AI is transforming healthcare. Typeless uses Natural Language Processing to reduce the hours clinicians spend on medical documentation, freeing up time for patient care. Dana highlights the role of interdisciplinary collaboration, supportive regulations, and Switzerland's ecosystem in advancing healthcare innovation. This episode shows how technology and life sciences intersect to improve clinical workflows and patient outcomes.

Read our key takeaways from episode 9 with Dana Ghosn from Typeless here.

Listen to the podcast here.

Episode 10: Supporting Innovation and Entrepreneurship in the Nordic Tech Scene

In episode 10, we are joined by Louise Lachmann, General Partner at Ugly Duckling Ventures, an early-stage venture capital firm helping Nordic startups scale rapidly in today's challenging investment landscape. Louise has also been appointed Chair of the Danish Foundation for Entrepreneurship, which seeks to promote entrepreneurship among young people. Interviewed by Martin von Haller Grønbæk, Commercial Of Counsel in our Copenhagen office, Louise shares her remarkable journey from the dotcom era to the current AI revolution, offering unique insights into the evolution of technology investment and entrepreneurship across the Nordic region.

Look out for episode 11, where our Intellectual Property Partner Melissa Murray, based in our Dubai office, chats to Lina Al Hashmi, Project Manager for the Intellectual Property Acquistion at Advanced Technology Research Council, and Ruxandra Cojocaru, Lead Researcher at the AI Digital Research Center within the Technology Innovation Institute.

Looking for more?

Forward to a colleague