Healthcare, Pharmaceutical and Life Science Update

Q3 - December 2025

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical, and Life Science Group in respect of the third quarter of 2025.

We hope you find our newsletter informative and engaging. Please get in touch if you would like to know more about what we have covered.

PHILIPLEE

DUBLIN | LONDON | NEW YORK

philiplee.ie

WELCOME

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical and Life Science group in respect of the third quarter of 2025. Please get in touch if you would like to know more about what we have covered.

Contact details for our team members can be found at the end of this publication which covers:

1. General Regulatory – EU
2. General Regulatory – Ireland
3. Global Insights
4. Competition Law
5. Data Protection
6. Healthcare

1. GENERAL REGULATORY – EU

1. The European Commission has publicly consulted on proposed updates to EudraLex Volume 4: Good Manufacturing Practice Guidelines (available here)

The European Commission has publicly consulted with stakeholders on its proposed revisions to EudraLex Volume 4 – Good Manufacturing Practice Guidelines (the consultation having closed on 7 October 2025).

The consultation focused on three key areas of the "Good Manufacturing Practice Guidelines": Chapter 4 (Documentation), Annex 11 (Computerised Systems), and a new Annex 22 (Artificial Intelligence).

The proposed updates to Chapter 4 incorporate changes which highlight the importance of documentation in GMP compliance and support the use of new technologies, hybrid solutions, and new services in the management of documentation.

The proposed update to Annex 11 incorporate changes to expands the scope of the Annex to include modern technologies such as cloud computing, mobile applications, and static AI models, while emphasising lifecycle validation and supplier oversight.

The proposed introduction of a new Annex 22 marks a significant development, introducing specific requirements for the use of AI in GMP-critical applications. It outlines standards for model selection, validation, and ongoing oversight, with a strong emphasis on data quality, explainability, and human-in-the-loop controls.

2. The European Medicines Agency (the "EMA") has published its third report on the use of real-world evidence (RWE) in regulatory decision-making (available here)

The EMA has published its third annual report on the RWE framework, covering the period from February 2024 to February 2025. The report highlights a significant expansion in the use of RWE to support regulatory decision-making, with a 47.5% increase in studies conducted, rising from 40 to 59 studies over the year.

The DARWIN EU network, which serves as the backbone of the EMA's RWE efforts has expanded from 20 data partners to 30 data partners across 16 European countries, now covering data from approximately 180 million patients. This expansion has contributed to a notable improvement in study feasibility, with 78% of proposed research topics deemed feasible, up from 60% in the previous reporting period.

The studies conducted focused primarily on drug utilisation (42%), safety monitoring (24%), and disease epidemiology (24%). These investigations supported a wide range of regulatory functions, including safety signal assessments, periodic safety update reports, and evaluations related to medicine shortages and public health emergencies. The median completion time for DARWIN EU studies was just four months, enabling timely integration into regulatory procedures.

3. The European Federation of Pharmaceutical Industries and Associations (the "EFPIA") issued its position paper on the

implementation of the EU Critical Medicines (available here)

The EFPIA has released its position paper in June 2025 on the implementation of the EU Critical Medicines Act ("**CMA**"). The paper supports the CMA's overarching goals of strengthening supply chain resilience and ensuring timely, equitable access to essential medicines across Europe, but urges caution in its execution to avoid unintended consequences.

The EFPIA highlights in its position paper the need for the CMA to be aligned with existing EU and national legislation to prevent duplicative administrative burdens that could deter investment or delay access to medicines. The paper warns against overly rigid contingency stock obligations and fragmented national requirements, which risk disrupting supply chains and reducing availability in smaller markets. Instead, the EFPIA advocates for proportionate, risk-based measures and EU-level coordination to streamline efforts.

The EFPIA supports the use of collaborative procurement only in exceptional cases where national efforts have failed and stresses the importance of maintaining national competence in pricing and reimbursement decisions.

4. **MedTech Europe's Reflection Paper Calls for a Risk-Based Approach to Technical Documentation Sampling under the In Vitro Diagnostic Medical Devices Regulation (the IVDR** (available here)

MedTech Europe has issued a reflection paper urging EU regulators to adopt a more proportionate, risk-based approach to sampling under the In Vitro Diagnostic Medical Devices Regulation ("**IVDR**"). MedTech proposal responds to growing concerns that current sampling practices, especially for Class B and Class C IVDR devices, are inefficient, burdensome, and misaligned with actual risk profiles. Under the IVDR, Notified Bodies are required to assess technical documentation for Class B and C IVDs through sampling during the validity of their certificates. However, MedTech Europe highlights that disproportionate attention is being paid to lower-risk devices, while higher-risk Class D devices receive comparatively less scrutiny. This imbalance, MedTech argues, undermines the regulatory goal of safeguarding patient safety and may delay access to critical diagnostics. Key recommendations from MedTech Europe include:

- **Prioritising High-Risk Devices:** redirecting sampling efforts toward Class D IVDs, which pose greater potential risks to patients,
- **Reducing Burden on SMEs:** streamlining documentation requirements for lower-risk devices to ease compliance for small and medium-sized manufacturers, and
- **Enhancing Efficiency:** aligning sampling intensity with device risk to optimise Notified Body resources and accelerate market access.

The proposal comes amid broader calls for IVDR reform, as stakeholders seek to balance regulatory rigour with practical implementation.

5. **The Notified Bodies Coordination Group for Medical Devices and the Team-NB Executive Committee propose a Central Medical Device Coordination Office to be created to reform governance of medical devices and in vitro diagnostic devices** (available here)

The Notified Bodies Coordination Group for Medical Devices and the Team-NB Executive Committees (the "**Notified Bodies**") have jointly released a position paper advocating for substantial reforms to the regulation of medical devices and in vitro diagnostic devices at EU-level. The position paper highlights growing concerns regarding the current landscape, detailing how it is often characterised by fragmentation and inconsistent implementation of the existing regulatory framework across various member states. The two bodies, representing key entities involved in the conformity assessment process, are calling for specific, structural changes to enhance oversight and uniformity.

The central and most critical recommendation detailed in their paper is the establishment of a new, dedicated Medical Device Coordination Office (the "**MDCO**"). This proposed office would serve as a centralised authority with the mandate of addressing the inconsistencies in the regulatory sector. The Notified Bodies believe that by creating a dedicated coordination hub, the EU can achieve standardisation in the interpretation and enforcement of medical device regulations, thereby bolstering reliability for manufacturers and increasing confidence for patients. The introduction of a formal MDCO aims to move beyond national interpretations towards a more cohesive and robust governance system for medical devices and in vitro diagnostic devices.

6. **TÜV SÜD, an undertaking active in the testing, inspection and certification market, has published a white paper on the implications of the EU AI Act for AI-driven medical devices.** (available here)

A newly published white paper by TÜV SÜD sheds light on the regulatory impact and offers practical guidance for industry stakeholders in respect of the EU's AI Act, set to be implemented in August 2027.

The paper builds on recent clarifications from the EU Medical Devices Coordination Group and the AI Board, which issued a joint FAQ in July 2025 addressing the interplay between the AI Act and MDR/IVDR. TÜV SÜD's analysis identifies key areas of misalignment.

One key concern that TÜV SÜD has is the divergence in risk classification approaches, which TÜV SÜD deems may result in inconsistent categorisation of AI-based medical devices and complicate conformity assessments. TÜV SÜD also sets out in its paper how the AI Act also introduces enhanced transparency requirements, particularly around explainability and user information, that may go beyond what is mandated under the MDR and the IVDR. AI-driven software, especially Software as a Medical Device (SaMD), is subject to dual scrutiny under both regimes, raising questions about the harmonisation of evaluation criteria. Overlapping conformity assessment pathways risk duplicative procedures and regulatory inefficiencies, especially for high-risk AI systems.

To mitigate these challenges, TÜV SÜD recommends that manufacturers of medical devices and in-vitro diagnostic devices:

(i) Engage notified bodies with dual expertise: collaborate with bodies familiar with the EU's AI Act, the MDR and the IVDR to streamline compliance strategies,
(ii) Strengthen AI risk management and data governance: align internal systems with GDPR and AI Act requirements to ensure ethical and lawful data use,
(iii) Begin voluntary compliance early: proactive alignment with the AI Act can reduce future regulatory friction and signal commitment to safety and transparency, and

The recommendations put forward by TÜV SÜD are proposed to allow manufacturers to test innovative AI systems under supervised conditions, fostering regulatory dialogue and refinement.

7. **The European Medicine Agency (the "EMA") and the Heads of Medicine Agency (the "HMA") warn of surge in illegal weight loss and diabetes medical products being advertised and sold across the EU** (available here)

The EMA and the HMA issued a warning in September highlighting a sharp increase in the illegal sale of unauthorised GLP-1 receptor agonists across the European Union. These substances, including counterfeit versions of semaglutide and liraglutide, are being falsely marketed for weight loss and diabetes treatment. The EMA and the HMA warn that these products are often distributed via fraudulent websites and social media platforms, bypassing regulatory oversight and posing significant health risks. Users of such illicit medicines may be exposed to incorrect dosages, harmful ingredients, or entirely different substances, leading to serious consequences such as treatment failure, adverse side effects, and dangerous drug interactions. The EMA and HMA have urged the public in their warning to

exercise caution and only obtain medicines through authorised healthcare providers and licensed pharmacies.

8. **The European Commission published a Staff Working Document in September 2025 Supporting its legislative proposal for the Critical Medicines Act** (available here)

   The European Commission published a Staff Working Document in September 2025 in which it provided its evidentiary basis for a legislative proposal aimed at strengthening the EU's resilience in the supply of critical medicinal products. This initiative supports amendments to the EU Regulation that established the Strategic Technologies for Europe Platform (*Regulation (EU) 2024/795*) and seeks to address ongoing challenges such as medicine shortages and supply chain fragility. The Staff Working Document outlines a proposed strategic framework to reduce dependency on non-EU suppliers, improve access to medicines deemed of common interest, and boost manufacturing capacity through targeted investment, regulatory alignment, and coordinated procurement efforts.

   It also presents an impact assessment covering economic, environmental, and social dimensions, and integrates contributions from the Critical Medicines Alliance to guide practical implementation.

9. **MedTech Europe published its position paper calling for simplification with respect to the EU's Sustainability Directives** (available here)

   MedTech Europe has released a position paper urging simplification of the proposed revisions to the Corporate Sustainability Due Diligence Directive and the Corporate Sustainability Reporting Directive. The organisation supports narrowing the scope of due diligence obligations to Tier 1 suppliers, arguing that this targeted approach would reduce complexity while preserving accountability across supply chains.

   The position paper also welcomes the removal of the harmonised EU civil liability regime, which MedTech Europe views as a positive step toward legal clarity and proportionality. Further recommendations include extending monitoring periods from 12 months to five years, capping penalties at 5% of company turnover, and retaining limited assurance requirements to avoid excessive compliance costs.

   Overall, MedTech Europe's proposals aim to balance effective sustainability oversight with practical implementation. By reducing administrative burdens and aligning obligations with sector realities, MedTech Europe hopes to support meaningful corporate responsibility without stifling innovation or competitiveness in the medical technology industry.

10. **Medicines for Europe responds to the European Parliament's draft report on Critical Medicines Act** (available here)

    Medicines for Europe has issued a formal response to the European Parliament's draft report on the Critical Medicines Act in which it generally welcomes the draft report but also urges the European Parliament to better reinforce the proposed regulation to better safeguard the supply of essential medicines. Presented to the Committee on Public Health, the draft report aims to enhance the resilience of Europe's pharmaceutical supply chains but Medicines for Europe warns that key gaps remain.

    Medicines for Europe highlights that only 40% of medicines in the general pharmaceutical market and around 50% of those deemed critical are currently subject to public procurement rules. Without mandatory inclusion of pricing and reimbursement policies in national plans, Medicines for Europe outlines its view that the Critical Medicines Act risks overlooking half of the medicines on its critical list.

    To address this, Medicines for Europe calls for the integration of security of supply criteria into both public procurement frameworks and national pricing and reimbursement strategies. This dual approach, it argues, is essential to ensure consistent access to vital treatments and to prevent supply disruptions across Member States.

As the legislative process continues, the organisation urges policymakers to adopt a more comprehensive and enforceable framework that reflects the realities of pharmaceutical market dynamics and supports long-term patient access.

11. **MedTech Europe responds to the European Commission's consultation on the proposed extension of the Cross Border Adjustment Mechanism (the "CBAM")** (available here)

MedTech Europe has formally responded to the European Commission's public consultation on the proposed expansion of the CBAM, voicing strong concerns about the potential impact of the extension on the medical technology sector.

The proposed extension would cover downstream products, anti-circumvention measures, and electricity sector rules, potentially bringing in medical devices and in vitro diagnostic devices separately regulated under the MDR and the IVDR.

In its submission, MedTech Europe warns that the inclusion of medical technologies — particularly those containing iron, steel, or aluminium components in the CBAM could undermine EU objectives on sustainable prosperity and global competitiveness. MedTech Europe argues that there is no evidence of carbon leakage within the sector to justify such measures, and that the proposed extension risks imposing disproportionate administrative burdens and compliance costs on manufacturers.
Key concerns raised by MedTech Europe include the complexity of data collection requirements, which may conflict with existing MDR and IVDR obligations, and the risk of manufacturing leakage out of the EU. MedTech Europe also cautions that the added regulatory pressure could negatively affect environmental outcomes and restrict patient access to essential medical technologies.

As the European Commission considers next steps, MedTech Europe urges policymakers to carefully assess the sector-specific implications of the CBAM and avoid unintended consequences for the innovation and delivery of healthcare.

12. **MedTech Europe urges for a streamlining of EU digital legislation for medical devices** (available here)

MedTech Europe issued a position paper in August 2025 calling for targeted reforms to simplify the implementation of EU digital legislation impacting the medical technology sector. The paper responds to the European Commission's broader regulatory simplification agenda and highlights the need for greater coherence between horizontal digital laws and existing sector-specific frameworks.

Central to MedTech Europe's recommendations is the alignment of key digital regulations such as the EU Artificial Intelligence Act, the Data Act, and the Cyber Resilience Act, with established medical device legislation, including Regulation (EU) 2017/745 (MDR), Regulation (EU) 2017/746 (IVDR), and the newly adopted Regulation (EU) 2025/327 establishing the European Health Data Space. The position paper underscores the risk of regulatory fragmentation and duplication if digital laws are not carefully integrated with the MDR and IVDR regimes. The paper urges clear guidance, streamlined conformity assessment procedures, and recognition of existing sectoral safeguards to avoid unnecessary burdens on manufacturers and notified bodies.

13. **The CJEU clarifies the rules on classification and precedence when a product falls into the medicinal products category and the foods for special medical purposes ("FSMP") category** (available here)

On 4 September 2025, the CJEU delivered its judgment in Case C-451/24: Kwizda Pharma II in response to a request from Austria for a preliminary ruling on the rules or precedence where a product meets the definition of a medicinal product but could also fall under another category (like FMSP.

The Court held that once a product has been definitively classified as a "medicinal product by presentation," it cannot simultaneously be placed on the market as food for special medical purposes, particularly where it has been found not to meet the relevant

conditions under EU food law. The ruling reinforces that national authorities must ensure clear product categorisation to prevent regulatory overlap and protect public health.

The CJEU further clarified that the rule of precedence under Article 2(2) of Directive 2001/83 applies only where there is genuine uncertainty as to whether a product falls within overlapping regulatory regimes. It does not apply where a product unambiguously meets the criteria of a medicinal product or a distinct non-medicinal category.

14. **The EMA updates pharmacovigilance requirements and concludes EudraVigilance pilot phase** (available here)

The EMA has issued guidance following the adoption of Commission Implementing Regulation (EU) 2025/1466, which formally ends the EudraVigilance signal detection pilot for marketing authorisation holders ("**MAHs**").

The change in the regulation means that all MAHs with authorised medicines in the European Economic Area, including Northern Ireland, must now monitor EudraVigilance data as a routine source of safety information. The amendment removes the previous requirement to submit validated signals via standalone forms and places full responsibility for signal management on MAHs in line with the Good Pharmacovigilance Practices ("**GVP**") Module IX.B.

MAHs are expected to update their internal procedures to integrate EudraVigilance monitoring into ongoing safety assessments, with review frequency tailored to product-specific risks.

The implementation timeline is as follows:

- **12 August 2025:** entry into force of key provisions related to EudraVigilance monitoring and the termination of signal validation standalone forms.
- **December 2025:** Extension of EMA compliance notifications for ICSRs to cover all organizations (previously limited to the top 20 MAHs).
- **February 12, 2026:** Full implementation of remaining provisions, including streamlined Pharmacovigilance System Master File (PSMF) documentation and strengthened third-party oversight.
- **Q1/Q2 2026:** Expected official update of GVP Module IX to reflect these changes.

15. **The EMA publishes draft reflection paper on patient experience data** (available here)

The European Medicines Agency has released a draft reflection paper encouraging the structured use of patient experience data ("**PED**") throughout medicines development and in regulatory submissions. PED information provided directly by patients or carers, without third-party interpretation, can inform understanding of treatment priorities, quality of life, and outcomes that matter to patients.

The paper is aimed at developers, regulators, researchers, and patient organisations, and sets out high-level principles for collecting, analysing, and presenting PED across the product lifecycle. EMA outlines key PED categories, including patient-reported outcomes, patient preference studies, and insights from patient engagement activities. Potential data sources span clinical trials, real-world datasets, pharmacovigilance systems, mobile/digital health tools, and appropriately governed social media research. The paper encourages early dialogue with regulators, via scientific advice or qualification of novel methodologies, to ensure PED is fit for purpose and methodologically sound.

The draft also addresses common challenges such as data quality and validation, representativeness, participant burden, and transparency in methods and reporting. The EMA signals support for international

convergence by collaborating with the International Council for Harmonisation.

Stakeholders are invited to submit comments to the reflection paper by 31 January 2026.

16. **The European Federation of Pharmaceutical Industries and Associations ("EFPIA") urges refinements to EU General Pharmaceutical Legislation to ensure innovation and regulatory alignment** (available here)

The EFPIA has welcomed the ongoing revision of the General Pharmaceutical Legislation ("**GPL**") as a significant step toward modernising the EU's regulatory framework for medicines. However, in a recent position blog, the EFPIA cautioned that several aspects of the proposal may unintentionally weaken the EU's innovation environment if not carefully revised.

The EFPIA highlighted concerns around provisions that could restrict the use of real-world evidence ("**RWE**") in regulatory decision making and limit marketing authorisation holders from contributing to labelling updates when new data are generated by regulators or third parties. According to the federation, these measures could reduce transparency, create operational uncertainty, and slow the uptake of new scientific evidence in product information.

The EFPIA has called for closer alignment between the GPL and other EU initiatives such as the proposed Biotech Act and Innovation Act, to ensure coherence across the EU's life sciences and industrial policy agenda. The organisation also endorsed modernising mechanisms in the reform package such as regulatory sandboxes and accelerated review pathways but stressed that success will depend on a science-based, collaborative, and digitally enabled regulatory culture within the EU Medicines Regulatory Network.

The EFPIA concluded that the revised GPL must be ambitious enough to position Europe as a global leader in health innovation, balancing regulatory oversight with agility, fostering investment, and improving patient access to transformative therapies.

17. **The EMA advises on submission timelines for type I variations ahead of year-end closure** (available here)

The EMA has issued updated guidance for MAHs on the submission of type I variations to ensure timely processing before the agency's year-end shutdown from 23 December 2025 to 5 January 2026.

To facilitate review within the statutory timelines, MAHs are encouraged to file type IA, type IAIN and super-grouping variations no later than 21 November 2025, and type IB variations by 30 November 2025. Applications received after these dates particularly from 1 December onwards may not be validated or processed until early 2026.

The advisory follows the entry into force of the amended Variations Regulation (Regulation (EC) No 1234/2008) in January 2025 and anticipates the implementation of the new Variation Guidelines on 15 January 2026. With a surge in year-end submissions expected, the EMA urges companies to plan early and submit type IB procedures well in advance to avoid delays in evaluation.

18. **The EMA published its Medicines Agencies Network Data Strategy** (available here)

The EMA published its Medicines Agencies Network Data Strategy on 3 October 2025, following a public consultation held between November and December 2024. The strategy sets out a framework to enhance how data is collected, managed, and used across the EU medicines regulatory network, with the goal of improving evidence-based decision-making and fostering greater collaboration between national authorities, the EMA, and external partners.

The strategy document outlines actions to ensure that data handled by the network meets consistent quality, standardisation, and interoperability requirements. It emphasises building a robust data infrastructure that supports efficient sharing and reuse of information, enabling regulators to draw on diverse data sources to better inform public health and regulatory outcomes.

The strategy builds upon the EMA's ongoing initiatives to leverage regulatory submissions data, substance and product master data, and real-world data, including electronic health records, patient registries, and observational studies. It aims to integrate these datasets into a unified regulatory data ecosystem that supports faster, more transparent, and scientifically sound assessments of medicines.

By improving the accessibility and reliability of data, the EMA seeks to ensure that the EU regulatory network remains at the forefront of digital transformation, using advanced analytics and data science to enhance public health protection across the European Union.

19. **The European Commission launches strategy to advance artificial intelligence in scientific research** (available here)

The European Commission has unveiled its European Strategy for Artificial Intelligence in Science. The strategy presents a roadmap to embed AI across the European research ecosystem and to strengthen Europe's global leadership in science-driven innovation.

At its core, the strategy proposes the creation of RAISE, a pan-European "*virtual institute*" that will act as a central hub to coordinate AI infrastructure, expertise, and resources across Member States. RAISE will operate through Thematic Networks of Excellence and a European Network of Frontier AI Labs, designed to foster collaboration between research institutions, industry, and policymakers. The initiative will be piloted under Horizon Europe and Digital Europe, with an initial investment of €108 million, and will be supported by a new AI Evaluation Hub led by the Joint Research Centre to assess AI models used in scientific applications.

The accompanying AI in Science Action Plan structures its objectives around five pillars:

- excellence and talent,
- computational resources,
- data access,
- research funding, and
- collaboration.

The Commission also committed to issuing updated guidance on the ethical and generative use of AI in research and to promoting AI literacy among scientists through dedicated training and mobility schemes. Governance of RAISE will include a high-level academic advisory board and structured engagement with the private sector.

The strategy was formally launched at the AI in Science Summit in Copenhagen on 3–4 November 2025, alongside a private sector pledging campaign to mobilise additional investment. Published in tandem with the Apply AI Strategy and building on the AI Continent Action Plan, the initiative forms a central pillar of the EU's broader vision to position Europe as a global centre for responsible and cutting-edge AI research.

2. GENERAL REGULATORY - IRELAND

20. **The Medical Council v. PQ (a Medical Practitioner) [2025] IEHC 390** (available here)

The High Court granted the Medical Council's application to suspend a general practitioner's registration, emphasising the need to protect the public and ensure patient safety. The practitioner, with a 35-year career in Ireland, exhibited signs of a "*persistent delusional disorder of persecutory type*," as diagnosed by a consultant psychiatrist. Despite the practitioner's refusal to accept the diagnosis and recommendations for conditions on their practice, the court found the evidence presented by the Medical Council sufficient to demonstrate a risk to the public. The court's decision allows for the suspension to be reviewed should the practitioner agree to the conditions proposed by the Medical Council, which align with the psychiatrist's recommendation.

3. GLOBAL INSIGHTS

21. **US - FDA Announces New Pharmaceutical Manufacturing PreCheck Program** (available here)

The U.S. Food and Drug Administration (FDA) has launched the FDA PreCheck Program, a new initiative designed to strengthen the US domestic pharmaceutical supply chain by significantly accelerating and streamlining the regulatory process for establishing new manufacturing facilities within the United States. This move is a direct response to a national imperative to reduce the current reliance on foreign-made drugs and active pharmaceutical ingredients, which currently account for more than half of all medicines distributed in the U.S. PreCheck aims to provide regulatory certainty and predictability, acting as an incentive for drugmakers to commit to onshoring their production capabilities.

The PreCheck program operates through a voluntary two-phase approach that facilitates enhanced, early communication between the agency and manufacturers. The first is the Facility Readiness Phase, which permits companies to engage with the FDA during the critical stages of site design, construction, and pre-production, well before a drug application is formally submitted. Manufacturers are encouraged to submit detailed facility-specific information, including planned layouts and quality system elements, via a Type V Drug Master File. By allowing the FDA to review designs and offer feedback on compliance early, this phase helps flag and resolve potential issues *before* construction is complete, saving manufacturers significant time and money on costly rework and delays.

The second phase, the Application Submission Phase, builds upon the groundwork laid in the first by streamlining the Chemistry, Manufacturing, and Controls portion of the actual drug application. Through pre-application meetings and early feedback, the FDA helps to align expectations and resolve regulatory questions proactively, ensuring a more efficient review process and ultimately a more predictable timeline for market readiness. This program, alongside other FDA efforts like a new pilot prioritisation for U.S.-made generic drugs, represents a shift towards proactive regulatory engagement, rewarding companies that invest domestically to create a more resilient and robust supply of essential medicines for the nation.

22. **The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (the "ICH") adopts new guideline on real-world data studies for medicine safety assessment** (available here)

The ICH has formally adopted its M14 guideline, establishing internationally harmonised principles for the planning, conduct, and reporting of non-interventional pharmacoepidemiological studies that utilise real-world data ("**RWD**") to assess the safety of medicines. The guideline marks a significant step toward improving the reliability, transparency, and regulatory acceptance of RWD-based safety studies globally.

The ICH M14 guideline provides a structured framework covering feasibility assessment, protocol design, data collection and management, and statistical analysis. It is intended to support consistent scientific and regulatory standards across jurisdictions, particularly in the context of post-marketing surveillance and risk management. The framework emphasises the importance of "fit-for-use" data and robust study methodologies that minimise bias and confounding, thereby strengthening the evidentiary value of RWD in pharmacovigilance.

Key aspects of the guideline include recommendations for early engagement with regulatory authorities to ensure study objectives and data sources are aligned with regulatory expectations, and detailed guidance on protocol development and documentation. It also addresses critical methodological considerations such as exposure and outcome definitions, validation of key variables, and sensitivity analyses to assess data robustness.

The adoption of M14 represents the culmination of extensive international collaboration between regulators and industry, reflecting the growing recognition of RWD as a complementary source of evidence alongside randomised controlled trials.

Moreover, its adoption aligns with the EMA-HMA Data Strategy 2025-2028, which is expected to facilitate more efficient global pharmacovigilance practices and support informed regulatory decision-making on medicine safety.

4. COMPETITION LAW

23. The European Commission fines Alchem International for cartel involvement (available here)

The European Commission has fined Alchem International Pvt. Ltd. and its subsidiary Alchem International (H.K.) Limited a total of €489,000 for participating in a long-running cartel involving a pharmaceutical ingredient. The cartel concerned N-Butylbromide Scopolamine/Hyoscine (SNBB), a critical input for producing the antispasmodic drug Buscopan and its generics. Between November 2005 and February 2018, Alchem engaged in illegal practices including price fixing, market allocation, and the exchange of sensitive commercial information across the European Economic Area.

While six other companies settled with the Commission in October 2023, Alchem opted out of the settlement process. Consequently, the Commission pursued a standard investigation, issuing a Statement of Objections in June 2024. This marks the first time the Commission has sanctioned a cartel in the pharmaceutical sector involving an active pharmaceutical ingredient. The investigation was initiated following a 2019 leniency application by C2 PHARMA, with further cooperation from Swiss and Australian authorities.

The fine was calculated under the Commission's 2006 Guidelines, taking into account the value of sales, the nature and duration of the infringement, and Alchem's lack of cooperation, which excluded it from leniency or settlement reductions. Victims of the cartel may pursue damages in national courts, with the Commission's decision serving as binding proof of the infringement under EU competition law.

24. Sun Pharmaceuticals settles antitrust claim for $200 million (available here)

Sun Pharmaceutical Industries Ltd. and its subsidiary Taro Pharmaceuticals have agreed to pay $200 million to settle claims in a long-running U.S. antitrust lawsuit concerning generic drug pricing.

The settlement resolves allegations brought by End Purchaser Plaintiffs in the Eastern District of Pennsylvania, who accused the companies of participating in a scheme to fix prices of generic medications, thereby inflating costs for consumers and insurers.

The settlement, which is part of the larger *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, resolves claims that the companies conspired to fix prices for certain generic drugs, and is subject to court approval.

Under the terms of the agreement, Sun Pharmaceuticals and Taro Pharmaceuticals will make the payment in exchange for a full release from all claims, without admitting any wrongdoing. The settlement is subject to court approval and may be reduced if a significant portion of the insured class members opt out of the putative class.

25. China's State Administration for Market Regulation ("SAMR") orders unwinding of completed pharma deal (available here)

In a move underscoring China's intensified scrutiny of the pharmaceutical sector, SAMR has ordered the unwinding of a completed merger between Wuhan Yongtong Pharmaceutical Co., Ltd. and Shandong Huatai Pharmaceutical Co., Ltd. The transaction, which closed in 2019, was below the mandatory notification thresholds under China's Anti-Monopoly Law but was later proactively called in for review by SAMR.

On 23 July 2025, SAMR issued its fourth-ever prohibition decision, and its first unwind order, requiring Yongtong to divest its 50% stake in Huatai. The regulator found that the acquisition had anti-competitive effects on vertically linked markets, particularly in active pharmaceutical ingredients and finished drug products.

This decision marks a significant expansion of SAMR's enforcement powers. It demonstrates the authority's willingness to intervene in transactions that were previously considered outside the scope of mandatory review, especially in sectors deemed strategically important or prone to concentration risks.

5. DATA PROTECTION

26. The European Data Protection Board ("EDPB") and the European Data Protection Supervisor ("EDPS") issue joint opinion on proposed GDPR record-keeping amendments (available here)

On 9 July 2025, the EDPB and the EDPS published a Joint Opinion on the European Commission's proposed amendments to the General Data Protection Regulation. The proposal seeks to simplify compliance for smaller organisations by extending the record-keeping derogation under Article 30(5) to entities with fewer than 750 employees, up from the current threshold of 250.

The amendments also introduce formal definitions for Small and Medium-sized Enterprises ("**SMEs**") and Small Mid-cap Companies ("**SMCs**") in Article 4 GDPR. Additionally, the scope of Articles 40(1) and 42(1) which relate to codes of conduct and certification mechanisms, is proposed to be extended to include SMCs, thereby offering tailored compliance tools for a broader range of organisations.

While welcoming the overall goal of reducing administrative burdens, the EDPB and EDPS called for greater clarity on the rationale behind the 750-employee threshold. They stressed that the derogation should not apply to processing activities likely to result in high risks to individuals' rights and freedoms, particularly those involving sensitive data under Articles 9 and 10 GDPR.

The regulators emphasised that public authorities should remain excluded from the derogation and recommended that the amended Article 30(5) explicitly reference the newly defined categories of SMEs and SMCs.

27. The EMA and the HMA issue guidance on masking personal data in Eudravigilance reports (available here)

Further to point 14 of this newsletter, the EMA and the HMA have also published an update to pharmacovigilance rules with the GVP Module VI Addendum II, focusing entirely on standardising how personal data is handled in Individual Case Safety Reports that are sent to the EudraVigilance database. This new guidance comes as a direct result of an audit by the European Data Protection Supervisor, which stressed the need for a consistent, unified approach to data masking among all reporting bodies.

The Addendum details a clear system for processing sensitive information, outlining precisely which data elements must be masked, which must be left blank, and which must be retained in their original form. This detailed instruction is vital because the retention or removal of specific data points directly impacts core safety monitoring activities like signal management, duplicate detection, and efficient case processing. By implementing this standardised masking policy, the EMA aims to strengthen data privacy compliance while ensuring the continued integrity and effectiveness of Europe's adverse reaction monitoring system. All entities submitting ICSRs are expected to adopt these new masking requirements promptly to maintain regulatory compliance.

28. The European Health and Digital Executive Agency (the "HaDEA") launches €1m tender for European Health Data Space implementation support (available here)

HaDEA has initiated a €1 million EU4Health tender aimed at securing essential support for the massive undertaking that is the implementation of the European Health Data Space ("**EHDS**").

Launched on 1 August 2025, this service contract falls under the 2025 EU4Health Annual Work Programme (specifically action DI-p-25-66) and seeks high-level

administrative and secretarial assistance to manage the operational rollout of the landmark EHDS Regulation ((EU) 2025/327). This funding reflects a significant commitment to digitally transforming European healthcare, moving beyond the immediate crisis response of previous years toward long-term system resilience.

This administrative support seeks to ensure the smooth functioning of the governance bodies and expert groups central to deploying the EHDS framework across the Union. These structures are responsible for everything from defining technical specifications for data exchange to ensuring secure cross-border access for both primary use (healthcare delivery) and secondary use (research and policy-making). HaDEA manages the majority of the EU4Health budget, and this specific procurement emphasises that the success of the EHDS, which aims to empower citizens with control over their health data and foster a single market for digital health solutions, depends heavily on effective, organised coordination behind the scenes.

The overall goal of this funding action is to strengthen health systems through effective digital governance, which is a key priority of the EU4Health programme, the largest of the EU's health initiatives running from 2021 to 2027. By contracting dedicated support, the EU ensures that the complex procedural and logistical requirements associated with enacting the new EHDS legislation are handled efficiently, thereby accelerating the establishment of a trusted, pan-European ecosystem for sharing and reusing sensitive health information for better patient care and innovation across Europe

29. **The EFPIA submits GDPR code of conduct on clinical trials and pharmacovigilance to Belgian Data Protection Authority** (available here)

The EFPIA has formally submitted its GDPR Code of Conduct on Clinical Trials and Pharmacovigilance to the Belgian Data Protection Authority for assessment. This marks the EFPIA's efforts to promote a harmonised and practical approach to data protection within the pharmaceutical sector.

The Code aims to provide a consistent interpretation of key GDPR provisions as they apply to clinical research and pharmacovigilance activities. By doing so, the EFPIA seeks to enhance legal certainty, reduce administrative burdens, and support innovation across the EU. The initiative responds to concerns raised in the Draghi Report on European Competitiveness, which highlighted the risks posed by legal fragmentation, gold-plating, and inconsistent enforcement of GDPR.

The EFPIA believes that the Code will help align data protection practices across Member States, offering greater clarity for researchers, patients, ethics committees, and regulators. It also aims to strengthen the link between the GDPR and other sectoral legislation, such as the Clinical Trials Regulation, and contribute to the goals of the European Health Data Space.

6. HEALTHCARE

30. **The European Commission launches strategy to boost life sciences in Europe** (available here)

On 2 July 2025, the European Commission unveiled its Life Sciences Strategy, an initiative aimed at making Europe the World's most attractive region for life sciences by 2030.

Backed by over €10 billion annually, the strategy seeks to address long-standing structural challenges that have hindered innovation, market access, and patient access to advanced treatments across the EU. The strategy outlines a comprehensive approach across the entire life sciences value chain. It focuses on accelerating innovation through an EU investment plan that supports multi-country clinical trials and promotes a One Health approach, integrating human, animal, and environmental health. It also includes targeted funding for microbiome-based solutions and cross-sectoral technologies such as advanced materials and biomanufacturing.

To improve market access, the Commission will propose a new EU Biotech Act and launch

a matchmaking interface to connect startups, industry, and investors. These measures aim to create a more innovation-friendly regulatory environment and streamline the path from lab to market.

Public trust and uptake of life science innovations will be supported through €300 million in procurement funding for solutions in areas like climate adaptation, next-generation vaccines, and affordable cancer treatments. A Life Science Coordination Group will be established to align policies and funding across sectors and engage stakeholders. The strategy builds on extensive consultation and evidence, including studies by the Commission's Joint Research Centre. It is part of the broader Competitiveness Compass and reflects the EU's commitment to revitalising its leadership in life sciences, which currently contribute €1.5 trillion to the economy and support 29 million jobs.

31. **The European Commission launches call for evidence on new EU cardiovascular health plan** (available here)

The European Commission has officially initiated a call for evidence on its planned EU Cardiovascular Health Plan, marking a key step in developing a major new strategic initiative to tackle the significant public health burden of cardiovascular diseases ("**CVD**") across the European Union. The planned framework is designed to move beyond traditional approaches, aiming to improve health outcomes through a comprehensive strategy that includes stronger prevention measures, enhanced systems for early detection, and the widespread adoption of personalised treatment pathways.

A central objective of this new plan is to address and reduce persistent health inequalities across the Member States, targeting disparities linked to region, gender, and vulnerable populations, ensuring that all citizens benefit from improved health standards. Furthermore, the plan is expected to boost the overall competitiveness and innovation of the EU health sector. It specifically aims to fill the existing research and innovation gap in cardiology by actively promoting policies that are grounded in the best available evidence and by supporting the development of high-quality health products and technologies.

Ultimately, the EU Cardiovascular Health Plan will serve as a mechanism to support Member States in meeting the relevant Sustainable Development Goals, particularly those focused on combating non-communicable diseases. By focusing on primary prevention, encouraging innovation, and integrating care across the Union, the Commission intends for the Plan to create a more resilient and equitable health landscape, reducing premature mortality and chronic disability associated with CVD throughout the EU.

32. **The Medical Device Coordination Group ("MDCG") updates borderline and classification manual under EU medical device regulations** (available here)

In September 2025, MDCG released an updated version of its Manual on Borderline and Classification for Medical Devices under the MDR and IVDR regulations. This manual is a reference for determining whether products fall within the scope of EU medical device legislation and how they should be classified. The latest revision introduces clarifications for several product categories to support consistent regulatory decisions and provide manufacturers with greater legal certainty.

Among the updates, red blood cell additive solutions containing adenine are now classified as Class III medical devices due to their direct interaction with blood and their critical role in preserving red cells. In contrast, dual-action creams containing menthol and capsaicin are not considered medical devices, as their pain relief effect is pharmacological. Similarly, lactose tablets for vaginal use fall outside the MDR's scope because their primary action is metabolic rather than physical.

The MDCG also addressed borderline consumer and professional products. Microabrasion dental stain removers were deemed non-medical devices, as their cosmetic whitening purpose lacks a medical

claim. However, the group noted that if future evidence shows a therapeutic effect, such as disease prevention, their classification could be reconsidered. Medical examination table covers were explicitly recognised as medical devices due to their role in infection prevention.

This update reflects the MDCG's ongoing commitment to regulatory coherence across the EU, aiming to reduce uncertainty and ensure appropriate oversight for products placed on the market.

33. **Medicines for Europe warns that amendments that the EU Council proposes to make to the Critical Medicines Act risk undermines EU health security** (available here)

Medicines for Europe has issued an open letter to the Committee of Permanent Representatives expressing concern that amendments that the EU Council proposes to make to the Critical Medicines Act risk would have the effect of weakening the legislation's capacity to safeguard the EU's health security. The trade association warns that the Council's position dilutes key provisions originally designed to address chronic medicine shortages and strengthen the Union's strategic autonomy in pharmaceutical supply.

Medicines for Europe cautions that by limiting measures to support manufacturing, diversify supply chains, and strengthen solidarity between Member States, the Council's position prioritises short-term cost containment over long-term resilience. This, it argues, risks deepening market consolidation, deflating prices, and increasing dependence on non-EU production, particularly in China.

Medicines for Europe urges the Council to restore the ambition of the Act through two core reforms: Mandatory inclusion of non-price criteria in procurement and reimbursement decisions, and the injection of€4 billion in EU funding to support manufacturing upgrades and supply resilience. This intervention follows the Council's adoption of the EU pharmaceutical reform package and underscores continuing debate over how best to balance affordability, competition, and strategic autonomy in Europe's medicines supply.

34. **Council of the European Union adopts conclusions on strategy to strengthen EU life sciences and biotechnology sectors** (available here)

The Council of the European Union (the "**Council**") has adopted conclusions outlining a new strategic vision to boost the competitiveness, sustainability, and global leadership of the EU life sciences and biotechnology sectors. The initiative recognises the sector's central role in supporting public health, economic growth, and the green transition, and calls for coordinated EU-wide measures to reinforce innovation, regulatory coherence, and societal trust.

The strategy sets out an integrated framework spanning healthcare, agriculture, industrial biotechnology, and environmental protection. It calls for targeted investments in research and innovation, with particular emphasis on advanced therapy medicinal products, clinical trials, and biomanufacturing capacity. The Council also highlights the need to modernise research infrastructure, expand access to funding, and improve career pathways for scientists and innovators to maintain Europe's talent base and research excellence.

For industry, the conclusions envisage a more agile and innovation-friendly regulatory environment through the reduction of administrative burdens, streamlined approval procedures, and better alignment between sectoral legislation. Public procurement and financing mechanisms are expected to play a stronger role in supporting market uptake of novel technologies. For citizens, the strategy aims to ensure that life sciences innovation translates into safer, more sustainable products, enhanced healthcare access, and broader economic resilience.

Central to the strategy is the creation of a dynamic EU innovation ecosystem. Proposed measures include the establishment of European Centres of Excellence, the

development of new platforms such as the European Life Sciences R&I Data Assembly and Virtual Human Twins Incubator, and the promotion of artificial intelligence and data-driven research. Education and skills development feature prominently, with commitments to strengthen STEM education, promote researcher mobility, and ensure long-term career sustainability in science and technology.

Governance and coordination will be overseen by a new Life Sciences Coordination Group, tasked with monitoring progress, facilitating stakeholder engagement, and ensuring policy alignment across Member States. The forthcoming European Biotech Act will further simplify regulatory pathways and reinforce Europe's position as a global hub for biotechnology innovation.

Through these measures, the Council aims to position the EU as the world's most attractive region for life sciences innovation by 2030, underpinned by sustained investment, responsible governance, and strategic international cooperation.

ABOUT

Philip Lee is one of Ireland's leading commercial law firms. We are recognised leaders in several areas of law, including healthcare and life sciences, competition, data, employment, energy, environmental, EU, intellectual property, PPP, procurement, real estate and tax. The firm has offices in Dublin, London and San Francisco. We represent pioneering Irish and international private companies operating in the world's leading sectors and public sector bodies with real vision. Philip Lee is the only Irish member of Multilaw. With 10,000 lawyers and a combined annual revenue of $5bn, Multilaw is ranked by Chambers Global as an 'Elite' international network of law firms.

We are a team of talented and innovative thinkers, who embrace collegiality within the firm and with our clients. For further information, please contact a member of our Healthcare, Pharmaceuticals and Life Sciences team.

CONTACT US:

Ronan Dunne
Partner
rdunne@philiplee.ie

Marie Kinsella
Partner
mkinsella@philiplee.ie

Anne Bateman
Partner
abateman@philiplee.ie

Daniel Hanrahan
Senior Associate
dhanrahan@philiplee.ie

PHILIPLEE

DUBLIN | LONDON | NEW YORK