

# Healthcare, Pharmaceutical and Life Science Update

Q4 - December 2025

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

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## WELCOME

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical and Life Science group in respect of the fourth 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. Data Protection
5. Healthcare

### 1. GENERAL REGULATORY – EU

#### 1. **Provisional agreement reached by EU lawmakers on comprehensive reform of EU pharmaceutical legislation** (available [here](#))

On 11 December, the EU Council and the Parliament reached a provisional agreement on a major overhaul of the EU's pharmaceutical framework, aiming to update rules on innovation, competition, and the security of medicine supply. The agreement introduces the following principal reforms:

- (i) a baseline 8-year data protection for new medicines followed by one year of market protection that prevents the sale of generics or biosimilars,
- (ii) Products for rare diseases with no current treatment ("*breakthrough orphan medicines*") can receive up to 11 years of market exclusivity.

The agreement also clarifies the "*Bolar*" exemption, confirming that studies and activities required for marketing authorisation, health technology assessments, pricing and reimbursement procedures, or procurement tenders do not infringe patent rights. This clarification is intended to support earlier entry of generic

and biosimilar medicines once exclusivity periods expire.

To address antimicrobial resistance, the agreement will introduce a "*transferable data-exclusivity voucher*" for priority antimicrobials, granting an extra year of data protection that may be applied to the antimicrobial itself or another centrally authorised product. Companies seeking approval for priority antimicrobials will need to provide stewardship plans and assess the risk of resistance as part of environmental risk evaluations. New requirements will also ensure antimicrobials are supplied only with a medical prescription and accompanied by specific information materials.

The agreement includes measures when, once introduced, will help streamline the European Medicines Agency's procedures, including electronic submission of applications and default unlimited validity for marketing authorisations unless safety concerns justify limits. The Commission may also establish regulatory sandboxes to support the development and supervised testing of innovative therapies.

To improve medicine availability, companies will be required to maintain and update shortage prevention plans for prescription medicines and other products identified as critical. Shortages will be monitored at national and EU levels, and the EMA will maintain a list of critical shortages.

This provisional agreement follows the Commission's 2023 proposal to modernise EU pharmaceutical legislation and will proceed to formal adoption by the Council before returning to Parliament for second-reading endorsement. The legislation is expected to undergo formal adoption in the coming months.

#### 2. **The EU unveils its dedicated AI in Science Strategy** (available [here](#))

In October 2025, the European Commission has published its Communication titled "*A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE)*" in the

Official Journal, marking a step toward integrating artificial intelligence into scientific research across the European Union. Central to this strategy is the establishment of RAISE (Resource for AI Science in Europe), a virtual institute designed to unify and coordinate AI-science infrastructure throughout the EU.

To bolster this initiative, the Commission has introduced the AI in Science Action Plan, which outlines a series of new and expanded measures across five key pillars: excellence and talent, computation, data, research funding, and collaboration between Member States and the private sector. Among the strategic actions are up to €600 million from Horizon Europe to provide EU researchers and startups with access to AI Gigafactories, €58 million for Networks of Excellence and Doctoral Networks aimed at cultivating top-tier AI and scientific talent, and support for integrating Data Labs within AI Factories.

The plan also includes a commitment to double Horizon Europe's investment in AI to over €3 billion by 2028 and to fund automation in scientific laboratories as well as the development and refinement of scientific foundation models through RAISE pilot calls. These initiatives will be formally launched at the AI in Science Summit in Copenhagen on 3–4 November 2025, which will also feature a private sector pledging campaign to further support the strategy's goals.

**3. The European Federation of Pharmaceutical Industries and Associations (the "EFPIA") has published a guest blog which calls for further refinement of proposed EU General Pharmaceutical Legislation** (available [here](#))

The EFPIA has published a guest blog commenting on the ongoing revision of the EU's General Pharmaceutical Legislation ("GPL"). In this blog, the author has welcomed the initiative as an important step towards updating the EU's pharmaceutical framework. The author views the reform of the GPL as a timely opportunity to modernise regulatory processes and better reflect scientific and technological progress.

However, the author cautions in its blog how certain elements of the current proposals may fall short of their objectives if not further refined. In particular, the author raises concerns regarding limited flexibility in the use of real-world evidence and proposals that would exclude marketing authorisation holders from decisions on product labelling where data is generated by regulators or third parties. The author suggests that these measures could constrain the effective use of emerging data sources and weaken collaborative regulatory decision-making.

The author, therefore, calls for a more adaptive and inclusive approach to the GPL reform, emphasising the importance of stakeholder engagement to ensure the revised legislation supports innovation, safeguards patient safety, and remains responsive to evolving scientific evidence.

**4. The European Medicines Agency ("EMA") updates its Frequently Asked Questions ("FAQ") guidance on parallel distribution procedures, including new clarification on QR code requirements** (available [here](#))

The EMA has published an updated version of its FAQ guidance on parallel distribution of centrally authorised medicines, introducing a number of clarifications relevant to parallel distributors and marketing authorisation holders. The revised guidance reflects practical and procedural issues arising in the operation of the parallel distribution framework and aims to improve consistency and transparency in its application.

The updated FAQ document includes revisions addressing several aspects of the parallel distribution process, including:

- Changes to organisational details, clarifying the steps distributors must take where there are updates to their company information.
- Situations where a Notice for Parallel Distribution cannot be issued, outlining the consequences and next steps in such cases.
- Post-notice obligations, setting out the responsibilities of parallel

distributors following the issuance of a parallel distribution notice.

- Implications of the Protocol on Ireland/Northern Ireland, providing further clarity on how parallel distribution procedures apply in this context.
- Recipients of parallel distribution notices, clarifying which parties receive formal notification.

In addition to these updates, the EMA has introduced a new FAQ addressing QR code requirements on packaging materials, reflecting evolving expectations around product identification and traceability.

Parallel distributors and other stakeholders involved in the supply of centrally authorised medicines should review the updated guidance carefully to ensure ongoing compliance with the EMA requirements and to assess whether any operational or documentation changes are required.

#### **5. The EMA publishes the European Medicines Agencies Network Data Strategy following public consultation (available [here](#))**

On 3 October 2025, the EMA published the European Medicines Agencies Network Data Strategy marking a milestone in the EU's efforts to modernise and optimise regulatory data use. Developed following a public consultation held between November and December 2024, the strategy outlines a vision for enhancing the quality, organisation, standardisation, and accessibility of data across the European medicines regulatory network.

The Data Strategy aims to strengthen collaboration among regulators and stakeholders, enabling more informed and timely decision-making in public health. Building on the EMA's existing initiatives, the Data Strategy emphasizes the integration of diverse data sources, including regulatory submissions, substance and product master data, and real-world evidence from electronic health records and patient registries, to support robust, evidence-based regulatory practices throughout the European Union.

#### **6. The European Commission adopts final implementing regulation on joint clinical assessments for medical devices under EU Health Technology Assessment framework (available [here](#))**

On 17 October 2025, the European Commission adopted the final implementing regulation required for the application of the Health Technology Assessment Regulation (Regulation (EU) 2021/2282) (the “**HTA Regulation**”). The HTA Regulation establishes detailed procedural rules for joint clinical assessments of medical devices and in-vitro diagnostic medical devices at EU level.

The implementing regulation sets out how joint clinical assessments will be conducted in practice, including rules governing cooperation between the Member State Coordination Group on Health Technology Assessment and the Commission, as well as interaction with notified bodies and relevant expert panels. It also defines procedures for engagement with health technology developers and other stakeholders, including consultation processes and timelines.

In addition, the implementing regulation introduces standardised formats and templates for submission dossiers and assessment reports, with the aim of promoting consistency, transparency, and efficiency across joint assessments. These procedural rules are intended to support smoother coordination between EU and national authorities while reducing duplication of clinical assessment work at Member State level.

This measure represents the sixth and final implementing regulation necessary for the full operation of the HTA framework, which became applicable on 12 January 2025. At the time of adoption, nine joint clinical assessments were already underway, primarily relating to new cancer medicines and advanced therapy medicinal products.

#### **7. Joint industry position paper released on “Digital label for Authorised Representative and Importer” in relation to medical devices and in vitro diagnostic medical devices (available [here](#))**

The joint industry position paper from MedTech Europe, AESGP (Association of the European Self-Care Industry), COCIR (European Trade Association representing the medical imaging, health ICT and electromedical industries) and Euromcontact (European Federation of Contact Lens and Lens Care Manufacturers) sets out a coordinated call for the EU to permit the use of digitalisation of labels for medical devices and in-vitro diagnostics in which information on Authorised Representatives and Importers would be detailed.

The authors of the position paper argues that current EU labelling rules require large volumes of non-essential information to be printed on physical labels, a requirement that has grown significantly under the MDR and IVDR and is further compounded by horizontal legislation affecting the sector. According to the authors of the position paper, this has resulted in overcrowded labels, increased packaging needs and administrative burdens when economic operator details change.

The authors of the position paper highlights that digital labelling technologies are already widely used in other sectors and that more than half of the global economy has adopted some form of e-labelling. The authors propose that importer and Authorised Representative details, information not essential to the safe use of a device, should be the first elements moved to a digital format as part of the upcoming MDR/IVDR legislative revision. The authors note that doing so would align medical device rules with other EU initiatives such as the Digital Product Passport and the EU's broader sustainability objectives under the Green Deal.

The authors of the position paper also points to practical challenges created by recent changes to the authorised representative symbol under ISO standards, arguing that digital provision of AR information would reduce the need for repeated physical relabelling. For importer information, the paper stresses that digital access would ensure end users reliably receive the

required details while avoiding waste and delays caused by reprinting labels when importers change.

The authors of the position paper urges the European Commission to allow Authorised Representatives and Importer information to be provided digitally in the ongoing MDR/IVDR revision, arguing that this would simplify compliance processes, reduce environmental impact and support timely device availability. The authors view this as a first step toward a broader transition in which all non-essential information could eventually be delivered through digital labels, subject to the outcomes of the ongoing IHI Digital Label project.

## **2. GENERAL REGULATORY - IRELAND**

### **8. The High Court confirms public interest may justify interim suspension of medical practitioner pending criminal proceedings (available [here](#))**

In *Medical Council v. RS (A Medical Practitioner)* [2025] IEHC 542, the High Court granted the Medical Council's application under section 60 of the Medical Practitioners Act 2007 for the interim suspension of a medical practitioner's registration, pending further steps under the Act. The Court also made associated orders prohibiting the practitioner from practising medicine in the State during that period.

The respondent, although registered in Ireland, had been residing and practising in the United Kingdom, where criminal charges had been brought against him. The application was supported by extensive material provided by the UK General Medical Council, including information relating to allegations of possession of indecent images of children and extreme pornographic material. The central issue for the Court was whether the public interest in protecting patients and maintaining confidence in the medical profession justified the making of interim orders, notwithstanding the respondent's entitlement to the presumption of innocence.

Applying the established three-stage test set out in *O’Ceallaigh v An Bord Altranais* [2000] 4 IR 54, the Court found that the allegations were of a very serious nature and that the Council had presented a strong case, supported by evidence connecting the respondent to the devices on which the material was allegedly found. While the Court accepted that the respondent continued to enjoy the presumption of innocence, it held that this did not preclude the granting of protective measures where the statutory criteria were otherwise met.

Having carried out the required balancing exercise, the Court concluded that the need to safeguard the public and uphold confidence in the regulatory system outweighed the competing interests and constitutional rights engaged. The Court was therefore satisfied that the public interest favoured the suspension sought and granted the full suite of orders requested by the Medical Council.

The judgment provides important clarification on the operation of section 60 of the 2007 Act and reaffirms the High Court’s willingness to grant interim protective measures where serious allegations raise concerns for patient safety, even in advance of the determination of criminal proceedings.

### 3. GLOBAL INSIGHTS

#### 9. The US Food and Drug Administration (“FDA”) proposes eliminating most comparative clinical efficacy studies for biosimilars to streamline approvals (available [here](#))

The FDA has issued draft guidance proposing a significant shift in its regulatory approach to biosimilar product development by largely eliminating the requirement for comparative clinical efficacy studies (“CES”) in support of biosimilarity determinations under section 351(k) of the Public Health Service Act. Published on 29 October 2025, the draft guidance reflects the FDA’s view that modern analytical and pharmacokinetic methods are frequently sufficient to demonstrate that a proposed biosimilar is “*highly similar*” to a

reference biologic without conducting resource-intensive clinical efficacy trials.

Under the updated draft framework, sponsors may rely on a robust comparative analytical assessment, combined with human pharmacokinetic similarity data and an immunogenicity assessment, to meet the statutory standard for biosimilarity where the proposed product and reference are well characterised and differences can be reliably assessed. Although the FDA retains discretion to require a CES in limited circumstances, the guidance signals a clear move toward a more flexible and science-driven evidentiary approach.

The FDA’s proposal is accompanied by the FDA’s broader efforts to accelerate biosimilar development, improve market competition, and lower drug costs by reducing development time and expenses that have traditionally been associated with large, comparative clinical trials. Early industry feedback suggests this shift could accelerate biosimilar market entry and align with similar trends in other regulatory jurisdictions that increasingly rely on advanced analytical methods in lieu of clinical efficacy studies

#### 10. The FDA published the “*Plausible Mechanism Pathway*” in the *New England Journal of Medicine* (available [here](#))

On November 12, 2025, the FDA Commissioner Marty Makary and Centre for Biologics Evaluation and Research (CBER) Director and FDA Chief Medical and Scientific Officer Vinay Prasad unveiled the new “*Plausible Mechanism Pathway*” in a *New England Journal of Medicine* article.

This initiative is designed to give regulators greater flexibility where conventional clinical trials prove unfeasible. The approach is built around five elements: a clearly defined molecular abnormality, a therapy that directly targets that abnormality, a well-characterised natural history, confirmation that the biological target has been successfully drugged or edited, and observable clinical improvement.

The pathway is initially oriented toward cell and gene therapies, but the FDA has signalled openness to extending it to small molecules and other modalities. Although the focus remains on severe childhood diseases and ultra-rare conditions, the agency has left room for its use in common diseases with profound unmet need.

Alongside this pathway, the FDA has been refining several complementary tools aimed at accelerating access while maintaining scientific integrity. These include enhanced use of real-world evidence, adaptive trial designs, and structured engagement with patient communities to better understand disease burden and meaningful endpoints.

For ultra-rare conditions, where natural history data may be sparse, the agency has increasingly encouraged sponsors to develop robust natural history studies early in the development cycle, enabling regulators to contextualise treatment effects even in very small cohorts. The FDA has also signalled a willingness to accept greater uncertainty at the time of approval, provided that post-market commitments are feasible and proportionate.

#### **11. UK regulators (the MHRA and NICE) receive additional funding to advance governance of digital mental health technologies and AI tools** (available [here](#))

UK health regulators have received additional government funding to support the development of clearer regulatory pathways for digital mental health technologies, including artificial intelligence-enabled tools. The funding will support work by the Medicines and Healthcare products Regulatory Agency (“MHRA”) and the National Institute for Health and Care Excellence (“NICE”) to strengthen oversight, evaluation, and adoption of digital mental health solutions within the UK health system.

Key initiatives include further development of regulatory guidance for software-based mental health interventions and the expansion of innovation support mechanisms, such as regulatory sandboxes, to enable controlled testing of novel

technologies. The measures are intended to address long-standing challenges around evidence generation, clinical validation, and reimbursement for digital mental health products, while ensuring patient safety and public trust.

The initiative reflects growing regulatory recognition of the role digital tools can play in addressing capacity constraints in mental health services. For developers and healthcare stakeholders, the enhanced regulatory focus signals increased opportunities for engagement with UK regulators, alongside clearer expectations around compliance, clinical evidence, and real-world deployment.

## **4. DATA PROTECTION**

### **12. The Joint Research Centre (“JRC”) publishes report on AI adoption in European scientific research** (available [here](#))

The JRC has released a report titled *“Role of Artificial Intelligence in Scientific Research – A Science for Policy, European Perspective”*, offering an in-depth examination of how AI is reshaping scientific inquiry across Europe. Published alongside the European Commission’s broader strategy, *A European Strategy for Artificial Intelligence in Science: Paving the way for the Resource for AI Science in Europe (RAISE)*, the report underscores the transformative potential of AI in accelerating research and innovation. It reveals that by 2024, two in five global AI players had participated in at least one research or innovation activity, such as filing AI patents or publishing scientific papers. Notably, the EU leads globally in this domain, accounting for 13% of AI research actors, outpacing the US (4%) and China (1%).

The report also highlights the strategic importance of investing in high-performance computing, AI factories, and open data repositories to maintain the EU’s leadership in AI-driven science. One standout example of AI’s impact is its application in life sciences, where AI tools are significantly enhancing protein analysis and expediting drug discovery. Looking ahead, the JRC will

spearhead the AI Evaluation Hub, a key initiative under the AI in Science Strategy, to assess AI models in critical scientific fields. The report offers a comprehensive roadmap for aligning policy and funding to harness AI's full potential in advancing European science.

### **13. The European Data Protection Board (“EDPB”) to focus 2026 coordinated enforcement action on GDPR transparency and information obligations** (available [here](#))

The EDPB has announced that compliance with transparency and information requirements under the EU General Data Protection Regulation (Regulation (EU) 2016/679) (“GDPR”) will be the subject of its next coordinated enforcement action, scheduled to commence in 2026.

The initiative will examine how organisations comply with Articles 12, 13 and 14 of the GDPR, which require controllers to provide clear, accessible, and timely information to individuals about the processing of their personal data. National data protection authorities (“DPAs”) will be invited to participate on a voluntary basis, with supervisory activities expected to begin in the coming weeks.

Findings from participating DPAs will be consolidated and analysed at EU level, with the aim of identifying common compliance challenges and informing targeted follow-up measures, including potential guidance or enforcement actions at both national and European levels.

The exercise forms part of the EDPB's Coordinated Enforcement Framework, established in 2020 to promote consistent application of the GDPR across Member States. Previous coordinated actions have addressed the role of data protection officers and the practical implementation of the right of access, highlighting the framework's increasing focus on core accountability and transparency obligations.

### **14. UK Tribunal confirms limited scope of section 166 of the UK Data Protection Act applications and strikes out challenge to**

### **Information Commissioner decision** (available [here](#))

In *Bishop v. The Information Commissioner* [2025] UKFTT 1217 (GRC), the UK First-tier Tribunal (General Regulatory Chamber) considered an application under section 166(2) of the UK Data Protection Act 2018 seeking to compel further action by the Information Commissioner in relation to a subject access request made to Liverpool Women's NHS Foundation Trust.

The applicant argued that the Liverpool Women's NHS Foundation Trust had provided only a partial response to the request and sought an order requiring the Information Commissioner to progress the complaint further. However, the First-tier Tribunal noted that the Information Commissioner had already completed its assessment and issued outcomes to the applicant on several occasions during 2024.

The Tribunal held that section 166 of the UK Data Protection Act 2018 is confined to addressing narrow procedural failures and does not permit challenges to the substance or merits of the Information Commissioner's conclusions. Significant weight was given to the Information Commissioner's assessment, as the expert regulator, that no further regulatory steps were warranted.

Accordingly, the proceedings were struck out for lack of jurisdiction and on the basis that the application disclosed no reasonable prospect of success. The decision provides clear guidance on the limited circumstances in which section 166 of the UK Data Protection Act 2018 may be relied upon and confirms that it cannot be used as a route to reopen concluded data protection complaints.

### **15. Delegated Regulation on data sharing with vetted researchers under EU Digital Services Act published in Official Journal** (available [here](#))

The European Union has taken a further step toward enhancing transparency and accountability in the digital ecosystem with the publication of Commission Delegated

Regulation (EU) 2025/2050 in the Official Journal on 9 October 2025. Adopted on 1 July 2025, this Delegated Regulation supplements the Digital Services Act (Regulation (EU) 2022/2065) by establishing the technical conditions and procedures for data sharing between very large online platforms and very large online search engines and vetted researchers.

The new rules aim to facilitate meaningful access to platform data for independent research, enabling deeper insights into systemic risks such as disinformation, algorithmic amplification, and online harms. By setting out clear protocols for how data should be requested, accessed, and protected, the Regulation ensures that research can be conducted securely and ethically, while safeguarding user privacy and platform integrity.

This move underscores the EU's commitment to fostering a safer, more transparent digital environment through evidence-based policymaking and robust oversight.

## 5. [HEALTHCARE](#)

### 16. Pharmaceutical industry groups challenge Commission study on costs of the implementation of the Urban Wastewater Treatment Directive (available [here](#))

European pharmaceutical industry associations, including the Association of the European Self-Care Industry (“AESGP”), the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) and Medicines for Europe, have criticised the European Commission's forthcoming study assessing the costs of implementing the Urban Wastewater Treatment Directive (“UWWTD”). The UWWTD, adopted in 2024, introduces an Extended Producer Responsibility framework requiring the pharmaceutical and cosmetics sectors to fund advanced (quaternary-level) wastewater treatment.

In a joint response, the AESGP and the EFPIA argue that the Commission's approach risks significantly understating the financial

impact on industry. Their key concerns include:

- Lack of industry consultation, with affected sectors not involved in the preparation of the study despite being subject to the new cost-recovery regime.
- Methodological limitations, with the study said to rely largely on inflation-adjusted figures rather than a full reassessment of sector-specific compliance costs.
- Underestimation of financial impact, with Member State analyses suggesting actual costs may be 300–600% higher than Commission estimates.
- Material budgetary consequences, potentially increasing annual compliance costs from approximately €1.18 billion to over €7 billion across the EU.

The controversy has also triggered responses at Member State level. Poland has initiated legal proceedings before the Court of Justice of the European Union challenging aspects of the Directive, while France and Germany have publicly called for revisions to the current framework. The debate highlights growing tension between environmental policy objectives and the need to ensure proportionality, predictability and industrial competitiveness within EU pharmaceutical regulation.

### 17. The EMA and pharmaceutical industry engage social media platforms to address misinformation and counterfeit medicines (available [here](#))

The EMA and the European pharmaceutical industry have launched separate initiatives aimed at tackling misinformation and unsafe practices relating to medicines on social media platforms, reflecting growing regulatory concern about the online promotion and sale of medicinal products.

In October 2025, the EMA launched its first coordinated social media awareness campaign, #HealthNotHype, focused on the safe and appropriate use of glucagon-like peptide-1 (“GLP-1”) receptor agonists used in the treatment of diabetes and weight management. The month-long campaign, which began on 21 October 2025, involved collaboration with healthcare professionals and nutrition experts from seven EU Member States who are active content creators on Instagram. Selected participants which are chosen for their credibility and commitment to evidence-based communication, are producing audiovisual content and interactive polls aimed at countering misinformation and promoting responsible use of these medicines. Collectively, the participating creators have an audience of approximately 1.4 million followers.

Separately, the European Federation of Pharmaceutical Industries and Associations (the “EFPIA”) announced a partnership with TikTok on 21 October 2025 as part of its “Don’t fall for dupes” campaign. This initiative seeks to raise awareness of the risks associated with purchasing medicines online, highlighting industry estimates that more than half of medicines sold through unauthorised online channels may be counterfeit. The campaign is intended to discourage illegal sales practices and improve public understanding of how to identify legitimate sources of medicines.

#### **18. The European Commission launches calls for projects boosting digital health innovation across the EU (available [here](#))**

The European Commission has recently opened several significant funding calls to accelerate digital health innovation across the EU. The funding calls under the Digital Europe Programme outline a broad set of investments aimed at strengthening Europe’s digital capacity across identity systems, data infrastructure, artificial intelligence, and sector-specific innovation. A

€15 million call is already open to advance the European Digital Identity Wallet and mobile driving licences, supporting the rollout of a unified and secure digital identification framework across Member States. Eight additional calls will open on 4 November, covering a range of initiatives tied to the EU’s digital policy agenda.

The upcoming calls include €79.2 million to consolidate, and €8 million to complete, the Network of European Digital Innovation Hubs, which assist businesses, particularly SMEs, in adopting digital technologies. Health-related digital infrastructure receives significant attention, with €22.5 million allocated to support biomedical research and personalised healthcare through the European Genomic Data Infrastructure, and €14.4 million dedicated to deploying AI-based tools in medical imaging. Industrial data sharing is supported through a €9 million call designed to facilitate cross-sector data exchange.

The automotive sector is addressed through €4.5 million in combined funding to establish the secretariat and collaboration platform for the European Connected and Autonomous Vehicle Alliance, intended to coordinate innovation in connected and autonomous mobility. A further €6 million will support the European Digital Media Observatory hubs, which focus on monitoring and analysing disinformation across the EU.

These calls follow the first amendment to the DIGITAL Work Programme 2025–2027, adopted earlier in the week, which updates the programme to reflect the Commission’s current political priorities and ongoing technological developments. More information on the calls and the application process is available on the [EU Funding & Tenders Portal](#).

## 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.

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