

Healthcare, Pharmaceutical and Life Science Update

Q1 - March 2026

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical and Life Science group in respect of the first quarter of 2026.

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.ie



PHILIPLEE

WELCOME

Welcome to the first quarterly Healthcare, Pharmaceutical and Life Science Group update for 2026.

This edition highlights several developments of particular significance for the sector, including progress on the Mental Health Bill 2024, reform of decision-making and capacity frameworks, steps towards the implementation of the European Health Data Space through the Health Information Bill 2024, and new regulatory guidance on the use of artificial intelligence in health and social care. We also cover important High Court decisions affecting healthcare providers and professionals, alongside key updates relating to medicines, medical devices and clinical trials.

The update is structured thematically, drawing together legislative reform, regulatory guidance, case law and sector-specific developments to provide practical insight into issues of ongoing relevance. The contents of this update are listed and hyperlinked below.

A. POLICY, LEGISLATION AND SYSTEM REFORM

- The General Scheme for the Disability (Amendment) Bill (Assessment of Need Process)
- General Scheme of the Judicial Council (Amendment) Bill 2026
- Mental Health Bill 2024
- Public consultation on draft national guidance for the responsible and safe use of AI in health and social care services
- Review of the statutory role of the Director of the Decision Support Service
- Assisted Decision Making (Capacity) (Amendment) Act 2026

B. COURTS AND LITIGATION

- Claim of dental assistant who tripped over vacuum cleaner at work dismissed
- High Court dismisses student's claim for injuries sustained while indoor bouldering
- Finding of no negligence on part of GP in child appendicitis case
- High Court refuses extension of time to bring defamation proceedings

C. PUBLIC HEALTH AND MEDICAL REGULATION

- Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill 2026
- Review of access to cannabis for medical use
- Medical Council launches public consultation on Code of Practice for anatomical examinations

D. DIGITAL HEALTH, DATA AND LIFE SCIENCES

- HIQA report assesses Ireland's readiness for the European Health Data Space Regulation
- Health Information Bill 2024 (European Health Data Space and electronic health records)
- Supply and Pricing of Medicines: New Framework Agreements signed
- Medical devices: mandatory use of key EUDAMED modules from May 2026
- Clinical trials: FAST EU pilot for accelerated multinational approvals

A. POLICY, LEGISLATION AND SYSTEM REFORM

1. The General Scheme for the Disability (Amendment) Bill (Assessment of Need Process)

The Department of Children, Disability and Equality published the General Scheme of the Disability (Amendment) Bill in February, following Government approval in December 2025. The proposed legislation would amend Part 2 of the Disability Act 2005, which governs the Assessment of Need process, with the stated objective of making that process more effective for children and families and increasing the number of assessments completed within the statutory six-month period.

The Department has emphasised that the proposals do not remove the right of parents to apply for an Assessment of Need, nor do they alter the statutory timeframe set out in the Disability Act. Instead, the General Scheme signals a shift towards changes in how assessments are organised and delivered, aimed at addressing operational challenges that have contributed to delays in practice.

An accompanying FAQ document has been published alongside the General Scheme and will be updated as the legislative process progresses.

Read the Press Release [here](#); and the General Scheme [here](#).

2. General Scheme of the Judicial Council (Amendment) Bill 2026

The General Scheme of the Judicial Council (Amendment) Bill 2026 was published in January, following Cabinet approval. The stated aim of the proposals is to make the process for the development, review and adoption of Personal Injuries Guidelines more transparent and comprehensive.

If enacted, the amendments would allow the Judicial Council to reconsider revised Guidelines in circumstances where the

Oireachtas does not approve those presented to it, creating a formal mechanism to address situations that have arisen in practice. The General Scheme also proposes extending the review cycle for the Guidelines from three to five years, calculated from the date on which new Guidelines are adopted.

The proposals would further require the Judicial Council to consult with the Personal Injuries Resolution Board and other relevant stakeholders during the review process, and to carry out and publish research on damages for personal injuries. This research would include analysis of court awards and decisions of quasi-judicial bodies outside the State, as well as damages assessed or mediated through the Personal Injuries Resolution Board.

Read the Press Release [here](#); and the General Scheme [here](#).

3. Mental Health Bill 2024

The Mental Health Bill 2024 has completed Committee Stage in Seanad Éireann. The Minister has indicated that a number of Opposition amendments were accepted at Committee Stage, and that further amendments, including transitional provisions, may be introduced at Report Stage. The Bill remains before Seanad Éireann and listed for further business in April 2026.

The Bill is intended to replace the Mental Health Act 2001 and to modernise Ireland's mental health framework. Key elements include strengthened rights protections for mental health service users, particularly those who are involuntarily admitted and those receiving care in acute settings. The Bill also proposes a substantial expansion of the regulatory remit of the Mental Health Commission, extending oversight to community mental health services, including community CAMHS, and specified residences, in addition to inpatient services.

For more information, see this legal briefing from our Healthcare team: [Ireland's Mental Health Reform: At a Glance](#).

Read the Press Release [here](#); and the Bill [here](#).

4. Public consultation on draft national guidance for the responsible and safe use of AI in health and social care services

In January, the Health Information and Quality Authority (HIQA) launched a six-week public consultation on its Draft National Guidance for the Responsible and Safe Use of Artificial Intelligence in Health and Social Care Services. The guidance was commissioned by the Department of Health and informed by an evidence review previously published by HIQA.

The draft guidance is intended to promote awareness of, and good practice around, the use of AI across health and social care services. It is structured around four core principles: accountability, a human rights-based approach, safety and wellbeing, and responsiveness. HIQA has emphasised that the guidance addresses practical issues, including governance arrangements, transparency, and public and service-user engagement.

The guidance is also intended to support organisations in navigating an evolving regulatory environment, including preparing for the implementation of the EU AI Act, alongside existing EU legal frameworks such as the Medical Device Regulations and GDPR.

Read HIQA's Update [here](#).

5. Review of the statutory role of the Director of the Decision Support Service

On 11 March, the Department of Children, Disability and Equality published the statutory review of the role of the Director of the Decision Support Service (DSS), as required under section 102(3) of the Assisted Decision-Making (Capacity) Act 2015.

The review assesses the effectiveness of the Director's role and the adequacy of the statutory functions conferred under the 2015 Act. Commissioned by the Mental Health Commission and carried out by Governance Ireland, the review concludes that the role is operating effectively in many respects but

considers areas where statutory functions lack clarity and where operational challenges have emerged.

The report makes a series of recommendations intended to inform future legislative amendment and policy development in relation to the Assisted Decision-Making (Capacity) Act 2015.

Read more [here](#).

6. Assisted Decision-Making (Capacity) (Amendment) Act 2026

The Assisted Decision-Making (Capacity) (Amendment) Act 2026 was signed into law on 31 March 2026, to address an identified issue arising in the implementation of the Assisted Decision-Making (Capacity) Act 2015, particularly in the context of legacy wardship cases.

The 2026 Act amends section 54 of the 2015 Act to allow the wardship court, in individual cases, to extend the statutory period within which a capacity declaration must be made under section 55(1). This power arises where there is good reason why the original timeframe cannot be met and where an extension is in the interests of justice. Further extensions may be granted only in exceptional circumstances and must be proportionate and no longer than necessary. The amendment is limited in scope and does not alter the overall policy objective of transitioning wards of court into the decision support framework established under the 2015 Act. Rather, it provides a practical mechanism to manage cases where statutory deadlines are imminent but cannot realistically be met, helping to avoid procedural difficulty and uncertainty.

This Act forms part of a broader package of measures supporting the phased transition away from wardship and addressing operational challenges identified since the commencement of the 2015 Act.

Read the Act [here](#).

B. COURTS AND LITIGATION

7. Claim of dental assistant who tripped over vacuum cleaner at work dismissed

In *Sharon Walsh v Juniper Orthodontics Limited* [2026] IEHC 99, the High Court dismissed a workplace personal injury claim arising from a trip over a vacuum cleaner hose on a staircase in a dental practice, reiterating that employers are not required to eliminate every possible risk of accident.

The plaintiff, a dental assistant, was injured while vacuuming an internal staircase between patient appointments. She paused to check whether the receptionist was on the telephone, leaving the rigid arm of the vacuum cleaner resting against the banister. The arm fell, the hose stretched across a step, and the plaintiff later stepped on it while descending, losing her balance and sustaining a significant ankle injury.

She alleged negligence, breach of statutory duty under the Safety, Health and Welfare at Work Act 2005, and occupiers' liability. The High Court rejected the claims, holding that, even on the plaintiff's account, the defendant had not been negligent as employer or occupier and had not breached any statutory duty. The accident was "very unfortunate" but not legally actionable.

The Court emphasised that an employer must take reasonable precautions against reasonably foreseeable risks. Pausing briefly while vacuuming stairs was characterised as routine, and the possibility of the vacuum arm falling when propped against a banister was not evidence of an unsafe system of work. The Court also rejected arguments that further controls (such as restricted cleaning times or warning systems) were required in a small dental clinic.

Read the Judgment [here](#).

8. High Court dismisses student's claim for injuries sustained while indoor bouldering

In *Kathryn Yates v Dublin Bouldering Gym Limited & Anor* [2026] IEHC 181, the High Court has dismissed a personal injuries claim arising from an accident at an indoor bouldering facility in Sandymount, holding that the plaintiff's injuries resulted from the materialisation of an inherent risk of the activity. Judgment was delivered on 13 March.

The plaintiff, an adult student and member of a university climbing society, fell from a climbing wall while bouldering and sustained ankle injuries. She alleged that the defendants were negligent in allowing her to participate in a hazardous activity without adequate induction, instruction, supervision or safety measures, and maintained that appropriate training would have reduced or avoided the risk of injury.

Mr Justice Paul Coffey rejected those arguments. The Court found that bouldering involves obvious and inherent risks, including the risk of falling, which would have been apparent to a participant of full capacity. The plaintiff's injuries were caused by the crystallisation of that inherent risk rather than by any breach of duty on the part of the facility operator or the educational institution.

In those circumstances, the Court held that the defendants were not required to eliminate or guard against risks intrinsic to the activity itself, nor was there an obligation to provide instruction or supervision beyond the arrangements already in place.

Read the Judgment [here](#).

9. Finding of no negligence on part of GP in child appendicitis case

In *Afolabi v Southdoc Services Ltd & Anor* [2026] IEHC 110, the High Court dismissed a medical negligence claim arising from an alleged failure to diagnose appendicitis in an 11-year-old child, finding that the GP involved met the required standard of care.

The plaintiff attended an out-of-hours GP service operated by the first defendant, SouthDoc, where she was examined by the second defendant GP. She presented with vomiting, abdominal pain and diarrhoea. Although the child's mother raised the possibility of appendicitis, the GP diagnosed gastroenteritis. The GP provided management advice, clear "red flag" warnings and a referral letter for use if the child's condition deteriorated. Three days later, the child was diagnosed with acute perforated appendicitis, requiring emergency surgery and resulting in significant complications and permanent scarring. The plaintiff alleged negligence in failing to diagnose appendicitis and refer the child to hospital at the initial consultation.

The High Court dismissed the claim, holding that neither the GP nor the out-of-hours service had acted negligently. Ms Justice Reynolds applied the principles in *Dunne v National Maternity Hospital* and *Morrissey v HSE*, finding that the diagnosis of gastroenteritis was reasonable on the child's presentation at the time.

The Court placed particular weight on the GP's safety-netting advice and the provision of a hospital referral letter. It found that, had the advice been acted upon promptly, the adverse outcome would likely have been avoided. The judgment reiterates that an adverse outcome, of itself, does not establish clinical negligence.

Read the Judgment [here](#).

10. High Court refuses extension of time to bring defamation proceedings

In *Sheila Dobell v Mater Misericordiae University Hospital* [2026] IEHC 173, the High Court has refused an application for an extension of time to bring defamation proceedings under section 11 of the Statute of Limitations Act 1957 and Order 1B of the Rules of the Superior Courts.

The application arose from statements contained in medical records and related communications following the death of the

applicant's husband, which the applicant contended falsely described her as his "ex-wife". The applicant argued that the statements only came to light through discovery in separate wrongful death proceedings and sought permission to issue defamation proceedings outside the statutory time limits.

Ms Justice Siobhán Phelan held that the applicant had not established circumstances justifying an extension of time. In reaching that conclusion, the Court considered the context in which the statements were made, the deceased's medical condition at the relevant time, and the absence of evidence that the communications were intended to injure the applicant's reputation.

The judgment emphasises that ambiguity or inaccuracy in medical records, without more, will not readily ground an extension of time in defamation proceedings, and confirms the cautious approach taken by the courts when asked to exercise discretion under the limitation regime.

Read the Judgment [here](#).

C. PUBLIC HEALTH AND MEDICAL REGULATION

11. Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill 2026

The Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill 2026 was published and introduced in the Dáil in early April. The Bill proposes significant amendments to the Public Health (Tobacco Products and Nicotine Inhaling Products) Act 2023, with the objective of strengthening controls on nicotine products that fall outside traditional tobacco regulation.

Key proposals include a statutory prohibition on the sale of specified nicotine inhaling and consumption products to persons under the age of 18, including nicotine pouches. The

Bill would also introduce restrictions on retail advertising and product display, including point-of-sale visibility controls, particularly in mixed retail environments.

The Bill further provides for more detailed regulation of product presentation, including packaging, labelling, device design and flavour restrictions. These measures are framed to support public health objectives and to ensure that the regulatory regime remains adaptable to new or emerging nicotine products.

The proposed amendments reflect a broader policy approach to reducing the accessibility and appeal of nicotine products, particularly among children and young people, and to closing regulatory gaps identified since the enactment of the 2023 Act.

Read the Bill [here](#).

12. Review of access to cannabis for medical use

On 1 April, the Minister for Health has announced the appointment of Professor Shane Allwright as Chair of the Review of Access to Cannabis for Medical Use. The Review Group has been established to examine current arrangements for patient access to medical cannabis in Ireland and to provide advice and recommendations to inform future policy and decision-making.

Medical cannabis access in Ireland is currently provided through the Medical Cannabis Access Programme (MCAP), which has been in operation since 2021 for specified products, alongside access to certain cannabis products granted under individual Ministerial Licence. The Review Group will assess how these access routes are functioning in practice and will consider the available evidence in relation to medical cannabis use.

In announcing the appointment, the Minister emphasised the importance of a thorough, balanced and evidence-based review process. The Government has indicated that it will consider the Review Group's report in

due course as part of its ongoing approach to medical cannabis policy.

Read the Press Release [here](#).

13. Medical Council launches public consultation on Code of Practice for anatomical examinations

The Medical Council has launched a public consultation on a draft Code of Practice relating to Part 4 of the Human Tissue Act 2024, which governs anatomical examinations.

The draft Code is intended to support doctors in understanding and complying with their professional obligations when carrying out anatomical examinations under the Act. Part 4 of the Human Tissue Act 2024 provides a statutory basis for anatomical examination and sets out the circumstances in which such examinations may be carried out, subject to appropriate consent and safeguards.

In launching the consultation, the Medical Council emphasised the importance of ensuring that the Code reflects best practice, ethical standards and the legislative requirements introduced by the 2024 Act. The consultation invites submissions from interested stakeholders, including members of the medical profession and organisations involved in healthcare, education and regulation.

Read the Press Release [here](#).

D. DIGITAL HEALTH, DATA AND LIFE SCIENCES

14. HIQA report assesses Ireland's readiness for the European Health Data Space Regulation

HIQA has published a new report assessing Ireland's readiness for the implementation of the European Health Data Space (EHDS) Regulation in the context of the secondary use of health data. The report, *Readiness Assessment for Data Holders*, was

undertaken as part of the HealthData@IE project, led by the Department of Health in collaboration with HIQA, the Health Research Board and other key stakeholders across the health system.

The assessment examined 21 major health datasets held by 16 health data holders across Ireland and explored how prepared those organisations are to meet their anticipated obligations under the EHDS Regulation. Under the Regulation, EU Member States will be required between 2029 and 2031 to establish health data access services to support the secure secondary use of anonymised health data for purposes such as research, innovation, policymaking and public health planning. This will involve the establishment of a national Health Data Access Body and new obligations on health data holders to make datasets available.

The report concludes that, while there are areas of good practice, substantial work remains to ensure compliance with the EHDS framework. In particular, it highlights the need for robust infrastructure, clear governance arrangements, improved data-sharing practices and detailed operational rules to support health data holders in meeting their obligations. The findings are intended to inform national planning and readiness activities as Ireland prepares for phased implementation of the EHDS Regulation.

Read the HIQA report [here](#).

15. Health Information Bill 2024 (European Health Data Space and electronic health records)

The Health Information Bill 2024 progressed through key stages during Q1 2026 and represents a central pillar of Ireland's preparations for the European Health Data Space (EHDS).

The Bill is expressly framed as giving further effect to Regulation (EU) 2025/327 on the EHDS and provides a comprehensive statutory framework for the collection, use and sharing of health information in Ireland.

In particular, it establishes the legal basis for the creation and assignment by the Health Service Executive of an Electronic Health Record (EHR) in respect of every patient and specifies the categories of information to be contained within that record.

A core feature of the Bill is the introduction of a statutory duty on health service providers to share personal health data in defined circumstances, where this is necessary for the care and treatment of a patient or for specified public interest purposes. The Bill also confers powers on the HSE to request health information from health service providers and other specified persons for purposes including service planning, performance oversight and compliance with EU health data obligations, with recourse to the Circuit Court where a request is not complied with.

The Bill completed Second Stage in Seanad Éireann on 10 February and proceeded to Committee Stage on 3 March. In introducing the Bill, the Minister emphasised the role of secure information sharing in improving patient care and enabling Ireland to meet its obligations under EU health data legislation. If enacted, the legislation will establish a foundational legal framework for digital health in Ireland, including the roll-out of electronic health records, structured information sharing across public and private providers, and alignment with the governance and secondary-use requirements of the EHDS

Read the Bill [here](#).

16. Supply and Pricing of Medicines: New Framework Agreements signed

On 4 March, the Minister for Health announced the finalisation and signing of new Framework Agreements on the supply and pricing of medicines with the Irish Pharmaceutical Healthcare Association and Medicines for Ireland.

The Agreements are intended to improve patient access to medicines, strengthen security of supply and reduce the risk of shortages, while also safeguarding the

financial sustainability of the health service. Measures include commitments aimed at facilitating faster access to innovative medicines and a structured process towards achieving a 180-day timeline for reimbursement decisions by Q1 2029.

The Agreements also signal an intention to develop a future strategic partnership between the State and industry, including work towards a pilot early access programme for rare diseases, in line with Programme for Government commitments.

Read the Press Release [here](#).

17. Medical devices: mandatory use of key EUDAMED modules from May 2026

The Health Products Regulatory Authority has confirmed that the mandatory use of four key modules of the European Database on Medical Devices (**EUDAMED**) will commence on 28 May 2026.

The modules becoming mandatory relate to actor registration, UDI and device registration, notified bodies and certificates, and market surveillance. The transition follows publication by the European Commission of a notice confirming that these modules are fully functional.

From the mandatory use date, relevant economic operators, including manufacturers, authorised representatives and importers, will be required to carry out specified regulatory activities through EUDAMED. Transition periods apply for the registration of certain legacy devices and existing certificates.

This development marks a significant compliance milestone under the EU Medical Devices and In Vitro Diagnostic Devices Regulations, with practical implications for registration, traceability and post-market oversight obligations.

Read the HPRA update [here](#).

18. Clinical trials: FAST-EU pilot for accelerated multinational approvals

Ireland is participating in the FAST-EU (Facilitating and Accelerating Strategic Clinical Trials) pilot, an EU initiative designed to accelerate the coordinated assessment and authorisation of multinational clinical trials conducted across multiple EU and EEA Member States.

The pilot operates within the existing EU Clinical Trials Regulation and the Clinical Trials Information System (**CTIS**). It provides for a maximum overall assessment timeline of 10 weeks from submission to final decision, including sponsor response times, with parallel validation and assessment and integrated ethics committee opinions.

FAST-EU opened to expressions of interest from sponsors in January and is expected to run on a pilot basis for one year. The initiative forms part of broader EU efforts to enhance the attractiveness and efficiency of the European clinical trials environment while maintaining scientific, safety and ethical standards.

Read more [here](#).

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