Healthcare, Pharmaceutical and Life Science Update

Quarter 2 2026

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

philiplee.ie

Healthcare, Pharmaceuticals and Life Sciences Update
Q2 | 2026

WELCOME

Welcome to the second quarterly Healthcare, Pharmaceuticals and Life Sciences Update.[1]

This edition covers significant developments across healthcare governance and system reform, public health regulation and policy, medicines and clinical research, and healthcare disputes. It includes updates on the Mental Health Act 2026, proposals concerning commercial sunbed use and nicotine products, the EU pharmaceutical reform package, the new EU template for clinical trial recruitment and informed consent procedures, and recent High Court decisions relevant to healthcare litigation and professional regulation.

The update is structured thematically, drawing together legislative reform, regulatory guidance and recent case law. The contents are listed and hyperlinked below.

We hope you find this update useful. If you would like to discuss any of the topics covered, please contact a member of our Healthcare, Pharmaceuticals and Life Sciences Group.

A. HEALTHCARE LAW AND REFORM

1. Committee publishes report on pre-legislative scrutiny of the Disability (Amendment) Bill 2025
2. Commencement of further provisions of the Health (Assisted Human Reproduction) Act 2024
3. Joint Committee on Health publishes report on Adult Safeguarding
4. Mental Health Act 2026 signed into law
5. Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill 2026
6. Sunbed Working Group recommends ban on commercial sunbed use in Ireland
7. Chair appointed to review access to medical cannabis
8. HSA publishes 2026 Code of Practice on chemical agents and CMR substances

B. MEDICINES AND CLINICAL RESEARCH

1. EU Pharmaceutical Reform Package: Compromise legislative texts published following political agreement
2. New EU standard template for clinical trial recruitment and informed consent procedures

C. HEALTHCARE LITIGATION AND CLINICAL NEGLIGENCE

1. High Court confirms limited scope of review of Legal Costs Adjudicator determinations in clinical negligence proceedings
2. High Court considers capacity, treatment ceilings and palliative care under inherent jurisdiction
3. High Court grants Medical Council application concerning doctor's registration
4. High Court stays clinical-negligence proceedings pending genetic testing

[1] This update covers developments occurring principally between 1 April and 30 June 2026. Legislative and regulatory status information has been updated to September 2026 where relevant.

A. HEALTHCARE LAW AND REFORM

1. Committee publishes report on pre-legislative scrutiny of the Disability (Amendment) Bill 2025

The Joint Committee on Disability Matters completed its pre-legislative scrutiny of the General Scheme of the Disability (Amendment) Bill 2025 and published its report on 17 April 2026. The Bill proposes amendments to Part 2 of the Disability Act 2005, with a particular focus on reforming the statutory Assessment of Need (**AoN**) process.

The Committee's report summarises evidence received from stakeholders and public bodies and identifies a number of concerns relating to access, consistency and the rights-based framing of assessments for persons with disabilities. It makes recommendations intended to inform the drafting and progression of the Bill, including issues relating to AoNs, timelines and alignment with Ireland's obligations under disability and equality frameworks. The report will inform the Government's preparation of the proposed legislation.

Note: The proposed legislation has been referred to as the Disability (Assessment of Need) Bill in the Government's Summer 2026 Legislation Programme. At the date of publication, the Bill had not yet been introduced in the Oireachtas.

Read the Report here.

Read the Oireachtas Library & Research Service's Briefing Paper on the General Scheme here.

2. Commencement of further provisions of the Health (Assisted Human Reproduction) Act 2024

S.I. No. 160 of 2026 appoints 20 April 2026 as the commencement date for paragraphs (b), (c) and (d) of section 232 of the Health (Assisted Human Reproduction) Act 2024 (the **2024 Act**). The commencement order was made by the Minister for Health on 13 April 2026 and notice of its making was published in *Iris Oifigiúil* on 17 April 2026.

The commenced provisions amend the Children and Family Relationships Act 2015 (the **2015 Act**) in relation to parentage for children born through donor-assisted human reproduction. The amendments address specified situations involving procedures carried out before the relevant provisions of the 2015 Act came into operation and procedures performed lawfully outside the State. They also make provision for the treatment of known and unknown donors, including consent requirements and circumstances in which the court may dispense with donor consent.

Read the commencement order here.

Read the 2024 Act here.

Read the 2015 Act here.

3. Joint Committee on Health publishes report on Adult Safeguarding

On 14 May 2026, the Joint Committee on Health published its report on Adult Safeguarding. The report makes a number of recommendations to both the Department of Health and the Health Service Executive (**HSE**). In comments accompanying publication, the Committee Cathaoirleach referred to legal and policy gaps in adult safeguarding and stated that the Department of Health had not yet finished drafting the General Scheme of a Safeguarding Bill, despite the issue being on the Government's legislative programme since Spring 2025.

The report addresses issues including mandatory reporting, powers of access, oversight and accountability, independence, cross-sectoral cooperation and independent advocacy. The Committee also refers to the Law Reform Commission's work on adult safeguarding and recommends that the Law Reform Commission's Criminal Law (Adult Safeguarding) Bill be swiftly enacted to provide for criminal offences for those who put adults at risk of harm, neglect or coercion, and those who perpetrate such acts.

Separately, the Criminal Law (Adult Safeguarding) Bill 2026 was introduced as a Private Member's Bill on 6 May 2026 and completed First Stage in Dáil Éireann. This is distinct from the Government's proposed adult safeguarding legislation, the General Scheme of which remains under development.

Read the Oireachtas Press Release here.

Read the 2026 Private Members' Bill here.

4. Mental Health Act 2026 signed into law

President Catherine Connolly signed the Mental Health Act 2026 (the **2026 Act**) into law on 7 May 2026, following the Bill's completion of all stages in the Oireachtas.

The 2026 Act establishes a substantially reformed statutory framework for mental health services. Commencement provisions and supporting implementation measures before the new regime becomes fully operational.

Once commenced, the Act will introduce additional safeguards for people accessing mental health services, strengthen rights protections and provide for all community mental health services, including residential services and community CAMHS, to be registered and regulated for the first time in the State.

The Department has confirmed that work is underway on commencement, including drafting secondary legislation, developing training and education for professionals, and raising awareness of the changes for people accessing services under the Act.

Read the Department of Health Press Release here.

Read the Mental Health Act 2026 here.

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

The Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill 2026 completed Report and Final Stages in Dáil Éireann on 24 June 2026 and is currently before Seanad Éireann at Second Stage. It has not yet been enacted.

The Bill includes measures relating to product packaging and appearance, restrictions on advertising and display, and an explicit prohibition on the sale of nicotine consumption products to children. It also provides for powers enabling the Minister for Health to regulate flavour names by order, reflecting concerns around product attractiveness.

If enacted, the Bill would expand enforcement powers and introduce additional offences under the public health legislation framework.

Read the Bill here.

6. Sunbed Working Group recommends ban on commercial sunbed use in Ireland

The Sunbed Working Group published a report examining the health, regulatory and policy implications of commercial sunbed use in Ireland and recommended a ban on commercial sunbed use as the most effective public health measure.

The report concludes that there is strong and consistent scientific evidence that exposure to ultraviolet radiation from sunbeds causes skin cancer and that there is no safe level of exposure. It also highlights evidence of continued sunbed use by persons under 18 despite existing legislative restrictions and notes challenges with enforcement and compliance.

A majority of the Working Group recommended a ban on commercial sunbed use, identifying it as the most effective and evidence-based policy option to reduce exposure to harmful UV radiation, particularly among children and young people.

In July 2026, the Department published its public consultation report. The report

identified differing views among stakeholders regarding a proposed ban and indicated that the findings would inform the next phase of policy development. No ban had been introduced at the date of publication.

Read the Sunbed Working Group Report here.

Read related publications on the Public Health – Sunbeds Policy here.

7. Chair appointed to review access to medical cannabis

On 1 April 2026, the Minister for Health announced the appointment of Professor Shane Allwright as Chair of the Review of Access to Cannabis for Medical Use.

The Review Group will examine existing routes of access to cannabis products for medical use and provide advice and recommendations to inform future policy development.

Read the Press Release here

8. HSA published 2026 Code of Practice on chemical agents and CMR substances

The Health and Safety Authority (**HSA**) published a new Code of Practice providing consolidated guidance on compliance with the Chemical Agents Regulations and the Carcinogens, Mutagens and Reprotoxic Substances Regulations. The Code reflects recent amendments to the underlying statutory instruments and gives effect to updated EU directives in this area.

The Code sets out practical guidance for employers on risk assessment, exposure control and occupational exposure limit values for a range of substances. It is intended to assist in meeting statutory obligations under health and safety legislation, particularly in workplaces where hazardous chemical exposure may arise.

A failure to observe the Code does not of itself constitute an offence. However, under section 61 of the Safety, Health and Welfare at Work Act 2005, the Code may be admissible in evidence in proceedings concerning an alleged breach of relevant statutory obligations, and evidence of compliance or non-compliance may be taken into account.

Read the Code of Practice here.

B. MEDICINES AND CLINICAL RESEARCH

9. EU Pharmaceutical Reform Package: Compromise legislative texts published following political agreement

The EU Pharmaceutical Reform Package moved forward during Q2 2026 following the political agreement reached by the Council of the European Union and the European Parliament in December 2025. During this period, compromise legislative texts were published, reflecting the outcome of the interinstitutional negotiations.

The package consists of a new Directive on medicinal products for human use, which will replace Directive 2001/83/EC, and a new Regulation governing EU authorisation procedures and the European Medicines Agency, replacing Regulation (EC) No 726/2004 and several related legislative instruments.

The package has not yet been formally adopted and is not yet in force. Formal approval by the European Parliament and the Council, translation into the official EU languages, publication in the Official Journal and the relevant entry-into-force and transitional arrangements remain outstanding.

The European Medicines Agency (**EMA**) has already established a dedicated implementation portal to support stakeholders and provide information on the practical implementation of the reforms once adopted.

The compromise texts provide the clearest indication to date of the likely shape of the

new regime and allow pharmaceutical companies, regulatory professionals and healthcare stakeholders to begin planning for implementation. However, the final binding legislation will be the text formally adopted and published in the Official Journal.

Read the Council Press Release here; and further information here.

10. EU clinical trials: New standard template for recruitment and informed consent procedures

MedEthicsEU, the European group of national representatives of medical research ethics committees, developed a revised standard template covering patient recruitment and informed consent procedures for clinical trials conducted under the Clinical Trials Regulation framework. The template was endorsed by the Clinical Trials Coordination and Advisory Group (CTAG) and is intended to support greater consistency in the ethical review of clinical trial applications across the EU and EEA.

The revised template seeks to harmonise the Part II documentation submitted through the Clinical Trials Information System (**CTIS**). While establishing a common EU framework, the template also allows additional information to be included where required to address Member State-specific legislative requirements.

From 1 September 2026, the revised template applies to new Part II submissions. The revised template does not apply retrospectively to clinical trials that have already been authorised or to applications that were under review at the time of publication.
The updated template can be found here.

C. HEALTHCARE LITIGATION AND CLINICAL NEGLIGENCE

11. High Court refuses review of legal costs adjudication in clinical negligence proceedings

In *BC [A Minor] v Health Service Executive* [2026] IEHC 283, the High Court considered its review jurisdiction under section 161 of the Legal Services Regulation Act 2015 in respect of decisions of the Chief Legal Costs Adjudicator and a Legal Costs Adjudicator. The underlying proceedings were a high-value clinical negligence action brought on behalf of a child and had settled without admission of liability, including provision for payment of 50% of damages when assessed or agreed and a €4 million payment on account.

The paying party challenged elements of the adjudication, including the solicitor's instruction fee and counsel brief fees, arguing that the adjudicator had overstated complexity and novelty, failed to provide adequate reasons and insufficiently engaged with comparator cases.

The High Court refused the application for review. It held that the paying party had failed to establish an error of fact, law or principle and, in any event, had not shown that the allowances were unjust within the meaning of section 161(5). The High Court emphasised that intervention under section 161 requires the applicant to demonstrate that the Legal Costs Adjudicator erred as to the amount of an allowance or disallowance so that the determination is unjust.

The decision highlights the restricted scope of judicial review of costs adjudications and the difficulty of overturning an adjudicator's assessment absent a clear statutory basis for intervention.

Read the Judgment here.

12. High Court considers capacity, treatment ceilings and palliative care under inherent jurisdiction

In *Health Service Executive v PJ* [2026] IEHC 291, the High Court considered an urgent application brought by the Health Service Executive under the inherent jurisdiction of the Court concerning a 78-year-old man detained in an approved centre. The Court was asked to determine issues relating to capacity, medical treatment, accommodation

and care needs, including whether treating clinicians could lawfully apply a ceiling of care excluding coercive feeding, coercive medical treatment and cardiopulmonary resuscitation. The
Court was also asked to determine whether Non-coercive palliative care may be provided in defined circumstances and whether the respondent's continued detention in the approved centre was necessary and proportionate.

The judgment emphasises that the application was not one to withdraw existing life-sustaining treatment, authorise any act intended to hasten death or deny care. Rather, the Court characterised the issue as whether clinicians could lawfully refrain from implementing invasive and coercive interventions which they considered, in good faith and in accordance with professional ethics, to be futile, harmful and disproportionate.

The Court recognised that the proposed ceiling of care engaged the respondent's constitutional rights at a fundamental level, including his rights to life, bodily integrity, dignity, autonomy and liberty.

Read the Judgment here.

13. High Court grants Medical Council application concerning doctor's registration

In *Medical Council v Yunos* [2026] IEHC 237, the High Court confirmed a decision of the Medical Council to cancel the medical registration of psychiatrist Amirul Mohd Yunos pursuant to section 71 of the Medical Practitioners Act 2007. The application followed the respondent's conviction on multiple sexual offences involving a minor patient and a decision of the Medical Council that he had permanently ceased to be a fit and proper person to practise medicine.
Barniville P. confirmed the Council's decision. Under section 76(3) of the 2007 Act, the Court was required to confirm the sanction unless there was "good reason" not to do so. The Court held that no such reason existed and described the case as "truly appalling and shocking". The Court observed that it was difficult to imagine a more serious case and stated that it was inconceivable that the respondent could remain on the medical register or ever be permitted to practise medicine again. The Court therefore confirmed the cancellation of his registration.

Read the Judgment here.

14. High Court stays clinical-negligence proceedings pending genetic testing

In *C. (A Minor) v Health Service Executive* [2026] IEHC 234, the High Court considered an application by the defendant to stay clinical-negligence proceedings pending a clinical genetics assessment and trio exome sequencing of the minor plaintiff and her parents. The underlying claim concerned an alleged delay in diagnosing and treating intracranial pathology. Although the defendant admitted specified breaches of duty relating to the failure to measure the child's head circumference, it did not admit that any breach caused or materially contributed to the child's injuries.

Mr Justice Garrett Simons confirmed that the court has an inherent jurisdiction to stay personal injuries proceedings where justice requires it following a plaintiff's refusal to undergo a medical examination.

The only medical evidence before the court on the application was provided by the defendant's consultant clinical and biochemical geneticist. Her evidence was that an underlying genetic diagnosis was likely and that trio exome sequencing represented the appropriate investigation. The plaintiff did not adduce medical evidence in response.

The Court held that the proposed testing was not merely relevant but was likely to have a

meaningful bearing on the outcome of the proceedings. The Court found that concerns regarding privacy, incidental findings, data security and bodily integrity had been adequately addressed by the proposed safeguards.

The proceedings were therefore stayed until the child and her parents attend for clinical examination and provide the samples required for trio exome sequencing.

Read the Judgment 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