Healthcare, Pharmaceutical and Life Science Update

Q3 - October 2026



Welcome to this update from the Philip Lee Healthcare, Pharmaceutical, and Life Science Group in respect of the third 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 Q3 | 2026

WELCOME

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

This edition covers developments including the EU Pharma Package, the HPRA's new Strategic Plan, the Smokefree Generation Bill, the Disability (Amendment) Bill 2026, home support and insurance reforms, and recent High Court decisions concerning medical treatment for minors and nursing home 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. EU Council adopts new EU Pharma Package
2. Smokefree Generation Bill introduced in the Oireachtas
3. Disability (Amendment) Bill 2026 introduced
4. Public consultation launched on proposed amendments to the Health and Social Care Professionals Act 2005
5. Health (Amendment) (Home Support Providers) Act 2026
6. Insurance (Disregard of Certain Medical History and Miscellaneous Provisions) Act 2026 ("Right to be Forgotten" Legislation)

B. MEDICINES AND CLINICAL RESEARCH

1. HPRA publishes Strategic Plan 2026-2029
2. *Merck Serono v Controller of Intellectual Property* [2026] IEHC 617
3. Advocate General's Opinion on pharmaceutical producer responsibility for wastewater treatment
4. Revised EU recruitment and informed consent template begins to apply

C. HEALTHCARE LITIGATION AND CLINICAL NEGLIGENCE

1. *In the Matter of FB (A Minor)* [2026] IEHC 341
2. *Chief Inspector of Social Services v Raidió Teilifís Éireann* [2026] IEHC 445
3. Medical Council v Lagun [2026] IEHC 624
4. *Meyler v Blimka* [2026] IEHC 482
5. *Alajbeg v Neto & Pro-Riso Dental Clinic Limited* [2026] IEHC 461

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

A. HEALTHCARE LAW AND REFORM

1. EU Council adopts new EU Pharma Package

The Council of the EU adopted the new EU Pharma Package on 28 September 2026, marking the first major revision of EU pharmaceutical legislation since 2004. The reforms aim to improve patient access to safe and affordable medicines while supporting innovation and competitiveness in the pharmaceutical sector.

The package introduces revised regulatory protection periods for innovative medicines. Companies placing a new medicine on the market will benefit from eight years of data protection and one year of market protection, with the possibility of additional protection where specified conditions are met. The package also provides specific incentives for orphan medicinal products used to treat rare conditions, including nine years of market exclusivity and the possibility of an additional two years for qualifying "breakthrough" orphan medicines.

The reforms also seek to tackle antimicrobial resistance by introducing a transferable exclusivity voucher for companies developing priority antibiotics. The voucher provides an additional year of market protection for a pharmaceutical product, subject to specified conditions. Member States will also be able to require companies to supply medicines benefiting from regulatory protection in sufficient quantities to meet patient needs.

The package expands the Bolar exemption, an IP exemption allowing manufacturers to take necessary preparatory steps, such as studies and trials, so that generic medicines can be made available from day one after the relevant IP rights expire. The exemption will also extend to the submission of applications for procurement tenders.

The Regulation and Directive must now be formally adopted by the European Parliament and will enter into force following publication in the Official Journal of the European Union.

Read the Council of the EU press release here.

2. Smokefree Generation Bill introduced in the Oireachtas

The Public Health (Tobacco) (Amendment) (Smokefree Generation) Bill 2026 was introduced as a Private Members' Bill in Dáil Éireann on 22 September 2026. The Bill proposes to amend the Public Health (Tobacco) Acts 2002 to 2024 to prohibit the sale and supply of tobacco products, nicotine products and nicotine inhalation products to anyone born on or after 1 January 2009.

The proposed legislation would create a "smokefree generation" through a rolling age restriction under which people born on or after that date would remain prohibited from being sold or supplied these products even after reaching the age of 18. The Bill also contains provisions relating to proxy purchasing, retailer obligations, enforcement, offences and penalties.

The Bill is currently before Dáil Éireann at Second Stage and will be subject to further consideration as it progresses through the legislative process.

Read the Bill here.

3. Disability (Amendment) Bill 2026 introduced

The Disability (Amendment) Bill 2026 was introduced on 18 September 2026 to make targeted amendments to the assessment of need process under the Disability Act 2005.

The Bill seeks to clarify that a determination of disability is a prerequisite to assessing the health and education needs arising from that disability, introduce statutory guidelines relating to the assessment of need process, and provide mechanisms for the withdrawal, closure and, where applicable, reinstatement of applications.

The proposed reforms also seek to shift the focus from a diagnostic led to a needs led approach, including by placing greater emphasis on the substantial restrictions experienced by an individual and the needs arising from those restrictions.

The Bill completed Second Stage in Dáil Éireann on 23 September 2026 and has been referred to the Select Committee on Disability Matters.

Read the Bill here.

4. Public consultation launched on proposed amendments to the Health and Social Care Professionals Act 2005

The Department of Health launched a public consultation on 4 September 2026 on proposed amendments to the Health and Social Care Professionals Act 2005 contained in the Regulated Professions (Health and Social Care) (Amendment) Bill. The amendments considered in the consultation relate to the regulation of the psychology profession, particularly the designation of the titles of clinical, counselling and educational psychologist.

The consultation formed part of a proportionality assessment being conducted pursuant to Directive (EU) 2018/958, which requires Member States to assess the proportionality of new or amended professional regulations that restrict access to, or the pursuit of, regulated professions. The Directive was transposed into Irish law by S.I. No. 413/2022.

Interested parties were invited to give their views on whether the relevant proposed amendments are proportionate. The findings will assist the Department in completing its Proportionality Assessment, which will subsequently be submitted to the European Commission in accordance with the Proportionality Test Directive. The consultation closed on 2 October 2026.

Read the consultation notice here.

5. Health (Amendment) (Home Support Providers) Act 2026

The Health (Amendment) (Home Support Providers) Act 2026 was signed into law by the President on 1 July 2026 and establishes a statutory framework for the registration and inspection of home support providers in Ireland. The Act amends the Health Act 2007 and provides for the regulation of home support providers by HIQA and the Chief Inspector of Social Services.

The new framework will apply to public, private and voluntary providers of home support services and is intended to improve the safety and quality of those services. It provides for registration, inspection and compliance mechanisms and for standards applicable to home support providers.

The Act has been enacted but has not yet commenced. Section 1 provides for its commencement by Ministerial order, including the possibility of different provisions being commenced on different dates.

The reforms represent a significant development in the regulation of home support services.

Read the Act here.

6. Insurance (Disregard of Certain Medical History and Miscellaneous Provisions) Act 2026 ("Right to be Forgotten" Legislation)

The Insurance (Disregard of Certain Medical History and Miscellaneous Provisions) Act 2026, signed into law on 15 July 2026, introduces a statutory “right to be forgotten” for certain cancer survivors applying for mortgage protection insurance.

The relevant provisions, contained in Part 2 of the Act, came into operation on 15 October 2026 pursuant to the Insurance (Disregard of Certain Medical History and Miscellaneous Provisions) Act 2026 (Commencement) Order 2026 (S.I. No. 443/2026).

Under the legislation, insurers must disregard an applicant's medical history in respect of a cancer diagnosis where the

applicant completed active cancer treatment at least five years before the application and has been in complete remission for at least five years.
The legislation places protections for eligible cancer survivors on a statutory footing, replacing the previous voluntary framework and providing greater certainty, consistency and protection for cancer survivors seeking mortgage protection insurance.

Read the Act here.

B. MEDICINES AND CLINICAL RESEARCH

1. HPRA publishes Strategic Plan 2026-2029

The Health Products Regulatory Authority ("**HPRA**") published its Strategic Plan 2026–2029 on 24 September 2026, setting out its priorities and direction for the next four years.

The strategy is structured around four strategic goals: Regulating for the future; Digital first, data driven; Partnerships, trust and transparency; and People, capability and culture.

The plan highlights the HPRA's role in supporting timely access to safe and effective health products, responding to emerging legislation and public health threats, driving digital transformation and harnessing the potential of artificial intelligence in its business and regulatory processes. It also seeks to strengthen the HPRA's partnerships with national, EU and international regulatory bodies and networks.

Over the next four years, the strategy aims to guide the HPRA's work in protecting public and animal health while enabling responsible innovation and supporting Ireland's position as a leading life sciences location.

Read the HPRA Strategic Plan 2026-2029 here.

2. *Merck Serono v Controller of Intellectual Property* [2026] IEHC 617

The High Court has upheld the Controller of Intellectual Property's refusal to grant Merck Serono S.A. a supplementary protection certificate ("**SPC**") for Mavenclad, a medicinal product containing cladribine for the treatment of relapsing remitting multiple sclerosis. Cladribine had previously been authorised as the active ingredient in Litak, a treatment for hairy cell leukaemia.

The key issue was whether a new therapeutic use of an existing active ingredient could qualify for an SPC under Regulation (EC) No 469/2009. Applying the CJEU's decision in Case C-673/18 *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, O'Donnell J held that "product" for these purposes means the active ingredient itself, irrespective of its therapeutic application. As cladribine had already been the subject of an earlier marketing authorisation, Mavenclad's authorisation was not the first authorisation for the product as required by Article 3(d).

The Court accepted that Mavenclad represented significant research and a distinct therapeutic use but held that this could not overcome the Regulation's requirements. It also declined to refer the matter to the CJEU, finding the position established in *Santen* sufficiently clear. The appeal was therefore dismissed.

3. Advocate General's Opinion on pharmaceutical producer responsibility for wastewater treatment

On 3 September 2026, Advocate General Kokott delivered her Opinion in *Republic of Poland v European Parliament and Council of the European Union* (Case C-193/25), concerning the revised Urban Wastewater Treatment Directive and its extended producer responsibility scheme for pharmaceutical and cosmetics producers.

The revised Directive requires quaternary treatment to remove micropollutants from

wastewater in certain agglomerations and provides that producers of pharmaceuticals and cosmetics are to fund at least 80 per cent of the associated costs. Poland seeks annulment of the relevant provisions, arguing that the scheme breaches the polluter pays principle and equal treatment, imposes disproportionate costs and was adopted without an adequate evidential assessment or statement of reasons.

The Opinion examines whether the EU legislature properly assessed the contribution of pharmaceuticals and cosmetics to wastewater toxicity, justified excluding other sources of micropollutants and considered responsibility across the supply chain. It also addresses whether the financial burden is proportionate, with particular attention to generic medicines producers, the cost of quaternary treatment and the scope of available exemptions.

Advocate General Kokott proposed that the contested producer responsibility provisions be annulled, identifying serious concerns regarding their design and proportionality.

The Opinion is not binding on the Court of Justice, which will give the final judgment. The case is significant because the outcome may affect the timing, allocation and scale of future wastewater treatment liabilities under EU law. It also sits alongside a preliminary reference from the Irish High Court concerning the validity of the same arrangements.

Read the Advocate General's Opinion here.

4. Revised EU recruitment and informed consent template begins to apply

A revised EU template for documenting patient recruitment and informed consent procedures for clinical trials under Regulation (EU) No 536/2014 has been introduced. The template is intended to promote greater consistency in the documentation used across EU Member States, while accommodating applicable national language and other Member State specific requirements.

The revised template took effect on 1 September 2026. It does not apply retrospectively to trials already authorised or to Part II applications already under review.

The template forms part of the European Commission's EudraLex Volume 10 guidance for clinical trials and supports compliance with the Clinical Trials Regulation, including its requirements concerning recruitment and informed consent.

See the template here.

C. HEALTHCARE LITIGATION AND CLINICAL NEGLIGENCE

1. In the Matter of FB (A Minor) [2026] IEHC 341

In this case, the President of the High Court, Barniville P., exercised the Court's minor wardship jurisdiction to authorise urgent, lifesaving medical treatment for an eight month old child suffering from sickle cell disease and acute splenic sequestration.

The child's mother opposed a blood transfusion on religious grounds and wished alternative treatments to be explored. Having heard evidence from treating clinicians, the Court accepted that the child faced a very serious risk of death or catastrophic organ damage without immediate transfusion and that there was no viable alternative treatment available.

Applying the principles set out by the Supreme Court in *In the Matter of JJ* [2022] 3 IR 1, the Court held that it was necessary for

the State to supply the place of the parents under Article 42A of the Constitution in order to protect the child's safety, welfare and life.

2. *Chief Inspector of Social Services v Raidió Teilifís Éireann* [2026] IEHC 445

The High Court granted a Norwich Pharmacal order requiring RTÉ to provide HIQA's Chief Inspector of Social Services with the complete unedited footage recorded during the making of the documentary RTÉ Investigates: Inside Ireland's Nursing Homes.

The footage, which was obtained through undercover researchers working in two nursing homes, was sought to assist the Chief Inspector in determining whether further regulatory action, enforcement measures or referrals were required following concerns regarding resident care and welfare.

Although Norwich Pharmacal relief is traditionally used to obtain information necessary to identify or pursue wrongdoers through legal proceedings, Egan J. held that the jurisdiction could extend to circumstances where disclosure was necessary to enable a statutory regulator to discharge functions directed towards the protection of vulnerable persons.

The Court concluded that a strong case of regulatory wrongdoing had been established, that the footage was necessary to inform potential enforcement action, and that disclosure was proportionate having regard to the significant public interest in the effective regulation of nursing homes and the protection of residents.

3. *Medical Council v Lagun* [2026] IEHC 624

In this case, the High Court confirmed the Medical Council's decision to attach conditions to the registration of a doctor who had retired from the Irish Defence Forces, following a finding of poor professional performance arising from a consultation with a Defence Forces colleague.

The complainant had attended the doctor to discuss an incorrect cancer diagnosis previously entered on her medical records. Despite that entry having been corrected, the doctor told her that there was a 90% chance that she would have cancer and that she was sitting on a "health bomb".

The Fitness to Practise Committee found beyond reasonable doubt that the comments were inaccurate, unsupported by the complainant's medical records and communicated inappropriately. It found that the doctor should have familiarised himself with the complainant's up to date records and that his conduct represented a serious failure to communicate accurately and appropriately with a patient.

The Medical Council imposed a censure and conditions, including requirements to notify the Council if he returned to Ireland to practise, complete an approved advanced communication skills course and provide evidence of successful completion.

On the Council's application under section 76 of the Medical Practitioners Act 2007, Barniville P. noted that the Court was required to confirm the decision unless there was "*good reason*" not to do so.

Finding no procedural irregularity, failure of natural or constitutional justice or material error, and describing the approach of the Committee and Council as "unimpeachable", the Court held that the sanction was appropriate, proper and proportionate and confirmed the conditions.

4. *Meyler v Blimka* trading as Bungee Fit and another [2026] IEHC 482

The High Court confirmed that, in a personal injuries action, a plaintiff must serve the affidavit verifying the personal injuries summons and file an affidavit proving that service in the Central Office before issuing a motion for judgment in default of appearance.

The plaintiff alleged that she suffered a complete rupture of her Achilles tendon and a soft tissue injury to her ankle during a bungee fitness class. Although the personal

injuries summons had been served and the affidavit of verification filed in the Central Office, the verifying affidavit was not served on the second defendant until well after the motion for judgment in default of appearance had issued.

Egan J. considered section 14 of the Civil Liability and Courts Act 2004 and Orders 1A and 13 of the Rules of the Superior Courts. While section 14 does not itself require service of the verifying affidavit, Order 1A, rule 11 requires a copy to be delivered to the opposing party.

Reading the Rules as a whole, the Court held that service of the verifying affidavit, together with an affidavit proving that service, is an essential proof for judgment in default of appearance and must be completed before the motion is issued. As that had not occurred, the Court refused the application.

5. *Alajbeg v Neto & Pro-Riso Dental Clinic Limited* [2026] IEHC 461

The High Court awarded €55,300 to a woman who suffered irreversible damage to six lower front teeth as a result of negligent orthodontic treatment and departed upward from the applicable bracket in the Personal Injuries Guidelines.

The plaintiff received braces between November 2018 and August 2020 to align her teeth and correct an overbite. During treatment, six lower front teeth were pushed outside the jawbone, causing irreversible bone damage and loss of support. She experienced continuing pain, recurring infections, disturbed sleep and repeated dental procedures, with an expert predicting that the teeth were likely to be lost over the following five to ten years. The trial proceeded as an assessment of damages only, and neither defendant appeared.

Coffey J. accepted that the injury fell within paragraph 9(F)(i) of the Personal Injuries Guidelines, which provided a range of €12,500 to €30,500. However, the Court held that the bracket did not adequately capture the prolonged pain, instability, recurring infection, invasive treatment and eventual loss of six teeth. A maximum Guidelines award would therefore have been unjust and disproportionate to the aggravating features of the case.

The Court awarded €45,000 in general damages and €10,300 in special damages for anticipated dental treatment, producing a total award of €55,300. The decision demonstrates that a departure from the Guidelines may be justified where the prescribed bracket does not fairly reflect the nature, duration and cumulative impact of an injury.

If you would like to receive a copy of any of the judgments discussed in this update, please contact us.

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.

ABOUT

Philip Lee LLP 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.

KEY CONTACTS

Anne Bateman
Partner
Litigation and Regulatory
+353 86 890 7103
abateman@philiplee.ie





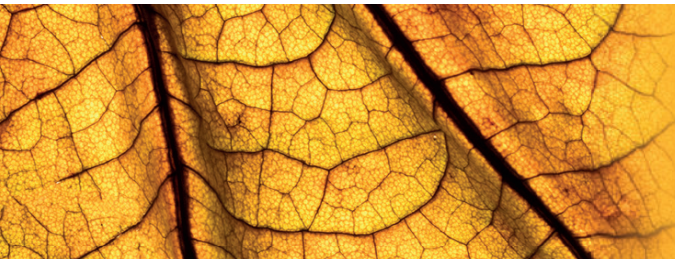
Ronan Dunne
Partner
Corporate
+353 83 038 8679
rdunne@philiplee.ie

Daniel Hanrahan
Senior Associate
Corporate
+353 1 237 3791
dhanrahan@philiplee.ie





Marie Kinsella
Partner
Litigation and Regulatory
+353 83 427 6344
mkinsella@philiplee.ie



The focus of the team in understanding our needs was unparalleled. Comprehensive, committed to understanding, personable and thoughtful. This amounted to the establishment of an early and a trusting relationship.

LEGAL 500 2026



PHILIPLEE