Healthcare, Pharmaceuticals and Life Sciences Update

February 2025

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical, and Life Science group in respect of the fourth and final quarter of 2024.

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 and final quarter of 2024. Please get in touch if you would like to know more about what we have covered.

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

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

1. GENERAL REGULATORY – EU

1. European Medicines Agency re-confirms that it will not be renewing its conditional authorisation of Translarna (here)

Having reviewed the available data, the European Medicines Agency (**"EMA"**) human medicines committee (**"CHMP"**) has recommended that the conditional marketing authorisation it previously issued for Translarna (ataluren) (a treatment that is used to treat patients that have Duchenne muscular dystrophy) not be renewed.

Since the EMA issued its marketing authorisation for Translarna, there has been uncertainty surrounding its effectiveness. The main reason that the EMA granted the authorisation originally was due to the lack of available treatments for those suffering with Duchenne muscular dystrophy.

If the European Commission confirms the EMA's recommendation, Translarna will no longer be authorised in the EU.

2. The Windsor Framework for medicines is now in force (here and here)

The Windsor Framework (the **"Framework"**) for medicines came into force on 1 January 2025 and was implemented by Regulation (EU) 2023/1182. The main import of the Framework is that full responsibility for the regulation of medicines has returned to the UK authorities.

In October 2024, the Health Products Regulatory Authority (**"HPRA"**) published updated questions and answers which clarify the Framework and explain its effects.

The Framework requires UK medicines to contain the label "*UK only*" on its outer packaging and removes the use of the NI/GB/UK label. It will further be prohibited for medicines on the Northern Ireland and Great Britian market that are labelled as "*UK only*" to carry the 2-D matrix serialisation safety feature required by the Falsified Medicines Directive. Marketing Authorisation Holders also must update their labelling to remove all NI/UK administrative details by 31 December 2027.

Joint outer labels between Ireland and the UK have been removed by the Framework and inner packaging between Ireland and the UK will differ to account for the separate administrative processes in both jurisdictions. However, the package leaflet and immediate packaging are entitled to remain the same.

The '*UK only*' label may be covered by a label on non-prescription medicines with the caveat that the new label is permanently attached to the outer packaging. Over-labelling is only permissible where it is carried out on a site which holds valid manufacturer's authorisation.

Batches of jointly labelled IE/UK medicines for the British and Irish markets that were produced before 31 December 2024 may remain on the

market until the expiry date of those medicines.

3. **European Medicines Agency publishes Reflection Paper on the use of AI in the medicinal product lifecycle** (here)

   On 9 September 2024, the EMA published a reflection paper (the **"Paper"**) in respect of the use of AI in the medicinal product lifecycle. The Paper is in response to the increased use of AI in drug discovery, non-clinical development, clinical trials, manufacturing and post-authorisation.

   The Paper encourages a risk-based approach for the development, deployment, and performance monitoring of artificial intelligence/machine learning (**"AI/ML"**) tools that enable developers to find risks. The degree of risk varies in accordance with the AI technology and data quality.

   The Paper references each step involved in the lifecycle of a medicine's lifecycle and identifies the areas that fall within the scope of the EMA or national authority. The stages of a medicines lifecycle that are covered by the Paper include: drug discovery, non-clinical development, clinical trials precision medicine, product information, manufacturing and post-authorisation phase.

   The paper emphasises that where an AI/ML system is planned for use in the context of medicinal product development, evaluation, or monitoring, and is expected to impact, even potentially, on the benefit-risk balance of a medicinal product, early regulatory interaction is advised. The level of scrutiny depends on the level of risk and regulatory impact posed by the system.

   A key principle is that it is the responsibility of the clinical trial sponsor, marketing authorisation applicant/holder or manufacturer to ensure that all algorithms, models, datasets, and data processing pipelines used are fit for purpose and are in line with legal, ethical, technical, scientific, and regulatory standards as described in EU legislation, GxP standards and current EMA guidelines.

   The reflection paper further highlights that a human-centric approach should guide all development and deployment of AI and ML.

4. **European Medicines Agency launch European Shortages Monitoring Platform** (here)

   The EMA announced on 28 November 2024 that the European Shortages Monitoring Platform (**"ESMP"**) had gone live with a core set of functionalities. The ESMP enables Marketing Authorisation Holders (**"MAHs"**) to submit data with a view of reporting shortages of centrally authorised medicines. There is a transition period ending 2 February 2025 and afterwards, use of the ESMP will then be mandatory.

   The ESMP illustrates the EU's efforts to prevent and monitor medicine shortages and improve the accessibility of medicines to patients across the European Economic Area. The ESMP offers centralised and automatised data collection and real-time, comprehensive information to regulatory authorities in respect of medicine shortages.

   The second version of the ESMP will launch in February 2025 and is intended to provide a full scope of functionalities for MAHs and national competent authorities (**"NCAs"**). From there on, MAHs and NCAs will be enabled to submit data regarding supply, demand and availability of centrally authorised medicines during crises and preparedness actions led by EMA's Executive Steering Group on Shortages and Safety of Medicinal Products.

5. **European Parliament adopts resolution on need to revise the Medical Devices Regulation** (here)

On 23 October 2024, the European Parliament (the **"Parliament"**) adopted a resolution on the need to revise the Medical Devices Regulation (**"MDR"**) and the In Vitro Diagnostics Regulation (**"IVDR"**).

The resolution acknowledges that the MDR and IVDR were adopted to strengthen regulation on medical devices and in vitro medical devices in the EU. However, the resolution cites the challenges in implementing the MDR and IVDR which consists of delays, shortages and difficulties in navigating regulatory procedures.

The Parliament have proposed changes to the European Commission regarding the MDR and IVDR, some of which include:

- The creation of transparent and binding timelines for procedural steps in conformity assessment by notified bodies,
- the elimination of unnecessary re-certification of products and the harmonisation of such provisions across the EU, and
- the need for fast-track and prioritisation pathways for the approval of innovative technologies in areas of unmet medical needs.

2. GENERAL REGULATORY - IRELAND

6. Irish Medical Council launches "CAREhub" (here)

On 5 November 2024, the Irish Medical Council launched CAREhub, a service which provides confidential wellbeing support to medical students, doctors and the public. This service is operated by Lyra Health International.

CAREhub offers its users independent, impartial and empathetic guidance within the Medical Council's regulatory processes, including: education, training, complaints, investigations, and fitness to practise procedures.

The service also grants its users access to trained counsellors in order to fulfil its role of providing mental wellbeing advice to individuals. Dr Suzanne Crowe, President of the Medical Council, made the following comment in relation to the service:

> *"CAREhub is a new initiative designed to enhance wellbeing of doctors and members of the public who are engaging with a regulatory process. The Medical Council's regulatory role spans the entire lifecycle of a doctor's career, ensuring the highest standards of care from education through to retirement."*

3. GLOBAL INSIGHTS

7. Medical implant maker Exactech files for bankruptcy following recall litigation (here)

At the end of October, Exactech, a medical implant manufacturer, filed for bankruptcy. The company sought to sell its assets in order to resolve approximately 2,600 different proceedings in respect of recalled knee, hip and shoulder implants.

Exactech entered bankruptcy with a debt of $352 million and a sale agreement to turn over the company's assets to its lenders. The sale agreement is subject to higher offers, with the support of 95% of the company's lenders.

8. Moscow-based criminal organisation member pleads guilty in international telemedicine scheme worth over $1.7 billion (here)

The seventh defendant of a Moscow-based criminal organisation has recently pleaded guilty for their involvement in an international healthcare fraud and money laundering scheme.

The scheme involved the acquisition of pharmacies within the US who had pre-existing relationships with private health insurance companies. The

pharmacies were used in conjunction with call centres to induce individuals into accepting unnecessary medications. From this, over $1.7 billion was generated in fraudulent prescriptions. US Attorney for the Eastern District of New York, Breon Peace commented that:

> *"Health care fraud victimizes American businesses and drives up the cost of care for all. Let these convictions serve as a message: we will work tirelessly to investigate and prosecute those who exploit American health care plans no matter where in the world they operate."*

The call centres were based in Utah but later operated from Russia and other countries. Beneficiaries of private health insurers were offered medications at a low cost without a medical exam to determine the necessity of such medication. In addition, doctors were recruited to review prescriptions by nurse practitioners and physician's assistants after telemedicine visits.

Contrary to what the recruited doctors were told, in many cases there were no telemedicine visits between the beneficiaries and any medical professionals. The co-conspirators also generated fraudulent prescriptions under the physicians' names and National Provider Identifier numbers. Despite the prescriptions, many beneficiaries never received the medications.

9. **Biden-Harris Administration expands access to life-saving organs for people with HIV** (here)

On 27 November 2024, the US Department of Health and Human Services (**"HHS"**) announced a final rule which expands access to kidney and liver transplants to HIV positive individuals.

The final rule further implements the HIV Organ Policy Equity (HOPE) Act, which removes clinical research and institutional review board requirements for kidney and liver transplants between donors with HIV and recipients with HIV. HHS Secretary Xavier Becerra commented the following:

> *"This rule removes unnecessary barriers to kidney and liver transplants, expanding the organ donor pool and improving outcomes for transplant recipients with HIV. This evidence-based policy update demonstrates our commitment to ensuring all Americans have access to the care they need."*

It is intended that this will increase the availability of organs to HIV positive individuals and streamline the transplantation process, reduce the stigma surrounding HIV and save lives. The final rule is only applicable to kidney and liver transplants where evidence for the necessity of the transplant is robust.

10. **Telehealth company Cerebral to pay $3.6 million for unauthorised distribution of Adderall** (here)

The US Department of Justice (the **"DOJ"**) has recently launched an enforcement action against the telehealth company, Cerebral, in respect of medications which treat attention deficit hyperactivity disorder (**"ADHD"**).

Cerebral entered into a non-prosecution agreement (**"NPA"**) with the US Attorney's Office for the Eastern District of New York whereby it agreed to pay over $3.6 million to the United States for engaging in practices that encouraged increased prescriptions of Adderall and other controlled substances through telemedicine.

From October 2020 to October 2022, Cerebral admitted that in attempting to grow its revenue, it developed internal plans to firstly, increase the rate at which new patients sign up for medication management to 95% and

secondly, to increase the rate of stimulant medications for individuals with ADHD up to 100%. In reaching such targets, Cerebral engaged in practices which included flags and strikes towards providers who under-prescribed ADHD medications as well as the provision of financial incentives for providers who conducted pre-prescription checks of prescription monitoring databases for ADHD patients.

The sum of over $3.6 million which the DOJ has ordered Cerebral to pay represents the increase in profits that the company received resulting from the overprescription of ADHD medicine. It also accounts for Cerebral's voluntary remedial measures to mitigate and correct its conduct. This included its voluntary decision in October 2022 to stop prescribing controlled substances and to refrain from the same in the future. Additionally, Cerebral agreed to pay a fine of $2,922,000, but this was subsequently deferred upon it being determined that Cerebral currently does not have the ability to pay.

11. **Association of British Pharmaceutical Industry releases updated Code of Practice** (here)

The latest update to the Code of Practice (the **"Code"**) for the Association of British Pharmaceutical Industry (**"ABPI"**) is effective as and from 1 October 2024. It pledges to increase the standards expected of pharmaceutical companies while providing more efficient and timely resolutions to companies.

The Code contains rules and procedures which determine the regulation of the UK pharmaceutical industry and is delivered by the Prescription Medicines Code of Practice Authority (**"PMCPA"**). Both aim to ensure responsible practice, high ethical standards and professional standards. The Code retains many of the elements contained with its predecessor. However, it introduces a set of new requirements.

Of significance in the new Code is clause 12 which provides a shift towards modernising the approach taken to prescribing information, as it now allows healthcare professionals to furnish prescribing information through a QR code. This enables individuals to gain immediate access to prescribing information for a medicine on promotional material. The QR code is only entitled to be used in certain circumstances and is not permitted where the use of multiple devices is required for access.

Another significant feature is the introduction of a new PMCPA Constitution and Procedure. This sets out the PMCPA's powers and responsibilities and defines its role in the self-regulating system. In addition, it provides information on the complaint's procedure for which there now exists two routes: the standard complaints procedure, and the new abridged complaints procedure which, precisely, aids the PMCPA in handling complaints in a proportionate and expeditious manner. The nature of the complaint's procedure will remain adversarial rather than investigatory.

The Code stipulates that certain provisions that were previously best practice or optional under the previous code, are now compulsory. The new compulsory stipulations include the disclosure of information regarding patient organisations or members of the public and the requirement for a written agreement between companies and healthcare professionals who have received support to attend events.

12. **China issues new Draft Administrative Measures for Management of Medical Representatives** (here)

The Chinese National Medical Products Administration (**"NMPA"**) issued the Draft Administrative Measures for Management of Medical Representatives (the **"Draft Management Measures"**). The deadline for comment on the Draft Administrative Measures has now closed. The Draft Management

Measures intend to replace the previous Administrative Measures for Management of Record-Filing for Medical Representatives (Trial Version).

The Draft Management Measures are directed towards medical representatives and provide broad requirements and restrictions in respect of the conduct of Marketing Authorisation Holders (**"MAHs"**), healthcare institutions and healthcare providers.

This development illustrates China's increased focus on anti-corruption and efficient enforcement. The Draft Management Measures introduce requirements such as having MAHs require medical representatives to sign compliance commitment letters, and requirements in respect of medical representatives' academic qualifications, professional experience and professional knowledge. It is prohibited to hire unqualified medical representatives or those have a record of commercial bribery.

The Draft Management Measures establish a formal mechanism for joint enforcement by the NMPA, the Ministry of Public Security, the State Administration of Market Regulation and other government agencies. It will be required that government agencies formally share information regarding misconduct.

13. **US Food and Drug Administration Releases New Draft Guidance for Expedited Program for Serious Conditions** (here)

On 6 December 2024, the US Food and Drug Administration (the **"FDA"**) published Draft Guidance entitled, "*Expedited Program for Serious Conditions — Accelerated Approval of Drugs and Biologics*" (the **"Draft Guidance"**). The Draft Guidance expands the FDA's present expediated programs.

The Draft Guidance provides an overview of the accelerated approval pathway, which was initially created by the FDA in 1992.

The accelerated approval pathway facilitates the quick development of drugs which treat serious and life-threatening conditions. Within the Draft Guidance, the FDA acknowledges the benefits created by accelerated approval but notes that the risks attached to it must be considered. Issues include safety risks towards patients where the drug ultimately lacks clinical benefit, and secondly, smaller and shorter clinical trials may result in a decrease in the creation of new information regarding rare or delayed adverse events.

The FDA, in its Draft Guidelines, states the conditions and requirements for accelerated approval, they include the following:

- A requirement that sponsors conduct post-approval studies to verify and describe anticipated clinical benefits of the drug,
- Prior to or when approved, the FDA will specify the conditions for post-approval studies,
- Sponsors must submit reports on the progress of required post approval studies approximately every 180 days which will be published by the FDA by requirement,
- Drug labelling must include a brief description of the limitations and uncertainties regarding the clinical benefits of the drug, and
- Sponsors are required to submit all copies of promotional materials to FDA.

The FDA states in its Draft Guidelines that the accelerated approval pathway should not be considered where it is not feasible to complete an adequate and controlled confirmatory study. Particularly, the FDA states that accelerated approval will not be available where "*the evidence is insufficient to support use of a surrogate endpoint or intermediate clinical endpoint, or when an*

adequate and well-controlled confirmatory trial would be infeasible."

4. COMPETITION LAW

14. Teva fined €462.6 million by EU Commission over misuse of patent system and abuse of dominance (here)

The European Commission (the **"Commission"**) has found that Teva abused its dominant position under Article 102 of the Treaty on the Functioning of the European Union (**"TFEU"**) in order to delay competition in the market for Copaxone, a medicine which treats multiple sclerosis. Teva has held a patent for the active ingredient in Copaxone, glatiramer acetate, since 2015.

The Commission found that Teva had abused its dominant position in markets for glatiramer acetate in seven Member States. Depending on the Member State, the conduct lasted between four and nine years.

The first instance of the abusive conduct was the artificial extension of patent protection for Copaxone. The patent for glatiramer acetate was due to expire and in response, Teva artificially extended its patent for Copaxone by misusing the European Patent Office's (**"EPO"**) rules and procedures on divisional patents.

This enabled Teva to file multiple separate patents which were spread out, creating a wall of secondary patents around Copaxone. The patents were challenged by rivals seeking market entry however in response, Teva sought interim injunctions and then strategically revoked the patents in a manner which afforded it protection. This allowed the artificially prolonging of the patents and impeded rival glatiramer acetate treatments from entering the market.

The second form of abusive conduct by Teva was the implementation of a systematic disparagement campaign. This involved the spread of misinformation against competing and cheaper glatiramer acetate medicines, all of which were approved by relevant health authorities. The disinformation was in respect of its safety, efficacy and therapeutic equivalence with Copaxone. The disinformation targeted doctors and national decision-makers. Teva's objective was to block the entry of competing glatiramer acetate treatments in Member States.

The €462.6 million fine accounts for the duration and seriousness of the competition infringements and the sales achieved by Teva by reason of their conduct. The Commission deemed the fine as proportionate and as having deterrent effect.

15. European Commission approves Novo Holdings' acquisition of Catalent (here)

On 6 December 2024, the European Commission (the **"Commission"**) gave the proposed acquisition of Catalent by Novo Holdings clearance on the basis that the transaction did not raise any competition concerns within the respective markets concerned in the European Economic Area (**"EEA"**). The transaction was notified to the Commission on 31 October 2024.

Novo Holdings is a pharmaceutical company which specialises in the treatment of chronic diseases such as obesity and diabetes, it supplies weight loss drugs such as Ozempic and WeGovy. Catalent is a contract developer and manufacturer organisation for medicines on behalf of other pharmaceutical companies and supplies Zubsolv, a treatment for opioid dependence.

The Commission investigated the transactions impact on the supply of (i) pre-filled syringes, and (ii) orally disintegrating tablets. The Commission concluded the following in their investigation:

- Customers of pre-filled syringes will continue to have access and will

have continued choice within the market. Therefore, the transaction will not result in the lack of supply in alternatives to Catalent, and
- Customers of orally disintegrating tablets will continue to have access to sufficient alternatives.

It was further found by the Commission that alternative drug formats exert competitive pressure on orally disintegrating tablets because customers have the ability to switch between various formats.

In granting unconditional clearance to the merger, the Commission found that the transaction would not raise any significant competition concerns on any of the markets examined in the EEA or any substantial part of it.

16. **European Commission approves €52 million in Slovenian State aid for Lek Pharmaceuticals** (here)

On 13 December 2024, the European Commission (the **"Commission"**) announced its approval of €52 million in Slovenian State aid towards Lek Pharmaceuticals (**"Lek"**) construction of a plant in Lendava to produce biological drug substances. The State aid will be received through a direct grant and is expected to create 330 jobs.

The Sandoz group, the parent company of Lek, will utilise the biological drug substances to produce biosimilar medicines that are clinically equivalent to biologics. Biosimilars are produced when patent protection for a biologics expires and these offer a cheaper alternative to biologics.

In the Commission's assessment of the State aid under Article 107 TFEU, it was found that:

- The State aid will allow a disadvantaged area to benefit from heightened employment, economic development and increased competitiveness,
- The State aid has incentive effect because in the absence of financial support, the beneficiary would not have carried out the project,
- The measure has a minimal impact on competition and trade within the EU and was necessary and appropriate in order to diversify Lek's output and contribute to regional development, and
- The State aid was proportionate because it is limited to the minimum amount necessary to enable the investment and does not exceed the maximum aid allowed.

5. DATA PROTECTION

17. **European Medicines Agency opens public consultation on Data Quality Framework for EU medicines regulation** (here)

The EMA has opened a public consultation that will run for the duration of January and February 2025 in relation to the application of the Data Quality Framework for EU medicines regulation (the **"Draft Framework"**).

This comes in conjunction with the EMA's release of guidelines in relation to the Draft Framework. The EMA intends to continue its efforts in working with stakeholders to utilise the Draft Framework concepts to develop practical recommendations for assessing the data's quality. Initially, this will focus on real-world data and adverse drug reactions.

The Draft Framework's chapter on real-world data is the subject of the public consultation. The HMA-EMA Steering Committee invites comments from regulators, pharmaceutical companies and academia representatives who use real-world data in their work.

18. **COCIR and MedTech Europe publish recommendations for strengthening cybersecurity in Europe's future healthcare systems** (here)

In 2024, European Commission President Ursala von der Leyen announced an action plan in regard to

the cybersecurity of hospitals and healthcare providers that will be published within the first 100 days of the mandate. In response, MedTech Europe and COCIR released recommendations for "Strengthening Cybersecurity in Europe's Future Healthcare Systems" (the **"Recommendations"**).

The Recommendations acknowledge that the NIS2 Directive, the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation are positive steps, however, regulation is not sufficient to address growing cybersecurity threats. Notably, effective implementation of this legislation requires investment in infrastructure, software and human resources.

The Recommendations stated by COCIR and MedTech Europe to implement the European action plan for cybersecurity in hospitals and healthcare providers include the following:

- *Increase capacity and expertise in healthcare*: develop and implement skills development in cybersecurity for healthcare providers, hospitals and health authorities. The upskilling programme should focus on enhancing expertise and building capacity within the healthcare sector to respond and mitigate cyber threats,
- *Address the risk of obsolete medical technologies and software*: create funding programmes which upgrade and replace outdated technologies and software within healthcare,
- *Awareness raising and stakeholder engagement*: launch a campaign to raise awareness in respect of the NIS2 Directive within healthcare by way of webinars to encourage collaboration and the exchange of best practice between those working within healthcare,
- *Guidelines for implementation of the NIS2 Directive in healthcare*: develop guidelines for the NIS2 Directive which clarify the requirements between different applicable regulations. There should be emphasis on the significance of shared responsibility and communication between healthcare delivery organisations and health technology providers,
- *Embedding cybersecurity in healthcare procurement*: update guidelines relating to cybersecurity considerations in healthcare procurement which reflect new developments in technology and legislation. The guidelines should ensure that cybersecurity is a fundamental criterion in selecting medical technologies and software.

19. US Food and Drug Administration releases final guidance on predetermined change control plans for AI-enabled device software functions (here)

On 4 December 2024, the US FDA published its final guidance on the "*Marketing Submission Recommendations for a Predetermined Change Control Plan [**"PCCP"**] for Artificial Intelligence-Enabled Device Software Functions*" (the **"Guidance"**). The FDA previously released draft guidance in respect of same in April 2023.

The Guidance contains recommendations on information to include in a PCCP for devices which include one or more AI-enabled device software functions. In addition, the FDA recommends how a PCCP may describe the AI-enabled device software functions, implement modifications and assess the impact of such modifications.

The Guidance is generally applicable to all AI-enabled devices, however, the FDA has stated that the majority of marketing submissions that contain PCCPs which have been reviewed by the FDA are submissions for devices that incorporate machine learning, a subset of AI. Therefore, much of the Guidance has been tailored to devices which utilise machine learning.

20. European Commission launches new platform for cross-border medical discussions on rare diseases (here)

The Commission has launched a new IT platform to facilitate cross-border medical discussions on rare diseases, namely, the Clinical Patient Management System 2.0 (**"CPMS 2.0"**) which supports the European Reference Networks (**"ERNs"**). The platform is intended to improve the diagnosis and treatment of rare diseases in Member States.

CPMS 2.0 replaces CPMS and is funded by the EU4Health programme. It will enable remote multidisciplinary discussions which will allow for collaboration between different clinicians across the EU in a patient orientated manner.

The platform code will be released as an open source and will be fully GDPR compliant. The platform code will also provide a basis to develop similar IT systems at national level free of charge.

6. HEALTHCARE

21. China launches whistleblower program for healthcare Sector (here)

The National Medical Products Administration (**"NMPA"**), the Chinese national bureau for drug supervision, has closed public comments in respect of the Draft Rule on Rewarding Internal Whistleblowers for reporting on the quality and safety issues of drugs and medical devices (the **"Draft Rule"**).

The new Draft Rule is a novel regulatory system designed for the purpose of increasing reporting on medical product safety in China. This will result in stricter supervision and more frequent enforcement actions by Chinese authorities.

The Draft Rule will be applicable to internal whistleblowers from pharmaceutical and medical device-related enterprises who report major breaches of drug and medical device safety concerns. In addition, there will be provision for related informants such as journalists and other individuals with knowledge of safety and quality issues to obtain rewards.

The Draft Rule applies to reports relating to the quality and safety of drugs and medical devices and, does not define what is meant by quality and safety. Where potential safety hazards are identified in relation to drugs or medical devices, it is required that authorities respond promptly, take immediate measures to address the issues or prevent hazards from spreading, and inform relevant entities.

A whistleblower will be eligible for an award if the following conditions have been met:

i) They have provided clear information about the entity, the specific illegal act or leads, and critical evidence has been provided,
ii) The reported matter is not known to the investigators, and
iii) Upon notifying, the reported matter has been investigated and resolved by regulators and has resulted in administrative or criminal penalties.

Regulators should inform the whistleblower within 15 working days after the case has been closed. An award for each case may be up to one million RMB (approximately €152,000). Commendations or other kinds of public recognition may be provided by the authorities without the whistleblower's consent.

Further, there is a prohibition on enterprises to retaliate against whistleblowers. Where enterprises refuse to cooperate with regulatory inspections, or falsify, destroy or conceal evidence, such conduct will be viewed by the authorities as an aggravating factor for any penalty imposed.

22. Amendments announced for the 2013 Care and Welfare Regulations (here)

On the 4 November 2024, Minster for Health Stephen Donnelly and Minister of State for Mental Health and Older People, Mary Butler, announced that regulations will be updated in order to strengthen the regulatory framework for nursing homes.

The regulations which amend the Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013 will come into effect on 31 March 2025. The amendments have been made in response to recommendations from the COVID-19 Nursing Homes Expert Panel Report and several reports from the Health Information and Quality Authority (**"HIQA"**).

The amendments introduce the following requirements:

- Protection of resident's visiting rights, even during outbreaks and the facilitation of communication between family members,
- Strengthen the qualification criteria for persons-in-charge to include a Level 8 management certificate,
- Enhancement of governance, quality improvement and risk processes,
- Implementation of infection prevention and control guidance, and
- Reduction of the notification period of a range of incidents to HIQA from 3 working days to 2 days.

Minister Stephen Donnelly commented:

> *"I am pleased to bring forward these amendments which will enhance and strengthen regulations in nursing homes. These welcome developments will place a greater focus on quality improvement, governance and residents' rights."*

23. Budget 2025 allocates €25.75 billion to Irish healthcare sector (here)

In the Irish budget for 2025, it was announced that the Department of Health has been allocated €25.76 billion.

The budget has made additional investments in the healthcare workforce with such funding enabling the recruitment of a net additional 3,346 whole time equivalent staff. Furthermore, nursing and medical education will be allocated more spaces.

The acute hospital sector will receive 39% of the healthcare budget 2025 in response to an increase in patient demand. Funding has also been allocated to primary, social inclusion and community services in the form of non-hospital services such as injury units, wound care clinics and extended GP hours.

Services for older persons will receive an additional 600,000 support hours, bringing the total delivered to 24 million. Furthermore, the creation of new nursing home spaces will be facilitated and continued funding will be provided for traditional care beds.

Budget 2025 allows for the ongoing implementation of the Women's Health Action Plan as well as funding being provided for improvements in maternity services, additional breastfeeding supports and post-mastectomy products. The provision of Hormone Replacement Therapy will also be free at the point of dispensing.

Funding will continue to be allocated to innovation with health services and the further development of healthcare infrastructure and major projects.

24. Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 now in force (here)

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 (the **"Act"**) came into effect on 26 September 2024. The Act intends to increase openness and transparency within the healthcare

system and is applicable to both public and private health services.

The cornerstone of the Act is based on healthcare providers engaging in open disclosure, which refers to the open, honest, compassionate and timely communication with patients and their relevant person in respect of patient safety incidents. This imposes the legal requirement to disclose specific incidents, namely "notifiable incidents" which are listed in Schedule 1 of the Act.

The Act allows for the designation of a patient's support person, who is an employee of the health service provider. The Minister of Health may add to the list of what constitutes a notifiable incident under the Act.

Where a notifiable incident has occurred, a health services provider must inform the relevant regulator (Mental Health Commission, Chief Inspector of Social Services, and the Health Information and Quality Authority) of the incident within 7 calendar days using the National Incident Management System ("NIMS"). Incidents may also be reported through other reporting channels where the circumstances require. Where information is shared, and an apology is made, it cannot be used for certain legal or regulatory purposes.

There is also a framework provided for clinical audits and protections for data gathered. The Chief Inspector of Social Services' discretionary power to carry out a review of specified incidents did not commence on 26 September 2024 but will commence once an essential technical update has been made to the Act.

Open disclosure will not occur where:

i) The patient or relevant person has declined open disclosure. Where this occurs, it is required that they are provided with information on how to contact the healthcare services at any time within the next 5 years to request open disclosure, or
ii) The patient or relevant person cannot be contacted despite reasonable attempts to do so.

A healthcare provider may potentially be fined up to €5,000 where it fails to conform with open disclosure or hold a review of cancer screening meeting or it fails to report a notifiable incident to the relevant authority without valid reason.

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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