PHILIPLEE

Healthcare, Pharmaceuticals and Life Sciences Update

July 2023

WELCOME

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical and Life Science group in respect of the second quarter of 2023. 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

GENERAL REGULATORY - EU

1. European Parliament's COVI committee issues recommendations on preparing for future health emergencies (here)

On 13 of June 2023, The European Parliament's Special Committee on the COVID-19 pandemic (COVI), endorsed recommendations to improve the EU crisis management for future pandemics.

COVI has recommended that the European Commission, or the World Health Organization (WHO) should take action under the following four 'pillars':

- Health;
- Democracy and fundamental rights;
- Social and economic impacts; and
- EU in the world.

Consideration was also given to the broader socio-economic impact of Covid-19, the implications for the rule of law and the international response to the challenges raised by the pandemic.

2. Mental health: European Commission proposes new approach to mental health (here)

On 7 June 2023, the European Commission adopted a new strategic approach to mental health. The Commission has endorsed three principles that should apply to every EU citizen:

- Access to adequate and effective prevention;
- Access to high quality and affordable mental healthcare and treatment; and
- Ability to reintegrate into society after recovery.

€1.23 billion in EU funding from different financial instruments has also been invested to overcome the barriers to efficient mental health provision.

3. EU General product Safety Regulation comes into force (here)

On 12 June 2023, The General Product Safety Regulation (EU) 2023/988) (the "**GPSR**") entered into force. It will apply as and from 13 December 2024.

The GPSR reinforces the safety rules for products sold both offline and online and will apply to economic operators involved in placing products on the EU market, even if they are not themselves established in the EU. The GPSR aims to address new challenges posed by the growth of online sales and, in particular, via online marketplaces, ensure a better enforcement of the rules, more efficient market surveillance and improved recalls of dangerous products.

Products which were placed on the market before 13 December 2024 will not need to comply with the new GPSR.

4. EU pharmaceutical reform: Council of the EU adopts Recommendation tackling antimicrobial resistance (here)

On 13 June 2023, the Council of the EU formally adopted a Council Recommendation on stepping up EU actions to combat antimicrobial resistance (AMR) in the fields of human health, animal health and the environment in a One Health approach.

AMR relates to the ability of micro-organisms to survive or grow despite the presence of an antimicrobial agent that normally inhibits or kills that micro-organism. AMR results from over or misuse of antimicrobials, in both the healthcare and food production systems, and is the cause of more than 35,000 deaths every year in the EU/EEA.

5. European Ombudsman opens case on EMA's proactive transparency policy for clinical trial data (here)

On 26 June 2023, the European Ombudsman announced that they had opened a case regarding the EMA's policy for proactively publishing clinical trial data for medical products for human use (Policy 0070).

Policy 0070 was launched in 2016 but has been suspended since 2018 due to changing staff priorities necessitated by the EMA's relocation to Amsterdam and the COVID-19 pandemic.

The Ombudsman has asked the EMA various questions concerning Policy 0070 including in respect of the plan and timeline regarding the publication by the EMA of clinical trial data.

6. EU pharmaceutical reform: European Commission adopts legislative package (here)

On 26 April 2023, the European Commission adopted a proposal for a legislative package to reform the EU's pharmaceutical legislation. The key measures being proposed include:

- The introduction of a simplified regulatory framework to enable faster authorisation of new medicines; the European Medicine Agency (EMA) will now have 180 days (reduced from the previous deadline of 210 days) to assess the medicines and the Commission 46 days (reduced from the previous deadline of 67 days) to authorise the medicines.
- The abolishment of marketing authorisation renewal in most cases and a streamlined authorisation procedure for generic and biosimilars.
- Minimum market exclusivity for new medicines before generics or biosimilars can enter the market are reduced from 10 years to 8 years (6 years of data exclusivity and two years of market exclusivity) with additional periods of protection available increasing the protection to a maximum of 12 years.
- For medicines to treat rare diseases the standard duration of market exclusivity will be 9 years with it possible to extend to a maximum of 13 years exclusivity depending on fulfilment of certain conditions.
- A non-legally binding recommendation of stepping up EU actions to combat antimicrobial resistance. The main objective is to foster a prudent use of antimicrobials by reducing the total consumptions of microbials among human, animals and plants.

The Commission's proposal will now go to the European Parliament and the European Council for further consideration.

7. The European Commission launches public consultation on proposal to increase pharmacovigilance fees. (here)

On 21 April 2023, the European Commission commenced a public consultation on a draft commission delegated regulation that will have the effect of increasing the European Medical Agencies' (EMA) pharmacovigilance fees by 10.4% in line with inflation.

The deadline to submit feedback to the Commission was 19 May 2023 with the final regulation anticipated to be adopted in Q3, 2023.

8. **The EMA begins public consultation on reflection paper on use of single-arm, clinical trials (here)**

Single-arm clinical trials involves a sample of individuals with a targeted medical condition (i.e., a rare cancer) that are given an experimental therapy to observe their responses to the treatment.

On 21 April 2023, the EMA commenced a public consultation on a *draft reflection paper* that considers the use of single-arm, clinical trials (SATs) for the purpose of obtaining evidence to support marketing authorisation applications (MAAs).

The reflection paper sets out the general characteristics of SATs, surveys the current state of thinking about their use and deals with a number of methodological and practical issues that arise in their design. The deadline for responses to the public consultation is 30 September 2023.

9. **Legislative Progress Made on the EU Artificial Intelligence Act. (here)**

On 14 June 2023, the EU passed a draft law known as the AI Act which aims to regulate Artificial Intelligence.

The Act is currently going through the ordinary legislative procedure with lawmakers discussing how to regulate AI systems with a general purpose.

Members of the European Parliament have amended the list of prohibited AI practices to include bans on intrusive and discriminatory uses of AI systems (e.g., real-time remote biometric identification systems in publicly accessible spaces) and have expanded the scope of high-risk areas (which would be subject to stricter risk management, transparency, and data governance requirements) by including harm to health, safety, fundamental rights, or the environment.

10. **European Commission publishes Implementing Regulation extending transitional periods for products without an intended medical purpose (here)**

On 21 June 2023, the European Commission published *Commission Implementing Regulation (EU) 2023/1194 amending Implementing Regulation (EU) 2022/2346*.
This Regulation extends the transitional periods applicable to medical devices without an intended medical purpose. The transitional period is extended until 31 December 2027 or 31 December 2028 depending on the risk classes of the devices.

11. **Extended Transitional Periods Expected for EU CE-Marked Medical Devices in the UK (here)**

On April 27, 2023, the UK Medicines and Healthcare products Regulatory Agency (MHRA) updated its guidance on the implementation of the future medical devices regulatory framework in the UK. It states that the government is aiming for core aspects of the future regime to apply from July 1, 2025.

In addition, the current Medical Device Regulations 2002 provide that the CE-marked medical devices (i.e., devices approved in the EU) can only be legally placed on the UK market until June 30, 2023; the UK government is introducing new legislation to extend this deadline to support supply of devices in Great Britain ahead of the new regime. The transitional arrangements will be extended to the following:

- 30 June 2028 for general medical devices compliant with the old EU medical devices directive (EU MDD) or EU active implantable medical devices directive (EU AIMDD) with a valid declaration and CE marking;

- 30 June 2030 for in vitro diagnostic medical devices (IVDs) compliant with the old EU in vitro diagnostic medical devices directive (EU IVDD); and

- 30 June 2030 for general medical devices compliant with the new EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic medical devices regulation (EU IVDR).

12. Advocate General opinion on revocation of wholesale distribution authorisation (ECJ) (here)

Advocate General (AG) Pikamäe has given an opinion on a question referred to the ECJ concerning the interpretation of Articles 77, 79 and 80 of Directive 2001/83/EC. The dispute involved a decision taken following the Bundesamt für Sicherheit im Gesundheitswesen (Federal Office for Safety in Healthcare, Austria) decision to revoke the authorisation to engage in activity as a wholesaler in medicinal products previously granted to the appellant.

The AG's opinion focused solely on the third question put to the ECJ:

(i) Whether Article 77(6) and Article 79 of Directive 2001/83/EC must be interpreted as meaning that it is not necessary to revoke the authorisation to engage in activity as a wholesaler in medicinal products in the case where one of the requirements laid down in Article 80 of that directive, which was initially no longer met, is once again met.

(ii) If the answer is in the negative, what other requirements of EU law must be taken into consideration in order to assess which of the two penalties (suspension or revocation) should be imposed.

The AG concluded that it was clear that through the provisions of Article 77(6) of Directive 2001/83/EC, the EU legislature did not intend to define the criteria governing the implementation of measures for the suspension and revocation of authorisation to engage in activity as a wholesaler in medicinal products or to specify the way in which those criteria are to be applied by the national authorities.

The AG noted that it is settled case law that the ECJ has no jurisdiction to rule in the context of proceedings under Article 267 TFEU on the interpretation of national laws or national regulations but only on the interpretation of EU law.

13. EMA consults on Clinical Trials Information System transparency rules (here)

Regulation (EU) No 536/2014 provides that the EU's Clinical Trial Information System shall be publicly available unless one or more exceptions apply, these include to:

(i) protect commercially confidential information;

(ii) protect confidential communication between member states; and

(iii) protect the supervision of clinical trials by member states.

On 3 May, the EMA opened a public consultation on transparency rules seeking submissions on how to balance the objective of transparency with protecting commercially confidential information and minimising the risk of patient data breaches.

Feedback will be used to amend the transparency rules, which are anticipated to be finalised by the end of the third quarter of 2023.

14. Nanomaterials: European Commission publishes guidance document on new definition (here)

On 10 June 2022, the Joint Research Centre (JRC) of the European Commission published a new Recommendation (2022/C 229/01) aimed at harmonising the interpretation of the term *'nanomaterial'* in regulatory contexts. The updated definition replaces that laid down in Recommendation 2011/696/EU.

The new definition holds that nano-materials consist of solid natural, incidental, or man-made particles with the majority of the particles in the 1-100 nanometre range.

On 2 May 2023, the Commission published a guidance document which will help industries and national authorities to implement the new definition. The document provides an overview of the key terminology and concepts, a decision tree to identify nanomaterials and addresses identification of nanomaterials through measurements. The guidance document will continue to be updated in light of technical and scientific progress.

15. Proposal for reform of EU Supplementary Protection Certificate system for medicinal products (here)

The European Commission has published proposals to reform the EU system for granting supplementary protection certificates (SPCs) for medicinal products, including provisions relating to the grant of SPCs for European Unitary Patents (Ups).

Currently SPCs have to be applied for through national patent offices throughout the EU. The SPC proposals seek to introduce a centralised procedure for granting national SPCs and a single SPC database. The proposal also intends to implement a Unitary SPC to complement the Unitary Patent (UP), which came into effect 1 June 2023.

The Regulation establishing the UP does not include provision relating to a Unitary Patent SPC. The proposal seeks to introduce a Unitary SPC that can be applied for through the centralised application system that is to be created.

The changes are intended to be purely administrative. However, the proposals do formalise the right of third parties to make observations during examination and to initiate opposition against an examination opinion. The proposal also includes a right of appeal from the decision of the central examination authority to the EU Intellectual Property Office.

16. European Commission seeks submissions on revision of guidelines concerning phthalates in medical devices (here)

Phthalates which may be carcinogenic, mutagenic, toxic to reproduction or have endocrine-disrupting properties are widely used as plasticisers of polymers incorporated into medical devices. The interaction between the polymer and the phthalates can be weak, so there is a risk that they may be released into the human body.

The European Commission have invited parties to submit information relevant to the revision of its 2019 Guidelines on benefit-risk assessment (BRA) to be conducted in certain medical devices, which risk over-exposure to phthalates.

17. European Parliament publishes a briefing note on revision of general pharmaceutical legislation (here)

On 23 May 2023 a briefing note was published by the European Commission to revise the EU's general pharmaceutical legislation. The briefing note highlighted that current legislation is not achieving those objectives.

The briefing note explains how the European Parliament has resolved to amend the current legislation to more equitably achieve access to medicines, to prevent medicine shortages and to combat AMR. The briefing note also summarises the position of the Council of the European Union, EU advisory bodies and provides examples of judgments delivered by the ECJ which provide guidance on the interpretation of the relevant legislation.

18. Product Liability Updates Industry's Request to EU Legislators on the Product Liability Directive (here)

On 16 May 2023, the European Federation of Pharmaceutical Industries and Associations (EFPIA) published a joint statement with various industry representatives regarding their concerns with the proposed Product Liability Directive (PLD) proposed by the European Commission on 28 September 2022.

It has been argued that although the revision of the PLD was well-intended, it has gone further than necessary and risks bringing uncertainty to a previously effective and balanced product liability regime.

Furthermore, a heavy burden on national court systems is a possibility as they try to implement new rules and could undermine Europe's competitiveness as a place to manufacture products. European Legislators have been asked to take into account significant points as they consider the proposed PLD. Some of the points include undertaking and ensuring disclosure orders will be necessary and proportionate, and limiting the alleviation of the burden of proof on consumers.

GENERAL REGULATORY – IRELAND

19. Medicinal products: Regulation introducing derogation for investigational medicinal products for UK-dependent European markets including Northern Ireland published in Official Journal (here)

On 20 June 2023, Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC was published. The Regulation will apply within one month of the provision of the written guarantees referred to in Article 8.

The objective of the Regulation is to allow for imports of British investigational medicinal products into the dependent markets without the need for manufacturing and import authorisation. This would be a permanent solution for Northern Ireland and a three-year derogation for the other dependent markets, which the Commission views as a sufficient transition period.

20. European Parliament formally adopts three Regulations following Winsor Framework (here)

On 9 May 2023, three regulations were adopted by the European Parliament. The three regulations are aimed at implementing the joint solutions agreed with the UK regarding public, animal and plant health issues, medicines and certain steel products.

The Windsor framework adopted in late February 2023 allowed the Northern Ireland Assembly to prevent any changes to EU goods regulations from applying in Northern Ireland as it was feared the changes would have a significant effect on everyday lives.

Another set of new rules will ensure that all medicines will be available in Northern Ireland at the same time as in the rest of the UK.

Northern Irish companies will thus no longer need to pay the 25% tariff linked to the EU safeguard measures currently in place for steel imports into the EU.

New rules for the movement of retail, human medicines will allow for easier trade mechanisms between Northern Ireland and the rest of the UK easier.

GLOBAL INSIGHTS

21. The WHO and the European Commission have launched a mutual digital health partnership (here)

In June 2023, WHO will take up the European Union system of digital COVID-19 certification to establish a global system that will help facilitate and protect citizens across the world from on-going or future health threats, including pandemics.

The European Commission and WHO have agreed to partner with each other in the area of digital health. The partnership will include close collaboration in the development, management and implementation of the WHO Global Digital Health Certification Network (GDHCN) system.

22. ChatGPT is Entering Hospitals: Health Care Systems Race to create Strategic Partnerships with Artificial Intelligence Companies (here)

More recently, healthcare systems and vendors have increasingly sought strategic partnerships with AI companies to increase efficiency of healthcare services, reduce the burden on providers, and improve patients' experiences.

In April, Microsoft and electronic health vendor Epic announced an expanded partnership to combine the Microsoft Azure OpenAI Service, including ChatGPT and GPT-4. Microsoft's Azure OpenAI Service uses AI algorithms to automatically fill in missing information in HER software allowing EHRs to become more accurate to focus on patient care.

An AI powered platform that converts large amounts of patients data into actionable treatment plans in Navina. Tampa General Hospital (TGH), one of the largest hospitals in the United States, announced that they will partner to integrate Navina's AI technology into TGH's primary care offerings.

Also on 18 May 2023, Detroit-based Henry Ford Health announced that they have partnered with CodaMetrix, an artificial intelligence spinoff from Massachusetts, to automate bedside medical coding. Inpatient bedside coding currently makes up 20% of Henry Ford Health system's coding costs, and autonomous AI for medical coding should result in lower costs and an improved patient experience.

23. Pharma Giants Move into Digital Health (here)

On 31 May 2023 pharmaceutical and biotech manufacturer Bayer announced it is launching a new precision medicine unit which will focus on the creation of digital health tools.

Bayer stated the new unit will focus on developing digital health tools that will allow patients to make improved choices.

24. Deputy Assistant Attorney General Lisa H. Miller Delivers Remarks at the American Bar Association's 33rd Annual National Institute on Health Care Fraud (here)

On 4 May 2023, Lisa H. Miller Deputy Assistant Attorney General delivered remarks at the American Bar Association's 33rd Annual National Institute on Health Care Fraud in Chicago, Illinois. There has been a crackdown on telehealth fraud and there is a continued focus in this area. Since 2018, the Health Care Fraud Unit has charged 163 defendants in connection with telemedicine schemes, including 40 medical professionals, involving more than US$4.75 billion billed and US$1.65 billion paid.

Recently two Utah business owners were accused of defrauding insurance companies out of US$250 million in a fraudulent prescription claims scheme. The call centres contacted individuals to enrol them into private insurance programs, offering no-cost medication without medical exams. The physicians would write prescriptions as requested by the practitioners and the prescriptions were sent to different pharmacies owned by the defendants. Henceforth insurance companies were billed for allegedly fraudulent, medically unnecessary medication. One owner pleaded guilty to one federal felony charge, while the other currently awaits trial.

25. HHS OIG Develops Toolkit to Analyze Telehealth Claims to Assess Program Integrity Risks (here)

On 20 April 2023, the Officer Inspector General- (the "OIG") released a toolkit for evaluating telehealth claims and identifying fraud and abuse risks. The toolkit is based on the Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks.

Amid a continued crackdown in fraudulent telehealth schemes, the toolkit has been designed with seven risk areas of concern to program integrity.

These risk areas include the billing of telehealth.

26. European Commission prepares Regulation on monitoring trade in drug precursors (here)

On 10 May 2023, the European Commission adopted a '*call for evidence*' which will prepare a future legislative initiative, likely a Regulation, with the aim of reducing the availability of drug precursors.

A recent and significant drug precursor development in the European Union is the use of non-scheduled substances that can be converted into illicit drugs without the need to involve the typical drug precursor at all.

27. EMA and HMA publish guidance on preventing and mitigating medicine shortages (here)

On 17 May 2023, the EMA and the HMA published a document entitled '*Good practices for industry prevention of human medicinal product shortages'.*

The document contains ten recommendations for how wholesalers, distributors and manufacturers of medicines can prevent shortages in the supply of their products. The recommendations include:

- Notifying national competent authorities of any potential shortages as soon as possible;
- Ensuring information relating to potential shortages is made available to national competent authorities; and
- Devising a shortage prevention plan and management plan to deal with any shortages that may arise.

28. European Commission publishes guidance on clinical investigation reports (here)

On 23 May 2023, the European published guidance on the content that sponsors are required to submit under Article 77(5) of the MDR.

The Commission's guidance provides details on the information to be included on the device being investigated and, in particular, what needs to be set out when recording the results of an investigation.

29. European Council takes action to mitigate risk of medical devices (here)

On 7 March 2023, the European Council adopted a regulation which extends the deadline for the certification of medical devices.

Producers of medical devices will have until 31 December 2027 for higher risk devices and 31 December 2028 for medium and lower risk devices to meet the legal requirements.

The regulation also reduces the risk of medical devices shortages by removing the "sell-off" date rule.

30. Medicines aspect of Winsor Framework to commence on 1 January 2025 (here)

On 9 June 2023, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that the medicines aspects of the Windsor Framework will apply from 1 January 2025. MHRA will be responsible for approving and licensing all medicines on a UK-wide basis.

Additionally, the Windsor Framework provides the MHRA with jurisdiction to approve licensed medicines in Northern Ireland, and it removes the requirement that such medicines need to display the features required by the Falsified Medicines Directive (2011/62/EU) (FMD).

Transition period stipulations include the following:

- Manufacturers may continue to supply medicines in EU legacy packaging until 31 December 2024;
- The Northern Ireland MHRA Authorised Route (NIMAR) will continue to operate in order to support the supply of medicines into Northern Ireland; and

- Centrally Authorised Products (CAPs) Bridging Mechanism has been created to ensure that, prior to 1 January 2025, new medicines that are awaiting approval by the European Commission can be supplied to Northern Ireland for up to six months where those medicines have been approved by the MHRA.

31. CAP bridging mechanism to apply in Northern Ireland until Windsor Framework takes effect (here)

On 9 June 2023, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a guidance document on the centrally authorised products (CAPs) bridging mechanism.

Under this bridging mechanism, patients in Northern Ireland can access novel medicines that have been approved by the MHRA even where those medicines have not yet been approved by the European Commission within the centralised procedure.

The bridging period will apply for up to six months or until the Commission authorises a CAP in Northern Ireland or refuses an application for the product.

32. FDA issues warning letter to sponsor of wearable ECG Monitoring Devices (here)

On 25 May 2023, the FDA issued a warning letter to IRhythm alleging, among other violations, that IRhythm is marketing its Zio AT System outside the scope of its 510(k) clearance, thereby rendering it an unapproved device.

The device at issue has a 510(k) clearance to continuously record and report patient symptomatic cardiac events and ECG information. The FDA asserts that claims in marketing materials, the website, and other documentation imply the Zio AT System is intended for high risk patients and offers near real time monitoring.

Various technology changes, including hardware changes, firmware changes, and algorithm changes that IRhythm made to the device require a new 510(k). Further, the warning letter also includes misbranding violations relating to failure to disclose an important performance limitation to healthcare providers as well as various quality system and MDR reporting observations.

33. FDA Petitioned to Take Action Against Opioid Prescribing Decision Support Software (here)

A recent Citizen Petition submitted by the Center for U.S Policy (CUSP) requested that FDA deem Bamboo Health NarxCare software a misbranded device and take appropriate enforcement action.

CUSP's petition raises concern about aspects of the NarxCare software that CUSP views as exceeding the scope of the 21st Century Cures Act exemption for non-device CDS software functions, including generation of predictive risk scores based on complex algorithm factoring (risk of addiction or overdose). The FDA has yet to respond to the petition.

34. FDA Requests Public Comment on Patient Access to At-Home Use Medical Technologies (here)

The FDA has established a docket for public comment on increasing patient access to at-home use medical technologies, including digital health technologies.

COMPETITION LAW

35. Condemnation of disparaging practices by dominant firms

The European Commission re-affirmed at the EU Pharma Law Forum 2023 its commitment to look more critically at disparaging practices (i.e., unsupported negative comments against generic/biosimilar competing products.)

The European Commission currently has two open investigations:

(i) assessing whether Vifor Pharma has restricted competition by illegally disparaging its closest, and potentially only competitor in Europe on the market for iron treatment, Pharamacosmos. (here)

(ii) assessing whether Teva has systematically spread misleading information about a competing product with a view to hinder its market entry and uptake. (here)

DATA PROTECTION

36. MedTech Europe Publishes a Position Paper on Cybersecurity (here)

On 23 May 2023, MedTech Europe published a position paper setting forth three focal areas to create a cyber-resilient medical technology ecosystem in Europe.

MedTech Europe emphasises its commitment to prevent cyberattacks, and in particular ransomware attacks.

MedTech Europe supports initiatives aimed at improving digital literacy and cybersecurity skills within staff, as well as increasing public awareness of the risks associated with cybersecurity in healthcare.

37. Opinion of the European Committee of the Regions on the European Health Data Space (here)

On 3 May 2023, the European Committee of Regions recommended amendments to the proposed European Health Data Space Regulation ("**EHDS**"). The recommendations include:

- prohibiting healthcare providers to see restricted health data where it would protect a manifest public interest;

- Shortening the time limit for notification requirements relating to serious incidents from 15 to 7 days; and

- Allowing Member States to determine priority categories of electronic health data.

HEALTHCARE

38. Assisted Decision-Making Capacity Act 2023

On 26 April 2023, the Assisted Decision-Making Capacity Act came into effect with the purpose of assisting persons with diminished mental capacity in making decisions regarding their affairs. The Act introduced 5 new decision support arrangements and establishes the Decision Support Service (DSS), the body charged with regulating and overseeing the arrangements under the Act. The new decision support arrangements are:

1. Decision-Making Assistant
2. Co-Decision-Maker
3. Decision-Making Representative
4. Attorney under an Enduring Power of Attorney
5. Designated Healthcare Representative for the purposes of an Advanced Healthcare Directive

The Act will completely alter the landscape in Ireland in relation to supporting those persons whose capacity is either diminished or absent and replaces the previous system of wardship.

While jurisdictions such as Canada and Sweden have similar legal processes in place, the five-tiered system of arrangements is unique to Ireland in that it provides a range of legal options for citizens through a singular state body.

39. The end of wardship and the protection of individual mental healthcare rights

As a result of the Assisted Decision-Making Capacity Act 2023, the wardship system in place for the last 144 years under the Lunacy Regulations (Ireland) Act 1871 was repealed. The end of wardship returns control from the State to the people of Ireland, protecting the human right to legal capacity regardless of circumstance or disability.

The courts are now currently in the process of assessing more than 2000 Wards of Court with the intention of discharging the person from Wardship or moving each adult Ward into the new tiered framework within the next three years. Wards who remain underage by the end of the three-year period will be reassessed within 6 months of turning eighteen.

Wards will continue to be supported by the Wards of Court Office, the Committee, and the High Court until the reviews are completed.

40. Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Early May 2023, the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 passed through the Oireachtas. This Act provides for mandatory open disclosure and of certain notifiable incidents, reviews of screening results for persons who have undergone screening and creates structure for carrying out clinical audit.

The Act emphasizes accountability for patient safety issues and aligns with the commitment for transparency to create a culture of care, support and clarity to foster relationships of trust, compassion, and respect between healthcare providers and their patients.

These provisions have gained public support from institutions such as the Mental Health Commission and the regulatory bodies that will be overseeing the open disclosure mandates and reporting processes.

41. Planned Human Tissue Bill 2022 aims to increase organ transplantation

As of 24 January 2023, the proposed Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill completed the third stage before the Dáil Éireann. This Bill provides that Ireland move from an opt-in system to an opt-out system as it pertains to organ donation. In addition to provisions in the Bill regarding the procedures, storage and use of organs, it also proposes post-mortem donation.

Minister for Health Stephen Donnelly spoke openly about the commitment to increase the donation and transplantation of organs in the country when he launched Organ Donation Awareness Week on May 16th of 2023.

The aim of this Bill is to increase organ donation for the hundreds of citizens currently on the waiting list for transplantation. Additionally, the Bill provides for certain conditions regarding consent and establishes a structure for regulation of organ donation for the first time in Ireland.

42. New platform promotes healthcare transparency

On 19th June 2023, the Health System Performance Assessment (HSPA) Framework was launched by the Ministry of Health in cooperation with the European Commission and the HSE. This new platform is designed to provide healthcare providers, patients, policy-makers and Irish citizens with transparent publications of data regarding varying areas of the healthcare sector.

This system examines the efficiency and impacts of healthcare policies in Ireland covering over 180 areas of healthcare such as disability, life expectancy, and more. The HSPA website is equipped with navigational panels to assist research and information about the acquisition of its data.

The prototype is still developing, but aims to mirror similar systems already in Malta, Italy and Belgium in an effort to identify the sectors of healthcare that need the most attention and improvement. The HSPA website is now operational and scheduled to have future updates of indicators in July, October, and December of 2023.

43. Public Health (Alcohol) (Labelling) Regulations 2023

New legislation from the Department of Health was signed into law on the 23rd of May 2023 known as the Public Health (Alcohol) (Labeling) Regulations 2023. These provisions will allow for a three year roll-out period where businesses will need to institute comprehensive health labelling on all alcoholic products informing the Irish public about the characteristics of the product and the risk of consuming alcohol.

Bodies such as the Health Safety Authority and the Health Products Regulatory Authority will be responsible for monitoring adherence to the new labelling rules.

As a result of the newly introduced regulations, many countries have raised concerns through the World Trade Organization surrounding the economic and logistical impacts this legislation will foster. As of late May 2023, nine members of the European Union have made notifications about their opposition to these provisions.

Minister of Health Stephen Donnelly welcomes the new regulations on the basis of providing medical and product information to citizens so that they can make informed decisions before consuming alcohol.

44. The Department of Health assures the public with comparable medicines

A cautionary recall of select medicines with the ingredient "valsartan" by the Health Products Regulatory Authority (HPRA) this June has sparked concern among the Irish public amidst a long evolving medicinal shortage issue.

Reports of 289 medicinal products being impacted have led to a reported 44% of patients encountering difficulties when re-filling their prescriptions. This is evidenced by the shortages of medicines having increased by 50% within the last six months.

The Department of Health released a statement declaring its commitment to mitigating the impact of these shortages through cooperation with the HSE and has assured the public that alternative medicines with similar strength or classes can be prescribed whilst current products remain unavailable.

45. Justice Plan 2023

The Justice Plan 2023, as a result of its goal to modernize the court system in Ireland and improve access to justice, could usher in long overdue reform to the management of clinical negligence claims.

Under the proposed provisions, those who have suffered severe injuries could benefit from reduced legal costs, greater legal resources, and sufficient compensation for their losses.

The movement towards a reduction in legal costs through early intervention with mediation and quicker processes through the addition of 24 judges by the end of 2023 will serve those seeking criminal negligence claims.

Moreover, possible reform to periodic payment orders through an indexation rate could ensure that those who have suffered injuries are compensated fairly for their damages based on current and future losses.

The Justice Plan 2023 has the potential to modernize the civil justice system and assist those involved in clinical negligence litigation for an easier, more efficient legal process to obtain the damages owed.

46. Court Proceedings (Delays) Bill 2023 to compensate Irish citizens

In the wake of the previous back log of pending court proceedings that were exacerbated by the Covid-19 pandemic, the Court Proceedings (Delays) Bill 2023 is aimed at providing domestic remedies for those who have experienced severe delays in pursuing legal action. This Bill also seeks to address Ireland's non-compliance with Articles 6(1) and 13 of the European Convention which requires member states to implement fair trials within a reasonable time and appropriate

remedies for those effected by delay in courts.

Section 17 of the new Bill provides that assessors must "have regard to" any injury suffered and reflect this in the damages awarded in each case. This is far less restrictive to circumstance than the recommendations of the Joint Committee and reflects a judicial awareness and motivation to help those negatively affected by delays in legal proceedings.

As a result of this Bill, many individuals or organizations who have pursued legal action in regards to healthcare may be entitled to damages for their court proceedings being postponed. Moreover, the Bill will foster a more efficient legal system aligned with the principles of the European Union.

47. HSE and Ms. A [2021] IEHC 836

HSE v Ms. A is a case concerning Ms. A, a woman who struggled with extreme anorexia nervosa for 25 years. Ms. A has been consistently resistant to treatment ranging from less severe approaches to coercive methods. As a result of her illness, Ms. A became a ward of the state in 2020 in an attempt to treat her in a psychiatric facility in Ireland as well as in a hospital in the UK.

Upon medical advice and expert opinion regarding Ms. A's treatment of her disorder since she became a ward of the state, it was proposed by her respective doctors to terminate the coercive treatment of feeding tubes and other treatments as her resistance was only further hindering her recovery.

A subsequent Court Order was made to terminate any coercive treatments for her anorexia nervosa and to return autonomy and peace of mind back to Ms. A, while acknowledging her continued capacity issues around feeding. This was a complex case, but on balance, it was considered to be more therapeutically beneficial to seek Ms A's co-operation with her own treatment, despite her frail condition.

With the end of the wardship system earlier this year and the replacement with new five tiered, more flexible and comprehensive framework under the Assisted Decision-Making (Capacity) Act 2015, the varying levels of decision support arrangements will facilitate persons in being able to make even the most complex decisions. This is in contrast to the previous uncompromising and all-encompassing wardship system.

48. Public Health (Tobacco Products and Nicotine Inhaling Products) Bill 2023

On 15 June 2023, the Public Health (Tobacco Products and Nicotine Inhaling Products) Bill 2023 went before Dáil Éireann in its second stage as an amendment to the Public Health (Tobacco) Act 2002. This new Bill provides for the licensing of sale of nicotine products, regulation of such licenses, and the offenses for violations of the 2023 Bill's provisions.

In addition to licensing requirements and the prohibition of selling nicotine products to those under the age of 18, the Bill bars the sale of e-cigarettes from self-service vending machines and in places meant for children. Under the new Bill, the advertisement of nicotine inhaling products will be banned from public transport, cinemas, and locations within a close proximity to schools.

Recent statistics report that 39% of 15-16 year olds have used e-cigarettes at one time or another, with 15.5% reporting to be active users. The Minister of Health and the Minister of State have publicly acknowledged their support for this Bill in aiming to protect the youth of Ireland by making the highly addictive substance less accessible.

One aspect that the Bill seeks to address is the promotional pricing of tobacco products.
In a discussion during the second stage of the Bill, Deputy Louise O'Reilly discussed the dangers of promotional pricing. She asserted that promotional pricing on packs of cigarettes is encouraging the public to smoke more by virtue of the lower price point for larger packets. She

proposed that the Minister of State consider unit-pricing on cigarettes to eliminate the risk of smoking that promotional prices facilitate, creating further legislation on sponsorship of cigarettes.

This occurred in the case of HSE v PJ Carroll & Co. Ltd., where Kearns P delivered a judgment regarding the allegedly illegal promotion of cigarettes to customers of Spar on the Dublin City University campus. The defendants had been incentivizing the promotion of 'Pall Mall' cigarettes through prizes to their employees in return for promoting the brand. Ultimately, this action could have been deemed a violation under Section 7 of the Public Health (Tobacco) Act 2004 prohibiting sponsorship.

Similarly, Deputy Thomas Pringle, who was also in support of the Bill, that the lack of regulation for chewing nicotine pouches should also be addressed arguing that nicotine is nicotine.

Deputy Pringle's comments echoed the judgment of Mr Justice Charleton in the case of HSE v Brookshore Ltd where he asserted, that "a roof is a roof." That case involved smoking taking place under an awning contrary to the 2002 Act. The District Court judge sought guidance as to whether an awning is a roof leading to Charleton J's public spirited and practical comment that a "roof is a roof"!

As a result of the conversations held in this second stage, it is possible that the announced changes to legislation may be accompanied by additions to the Bill to address the issue of nicotine addiction more fully. The widespread concern by those involved in the debate suggests that this legislation will likely not be the last action Ireland sees in the near future.

49. The imbalance in health insurance cover for life-changing cancer drugs (here)

There has been some recent publicity surrounding the potential for patients with terminal cancer losing out on access to the newest and most important cancer treatments due to the private health insurer that such customers may have health insurance with in comparison to other providers.

50. Health Insurance costs over 2 million people expected to rise in the coming weeks (here)

Health insurance companies are expected to impose an average price increase of 5 per cent to their customers over the coming weeks.

ABOUT

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