PHILIPLEE

Healthcare, Pharmaceuticals and Life Sciences Update May 2022

WELCOME

Welcome to this update from the Philip Lee Healthcare, Pharmaceuticals and Life Science group in respect of the first quarter of 2022. Please get in touch if you would like to know more about what we have covered.

Contact details for the team members can be found at the end of this publication.

GENERAL REGULATORY – IRELAND

1. Irish Government publishes Legislation Programme Spring 2022 (link here)

In January, the Irish Government published its Legislation programme for Spring 2022. There are forty-four pieces of priority legislation set to be drafted and published this session. Among these are four healthcare bills:

- The Assisted Human Reproduction Bill, to provide a legislative framework for the regulation of assisted human reproduction practices and associated research,

- The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill, to deal with organ donation and transplantation in respect of both deceased and living donors, an opt-out system of consent for decreased organ donation, post-mortem practices and procedures, anatomical examination/education and training and public display of bodies after death,

- The Public Health (Tobacco and Nicotine Inhaling Products) Bill, to introduce a licensing system for the sale of tobacco and nicotine inhaling products (including e-cigarettes) and other related matters, and

- The Safe Access to Termination of Pregnancy Services Bill, to ensure safe access to premises at termination of pregnancy services may be provided.

2. Potential new EU law to help consumers take 'collective action' against firms (link here)

The Irish Government announced its intentions to begin drafting a new Bill to transpose Directive (EU) 2020/1828 on representative actions for the protection of collective interests of consumers. The Directive obliges all Member States to establish a mechanism for the protection of the collective interests of consumers.

"*Qualified Entities*" will be designated by the Irish Government to represent the interests of consumers in their respective fields. Provided Irish consumers have the support of Qualified Entities, consumers will be enabled to group together and have their interests represented by the particular Qualified Entity in the given field. These Qualified Entities will be non-profit making in nature and will take legal action against firms where appropriate on behalf of groups of consumers.

Firms who are found to be liable will be obliged to provide "*Redress Measures*", which include "*compensation, repair, replacement, price reduction, contract termination or reimbursement of the price paid*".

The Government is yet to designate a Qualified Entity for the pharmaceutical sector, which will likely be set out upon the initial draft of the Bill. Undoubtedly this is a key development which merits further consideration and discussion in due course.

3. HPRA Provides updated guidance for submitting mock-ups for labels and leaflets (link here)

The Health Products Regulatory Authority issued updated guidance in February on the use of labels and leaflets for human medicines. The guide now requires that the registered text for labels and leaflets is contained in the text versions of those documents. Label mock-ups are only reviewed by the HPRA "*for design, layout and readability issues*".

In order to facilitate the timely issuing of new licences, the HPRA has also now separated the approval of label mock-up from the issuing of the licence. The HPRA now requires a separate Article 61(3) submission with the proposed label mock-ups which can be submitted in advance of the new licence being issued.

GENERAL REGULATORY – EU

4. Heads of Medicines Agencies, European Commission and European Medicines Agency launched Accelerating Clinical Trials initiative (ACT EU) to transform how clinical are designed and conducted in the EU

The initiative sets out to change the ways in which clinical trials are initiated, designed and conducted in the EU. In its strategy paper, the group acknowledge the "*disharmony of regulatory requirements between Member States*" which "*complicate the submission of multi-trial applications*".

In order to encourage the conduct of multi-state clinical trials, ACT EU sets out ten priority actions:

i. Map existing initiatives and develop a governance rationalisation strategy,

ii. Successful and timely implementation of the Clinical Trials Regulation and its implementing acts,

iii. Establish a multi-stakeholder platform, including patients, after stakeholder analysis,

iv. Implementing the Good Clinical Practice modernisation,

v. Analyse clinical trial data leveraging academic, non-profit, European, and international initiatives,

vi. Plan and launch a targeted communication campaign to

engage all enablers (including data protection experts, academia, SMEs, funders, HTA bodies, healthcare professionals),

vii. Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain,

viii. Develop and publish key methodologies guidance,

ix. Successfully establish CT safety monitoring and bridge to the EU4Health Joint Action and start its integration into a pre- and post-marketing safety monitoring framework, and

x. Deliver a clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs

5. The European Commission has launched a public consultation on the revision of REACH, the EU's chemicals legislation

The Commission launched a public consultation in January on the revision of the Regulation on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). The purpose of the revision is to achieve establish safe and sustainable chemicals and a high level of protection of health and the environment. The public consultation will run until mid-April 2022 and can be accessed here.

6. EU adopts updated proposals to ensure the continued supply of medicines to Northern Ireland, Cyprus, Ireland and Malta (link here)

The European Parliament and the Council adopted the European Commission's proposals to ensure the continued supply of medicines from the UK into Northern Ireland. The new laws are a welcome development to ensure the continued flows of medicines into Ireland from Northern Ireland and apply retroactively from 1 January 2022 and 31 January 2022 until 31 December 2024. The EU expects within these three years these markets will gradually phase out dependency on the supply of medicines from "*parts of the UK other than Northern Ireland*." The European Commission has stated it will make proposals to revise the EU's pharmaceutical legislation later this year.

7. Regulation 2019/6, the Veterinary Regulation has come into force throughout the EU

The Veterinary Regulation came into force throughout the EU on 28 January 2022 after a three year implementation period. The regulation modernises the existing rules on the authorization and use of veterinary medicines in the EU. The key objectives of the regulation are to:

- Simplify the regulatory environment and reduce the administrative burden for pharmaceutical companies developing veterinary medicines,
- Stimulate the development of innovative veterinary medicines,
- Improve the functioning of internal market for veterinary medicines, and
- Strengthen EU action to fight antimicrobial resistance through specific measures, including reserving antimicrobials for the treatment of infections in people.

8. European Commission adopts legislative proposal for a Corporate Sustainability and Due Diligence Directive (link here)

The Commission adopted a legislative proposal in February for a directive to introduce a sustainability due diligence duty on large EU companies and non-EU

companies with significant EU activity in order to address adverse human rights and environmental impacts in their own operations, their subsidiaries and their value chains. The proposal acknowledges it may be difficult for large EU companies to identify and mitigate against risks of in their value chains and suggests stronger due diligence on the part of such companies in this regard.

GLOBAL INSIGHTS

9. Takeda's Exkivity receives MHRA conditional marketing authorisation (link here)

The UK's Medicines and Healthcare Products Regulatory Agency have granted a conditional marketing authorisation to Exkivity (mobocertinib), a rare lung cancer treatment developed by Takeda. Previously, there had been no targeted treatments for patients with epidermal growth factor receptor (EGFR) locally advanced or metastatic non-small cell lung cancer. This type of lung cancer primarily affects younger people and non-smokers and carries a worse prognosis than other EGFR mutations. The approval marks a significant milestone and is hoped to lead to improvements in the treatment for this type of lung cancer.

10. Novel therapeutic strategy shows promise against pancreatic cancer (link here)

Albert Einstein College of Medicine in New York have published the findings of a study which appears to yield promise for treatment of pancreatic cancer. The new developments have reportedly succeeded in "*making pancreatic tumours visible to the immune attack, reducing cancer metastases by 87%.*" The paper describing the findings was published online in the journal of Science Translational Medicine. The treatment utilises T cells generated by the tetanus vaccine. It reportedly "*reduced the size of the pancreatic tumours in the mice by an average of 80% and also significantly reduced the number of metastases by 87%, while the treated animals lived 40% longer than untreated (control) animals*".

COMPETITION LAW

11. New Competition Amendment Bill in Ireland (Guidance note)

The Irish government published the Competition Amendment Bill in January 2022. This Bill represents the most significant change in Irish competition law since the introduction of the Competition Act in 2002.

The purpose of the Competition Amendment Bill is to implement the Directive (EU) 2019/1, the ECN+ Directive, which was introduced at a European level in 2018, and thereby introduce measures that will strengthen the power of the national competition authorities in Ireland (both the CCPC and ComReg) and provide them with stronger means to tackle anti-competitive practices.

For the first time, the Bill will allow the CCPC to impose fines of up to the greater of €10 million or 10% worldwide turnover for breaches of competition law without the need for direct judicial oversight to do so. The Bill will also allow for the continuance of competition law breaches being prosecuted at a criminal level.

Significant changes are also introduced to Ireland's cartel leniency and merger control regimes.

12. Commission issues draft guidelines on information exchange in dual distribution (link here)

The European Commission has been reviewing the Vertical Block Exemption Regulation since 2021. In February 2022, the Commission published draft guidance on information exchange between competitors in a vertical scenario. Crucially, the Commission has, for the first time, given real and tangible examples of information which may be exchanged and not be considered a breach of

competition law in dual distribution scenarios. This is a welcome development and provides much needed clarity on information exchange between companies. The draft guidance clarifies that information exchange that is "*necessary to improve the production or distribution of the contract goods or services by the parties*" will not be considered a breach of competition law. It remains to be seen whether this approach will be taken in other types of agreements where undertakings agree to share information with each other. The new Vertical Block Exemption rules will enter into force from 1 June 2022.

13. The European Commission invites public consultation on new changes to guidance on horizontal agreements (link to EC website here)

The European Commission published two draft revised horizontal block exemption regulations in March on Research and Development ("R&D") and Specialisation agreements. The drafts are open to consultation with the public until 26 April 2022. The new horizontal guidelines and rules will enter into force from 1 January 2023. Similar to the guidance issues in vertical scenarios, the Commission have also issued guidance on information sharing in relation for horizontal scenarios. There is also some guidance on exchanges of information in the context of mergers and acquisitions, and the use of data.

DATA PROTECTION

14. Data Protection Act 2018 (Access Modification) (Health) Regulations 2022 enter into force

The *Data Protection Act 2018 (Access Modification) (Health) Regulations 2022* entered into force in March, revoking and replacing the previous regulations in place since 1989. Organisations which process health data relating to individuals ("**controllers**") and receive Data Subject Access Requests ("**DSARs**") are now permitted to exercise their own discretion in deciding whether to consult a health practitioner before providing access to an individual's data pursuant to a DSAR, subject to the fulfilment of certain preconditions. Previously under the 1989 regulations, all controllers processing health data who were not health service provider (e.g., an insurance company) were under an obligation to consult an "*appropriate health professional*" (i.e., a healthcare practitioner) before providing access to an individual's health data. This is a welcome development as these regulations will allow controllers to respond to Data Subject Access Requests more quickly and efficiently.

15. The UK adopts new International Data Transfer Agreement and Addendum for the transfer of data ("IDTA") (ICO here)

The UK Government approved the IDTA in March, designed to act as an appendage to the Standard Contractual Clauses applying in the context of transfers of data outside of the EU (where data protection concerns arise) pursuant to the GDPR. Now organisations in the UK are able to use the IDTA or Addendum to the new Standard Contractual Clauses as a transfer mechanism when transferring personal data from the UK. From 21 September 2022, all new contracts involving the transfer of personal data from the UK to third countries that do not offer adequate protection will be obliged to use either the IDTA or the Addendum.

16. Data Protection Commission imposes €17 million fine for data breaches on Meta Platforms Ireland Limited (formerly Facebook Ireland Limited) (link here)

In March, the Data Protection Commission adopted a decision to impose a fine of €17 million on Meta Platforms following an inquiry into twelve data breach notifications received between 7 June 2018 and 4 December 2018.

The DPC found that Meta Platforms failed to have in place appropriate technical and

organisational measures which would enable it to readily demonstrate the security measures that it implemented in practice to protect EU users' data, in the context of the twelve personal data breaches.

Given that the processing under examination constituted "*cross-border*" processing, the DPC's decision was subject to the co-decision-making process outlined in Article 60 GDPR and all of the other European supervisory authorities were engaged as co-decision-makers. While objections to the DPC's draft decision were raised by two of the European supervisory authorities, consensus was achieved through further engagement between the DPC and the supervisory authorities concerned. Accordingly, the DPC's decision represents the collective views of both the DPC and its counterpart supervisory authorities throughout the EU.

17. Psychotherapy centre Vastaamo in receipt of fine imposed by the European Data Protection Board for data protection violations (link here)

Vastaamo, a Finnish private psychotherapy provider was hacked in 2020. The company has since gone bankrupt and its assets and staff have since been transferred to Verve. However, in January 2022, the European Data Protection Board announced its final decision to fine Vastamoo €608,000 for "*acts of negligence*" in failing to notify the European Data Protection Board intentionally, which also found that Vastaamo "*neglected in its duties related to the safe processing of personal data as well as reporting a data breach*." As to whether Vastaamo will have the means to pay this fine in its bankruptcy, it is worth noting that administrative fines are the lowest claim in priority during a bankruptcy.

18. The Finnish Motor Insurer's Centre fined for collection of unnecessary patient information (link here).

The European Data Protection Board imposed a fine of €52,000 for the collection of unnecessary patient information to the Finnish Motor Insurer's Centre. The Centre had requested patient records from health care providers while processing claims. Further the Centre had "*systematically requested the claimants[' data]*" instead of "*limiting their request to the information necessary for claims handling*". The decision emphasises the need for any controller in receipt of personal data to limit their collection to processes which comply with the GDPR.

HEALTHCARE

19. Personal injury guidelines: The aftermath

A report published by the Personal Injury Assessment Board (PIAB) on April 11th shows the effect that the Personal Injury Guidelines, published in April of last year, have had on the value of awards.

The report is based on the value of awards from April 24th, right after the guidelines had been published, to December 31st of 2021.

Although a change in the value of awards was expected, the extent of that change was difficult to estimate. The report published by the PIAB has provided statistics illustrating just how significant of a change has been made.

The report includes that:

- Motor liability accounted for 68% of awards, public liability accounted for 19%, and employer's liability stood at 13%.
- All categories had an overall 42% drop in the value of awards.
- 49% of awards fell below 10,000 euros in 2021, in comparison to just 12% in 2020.
- In 2020, 44% of claims exceeded an award of 20,000, however this fell to just 17% for 2021.
- 20% of awards are now under 5,00 euros.

- The average award (excluding those over 100k) was 13,403 euros.
- Neck and back injuries remain the most common, accounting for 53% of injuries (Neck 28% and Back 25%).

20. Personal Injuries Resolution Board Bill 2022: A proposal to amend the Personal Injuries Assessment Board Act 2003-2019

As of February 2022, the Government has agreed to commence the drafting of the 'Personal Injuries Resolution Bill 2022'. The overall aim of such a bill is to avoid litigation and increase the number of cases settled through the PIAB.
Includes that:

- PIAB will offer mediation as a means of resolving a claim: Parties have the right to obtain legal advice and/or to be represented by a legal advisor. It is unclear as to who the mediators would be.
- PIAB will retain claims of a wholly psychological nature.
- PIAB will have additional time to assess claims where an injury is yet to settle rather than releasing to litigation.
- PIAB will promote public awareness and conduct public information campaign.
- PIAB will seek proof of identity on application and may disclose information to An Garda Síochána to reduce fraud.
- Court's discretion regarding costs in litigation will be tightened.

The new bill can help avoid the high costs and lengthy time that is associated with litigation.

21. Finally, the long Awaited: Assisted Decision-Making Capacity Act

Signed into law by President Michael D. Higgins back in 2015, this Act has been long awaited and is set to commence in June.

The Act is ground-breaking in many respects and provides for a range of decision supports for persons whose capacity is at issue or might shortly be in issue. In a new departure from the old norms, where capacity was assessed on the basis of the status of the person, the Act now requires that capacity must be "construed functionally.'' This means that capacity is to be considered as being issue, decision, and time-specific. In other words, where a person may not have the capacity to make one decision, it does not necessarily mean that they do not have the capacity to make another decision. The Act also creates a new public service, the Decision Support Service ("DSS") which is charged with overseeing the operation of the Act. Some of the decisions supporters provided for in the Act are:

- Decision Making Assistant: If a person requires support or advice from another person, they can now formally appoint a 'decision-making assistant'. The assistant does not make the decision for the person, they are simply there to assist and support the person on their route to making such a decision by for example obtaining information or documentation. The agreement appointing the assistant is overseen by the DSS.

- Co-Decision Maker: This is where the person appoints a co-decision maker to make the decision jointly with him or her. The co-decision-making agreement must be registered with the Decision Support Service.

- Decision Making Representative: Where the person lacks capacity, the Court can appoint a representative to make certain decisions for a person who cannot make such decisions for him or herself. This will be done where someone does not have a suitable person that they can appoint as a decision-making representative. More than one representative may be appointed, and suitable

representatives will be chosen based on factors such as general suitability and expertise in particular areas. The order appointing the representative is overseen by the DSS.

22. Patient Safety (Notifiable Patient Safety Incidents) Bill 2019

As of March 10th, this bill is currently before Dail Eireann (the fourth stage).
The bill provides for mandatory open disclosure by both public and private health service providers. It will apply in respect of 'notifiable patient safety incidents' which are listed in Schedule 1 of the bill and include matters such as wrong-site surgery and unexpected death. A health practitioner is obliged to make the health service provider aware of a notifiable incident and make the open disclosure to the patient and his or her family. It is important that patients and their families are treated with compassion and offered openness and transparency if such an incident occurs.

The procedure for making an open disclosure is laid out under Part 3 of the Bill, which includes the following:

- A designated person shall meet with the patient and their family (preferably in person unless requested otherwise)
- The relevant information is to be provided to the patient and their family at
- the open disclosure meeting (such information must also be provided in writing)
- Records should be kept by health services providers

The information provided will be required to describe the incident, the effects of it, as well as the treatment relevant to the patient and the steps that will be taken to prevent such an incident happening again.

In addition to notifying the patient, the bill will also require health services providers to notify such incidents to either the Health Information and Quality Authority (HIQA), the Chief Inspector of Social Services (CISS) or the Mental Health Commission (MHC) whichever is relevant. Finally, the bill also lays out sanctions, such as fines, for non-compliance.

23. The decision made in the Nervous Shock case of Warren Harford v Electricity Supply Board (2020) has been overturned by the Court of Appeal

The vexed question of nervous shock was dealt with by the Court of Appeal (CoA) in the recent case of *Warren Harford v Electricity Supply Board (2020)*. In this case, the plaintiff, Mr Harford, claimed that he had suffered a psychiatric injury after repairing a streetlight, because of what 'could have happened' to him whilst doing so.

Mr Harford claims that he could have been injured because he was using a new machine, which the ESB later admitted was in fact, unsafe.

The High Court had granted an award of €83,000 in damages to the plaintiff for nervous shock. However, on appeal, the Court of Appeal found that the plaintiff had not satisfied the full extent of the test laid out by Hamilton C.J. in the 1995 Supreme Court case of Kelly v Hennessy. The second principle of the test provides that such an injury must be 'shock induced', which Noonan J. held was not evident in this case, and further held that there was no 'sudden calamitous or horrifying event' present in the case. Instead, injury had just been narrowly avoided.

Mr. Justice Noonan, although sympathizing with Mr Harford, and acknowledging the existence of his psychiatric injury, ultimately held that the ESB could not be liable. He further held, that if they were to be found liable, it would go beyond existing law and lead to uncertainty in this area of law.

The CoA held that it was not up to them, but rather a matter for the Supreme

Court, to decide on the extent to which the law on nervous shock shall go.

24. English Supreme Court appeal: Puberty Blockers case

The issue of the capacity of children to consent to medical procedures in the UK was recently addressed in the case of Bell and another v The Tavistock and Portman NHS Foundation Trust. In the UK if a child under the age of 16 years is considered to be mature enough to understand the decision, then they can give a valid consent. In this case the plaintiff, Keira Bell, took a case against Tavistock and Portman NHS Trust with the aim to prevent the prescription of puberty-blocking drugs to Transgender children under the age of 18.

Ms. Bell claimed that children cannot consent to such puberty blocking treatment and that she herself regrets taking them when she was 16 years old. She claimed that she should have been questioned, and challenged more, over her certainty of transitioning.
She further stated that the current system is 'harming children' and had harmed her. Despite proceeding to get her breasts removed after the puberty blocking drugs, she claims she now regrets her decision to transition to a male.

The High Court initially ruled in favour of Ms Bell and found that it is 'doubtful' that 14 and 15 year-olds could consent to receiving puberty blockers. However, the decision of the High Court, was overruled by the Court of Appeal who said that the High court was 'not equipped' to say that transgender children did not have the competence to make such decisions for themselves.

ABOUT

Philip Lee is one of Ireland's leading commercial law firms. We are recognised leaders in several areas of law, including competition, construction, data, employment, energy, environmental, EU, intellectual property, healthcare and life sciences, PPP, procurement, real estate and tax. The firm has offices in Dublin, Brussels, San Francisco and London. 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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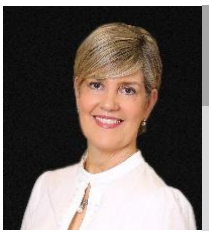

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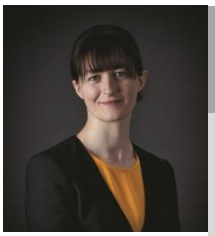

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