PHILIPLEE

Healthcare, Pharmaceuticals and Life Sciences Update ● January 2023

WELCOME

Welcome to this update from the Philip Lee Healthcare, Pharmaceutical and Life Science group in respect of the fourth quarter of 2022. 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 – Ireland
2. General Regulatory – EU
3. Global Insights
4. Competition Law
5. Data Protection
6. Healthcare

GENERAL REGULATORY IRELAND–

1. Guidance issued by the HPRA on appeals under Cosmetic Products Regulation 2013 (here).

The Health Products Regulatory Authority (the "**HPRA**") has issued updated guidance on the procedure for appealing compliance notices or measures under Regulations 12 and 17 of the European Union (Cosmetic Products) Regulations 2013 (S.I. No 440 of 2013).

The updated guidance provides further details about the appeals procedure and the applicable appeal timeframes involved in line with the principles of "*proportionality, fairness and transparency*".

GENERAL REGULATORY EU-

2. European Commission adopts Report on implementation of the Organ Transplantation Directive (here).

On 30 November 2022, the European Commission has published a Report on the implementation of Directive 2010/53/EU (the "**Directive**") regarding the standard of quality and safety of human organs intended for transplantation.

Pursuant to Article 22 of the Directive, Member States must report to the Commission on the activities undertaken and experience gained in implementing the Directive once every three years. The Commission must then publish a report on the implementation of the Directive.

Some of the conclusions contained in the 2022 report include:

- Overall, Member States did not experience substantial difficulties with the implementation of the Directive;

- The current legal framework ensures a high level of safety and quality in the organ donation and transplantation field; and
- Member States reacted quickly to ensure the safety of transplantations with the new challenges created by the pandemic.

3. Common Specifications have been introduced for Devices without an Intended Medical Purpose.

On 2 December 2022, *Commission implementing Regulation (EU) 2022/2346 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 on medical devices* was published.

The common specifications introduced cover the following products under Annex XVI to the Medical Devices Regulation:

- Contact lenses;
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing and piercings;
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;
- High intensity electromagnetic radiation emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;
- Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

The Regulation became effective as and from 22 December 2022.

4. Regulation on European Centre for disease prevention and control published in Official Journal (here).

On 6 December 2022, the Commission published *Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) 851/2004 establishing a European Centre for disease prevention and control*.

The Regulation is expected to improve the EU's capacities in responding to potential future pandemics. Areas of surveillance, early warning preparedness, and response are expected to be strengthened in the Regulation.

Under the Regulation, the *European Centre*'s mandate has been updated to include the creation of an *EU Health Task Force*. This task force will assist in responding to the outbreak of diseases, providing expertise to Member States and the European Commission.

The Commission will report on the *European Centre*'s activities by 2025.

5. Regulation on serious cross border threats to health published in the Official Journal (here).

On 6 December 2022, the Commission published *Regulation (EU) 2022/2371 on serious cross border threats to health and repealing Decision 1082/2013/EU*.

An EU health crisis and pandemic plan is provided for in the new legislation.

Further measures include:

- The Commission being able to declare a public health emergency at EU level, based on opinions issued by a special Advisory Committee;
- The implementation of stress-tests to ensure the operation of the EU prevention, preparedness and response plan; and
- The drafting of reports on Member States' preparedness and response planning for pandemics.

The Health Security Committee will assist in the implementation of the Regulation.

The Regulation came into force as and from the end of December 2022.

6. Reclassification of Certain devices without an Intended Medical Purpose

On 2 December, the Commission published "*Commission Implementing Regulation (EU) 2022/2347 laying down rules for the application of Regulation (EU) 2017/745 as regards reclassification of groups of certain active products without an intended medical purpose*."

The legislation came into effect as and from 22 December 2022.

3 groups of medical devices without an intended medical purpose have been reclassified as follows:

- High intensity electromagnetic radiation emitting equipment intended for use on the human body for hair removal has been reclassified as Class IIa and high intensity electromagnetic radiation emitting equipment intended for use on the human body for skin treatment has been reclassified as Class IIb;
- Equipment intended to be used to reduce, remove or destroy adipose tissue has been reclassified as Class IIb; and
- Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain has been reclassified as Class III.

The reclassification of the above medical devices will mean the applicable conformity procedure that such products will require to undergo will change.

7. Proposal to extend Transitional Deadlines for the Medical Devices Regulation and the In Vitro Diagnostic Devices Regulation

The European Commission has put forward a proposal to extend the transitional deadlines set out in the Medical Devices Regulation ("**MDR**") and the In Vitro Diagnostic Medical Devices Regulation ("**IVDR**") as follows:

- Until 31 December 2027 for Class III and Class IIb implantable devices
- Until 31 December 2028 for Class IIb, Class IIA and Class I devices placed on the market in sterile condition or having a measuring function;

The proposal will now be considered for adoption by the European Parliament and the European Council through a co-decision procedure.

8. New European Commission Expert Group on Public Health (here).

On 7 December 2022, the European Commission adopted a decision to set up a new expert group on public health tasked with advising the Commission on policy development in respect of public health challenges.

The new expert group replaces a former group focusing on non-communicable diseases (the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases).

9. European Commission Changed Labelling Requirements for Investigational Medicinal Products (here).

On 15 November 2022, the Commission published *Delegated Regulation 2022/2239* in order to introduce a change to the Clinical Trials Regulation.

The change will mean that the current requirement to re-label expiry dates on both the internal and external investigational medicinal products will be removed in certain cases given the potential risk to the quality and safety of these products should they be re-opened on a frequent basis.

10. Publication of European Commission note on the revision of EU pharmaceutical legislation.

On the 2 December 2022, a European Commission note on the proposed revision of EU pharmaceutical legislation was published in the Council Register.

Directive 2001/83/EC on the Community code relating to medicinal products for human use, and *Regulation (EC) No 726/2004 laying down EU procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency* is the current overarching legislation governing EU pharmaceuticals (as complemented by further legislation) which will all be subject to the Commission's review proposal.

GLOBAL INSIGHTS

11. European Health Data Space (here).

In September 2022, the European Parliament published a briefing paper on the European Commission's proposal for a regulation on the European Health Data Space (the "**EHDS**"). The aim of the Commission's proposal is to improve individual's access to their electronic personal data, whilst facilitating data re-use for societal good across the EU. Therefore, the EHDS will attempt to force digital health providers to meet a series of new legal requirements applicable to the systems they use for processing health data.

The proposal put forward by the Commission provides for three specific objectives –

i. Ensuring individuals' control over their electronic health data;

ii. Setting the rules for the solutions offered on the market for health record systems and wellness applications;

iii. Allowing researchers, innovators, and policy makers to harness the health data available.

The EHDS will rely on a central platform to ensure cross-border flow of health data and to ensure that the EDHS's participants remain connected.

12. Novo Nordisk and Microsoft announce collaboration to accelerate drug discovery (here).

A collaboration between Novo Nordisk and Microsoft was announced on 12 September 2022 to accelerate drug discovery and development, through the use of Microsoft's computational services, cloud and artificial intelligence.

Microsoft will offer artificial intelligence technology, foundational science models and capabilities through the collaboration. They will further work with Novo Nordisk's data researchers, and domain specialists from initial research and development regions.

Where artificial intelligence models are developed as a result of the collaboration, they will be applied by Novo Nordisk and Microsoft to a range of use cases.

13. Report on EU Covid-19 Vaccine Procurement Performance (here).

A special report, published by the European Court of Auditors, was released

in September 2022, which evaluated the EU's performance in procuring Covid-19 vaccines during 2020 and 2021. The Commission's preparations, the conduct of the negotiations, and the remedies available to the EU when faced with possible supply disruptions were amongst the factors examined.

The report concluded that the EU successfully procured the number of required Covid-19 vaccines, and that the preparations for the procurement of these vaccines were '*mostly effective*'. However, the report found that the Commission lacked sufficient leverage to overcome supply challenges and did not adequately analyse supply chain challenges involved until all contracts had been fully signed. The majority of these contracts did not include provisions which addressed chain supply disruptions.

The report recommended that pandemic procurement guidelines should be prepared on the basis of the lessons learned.

14. European Commission Work Programme 2023: Life Sciences Initiative (here).

On 18 October 2022, the European Commission published their 2023 Work Programme. The Work Programme includes the following life sciences initiatives:

- The bringing forward of legislation regulating new genomic techniques to maintain a high level of protection for human and animal health;
- The outlining of a Commission patent licensing package which will contain a framework for standard essential patent licensing; and
- The implementation of the Commission's Beating Cancer Plan.

15. Transformation of the General Product Safety Directive 2001.

A provisional agreement was reached by the Council and the European Parliament, on 29 November 2022, pertaining to a new General Product Safety Regulation ("**GPSR**") which will update the General Product Safety Directive 2001. The safety of products sold both online and offline will be addressed under the GPSR.

The announcement by the European Parliament highlighted the following:

- Products will only be capable of being sold when an economic operator (such as the manufacturer, distributor or importer) is established in the EU and that economic operator is responsible for the product's safety;
- A single point of contact for national surveillance authorities will have to be provided for on online marketplaces; and
- The rules around safety recalls will become more stringent.

The European Parliament and Council are yet to endorse the agreement on the GPSR.

16. Publication of "Health at a Glance: Europe 2022" by the European Commission and the OECD (here).

The Commission and the OECD announced the publication of their report "*Health at a Glance: Europe 2022*" in late December 2022. The report examines the key challenges that came to light from a health perspective during the COVID-19 pandemic.

17. Quality Innovation Expert Group established by EMA (here).

A press release issued by the EMA on 21 November 2022, announced the establishment of a Quality Innovation Expert Group ("**QIG**"), to assist in supporting innovative approaches for the development, manufacture, and control of medicines for patient use in the EU.

The QIG will ensure the European medicines regulatory network is keeping up with innovation and will seek to identify and address any gaps in the regulatory framework governing medicines. Further tasks of QIG include:

- Horizon scanning to identify future innovative technologies;
- Acting as a forum for exchange and interaction within the EU regulatory network;
- Establishing close collaboration with international partners to facilitate global regulatory convergence; and
- Assessment of medicines using innovative technologies in regulatory submissions.

DATA PROTECTION

18. First partners for data analysis and real-world interrogation network selected by the EMA (here).

The EMA issued a press release on the 23 November 2022, announcing the selection of the first set of data partners to collaborate with Darwin EU (the Data Analysis and Real-World Interrogation Network). The eight data partners include both private and public healthcare institutions and providers across six different countries including Finland, France, the UK, Estonia, Spain and the Netherlands.

19. Public Consultations launched by the EMA on data quality and real-world data sources (here).

On 10 October 2021, the EMA announced the launch of public consultations on two draft documents:

- The first draft document, the Data Quality Framework, explores the quality of data types used in regulatory decision making. The quality criteria for data used in medicine regulation is provided for, which will ensure they are fit for purpose to support benefit-risk decisions. The Framework produces a 'coherent umbrella' to 'further develop data quality assessment procedures and recommendations for current novel data types.' The public consultation closed on the 18 November 2022.

- The second draft document, the Good Practice guide for the use of EU Metadata Catalogue of Real-World data sources, is set to replace the existing catalogue of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance in the final quarter of 2023. The draft document provides direction on how to use the catalogue of real-world data that is being built currently.

HEALTHCARE

20. EMA publishes ICH guideline E19 on selective safety data collection in specified clinical trials (here).

On 6 October 2022, the EMA published the final version of the *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**") guideline E19* (EMA/782210/2022) in respect of a selective approach to safety data collection in specified late-stage pre-approval or post-approval clinical trials. The new guideline will be effective as and from 16 March 2023.

The guideline was adopted by EMA Committee for Medicinal Products for Human Use ("**CHMP**") on 16 September 2022, following drafting by the ICH.

The objective of the guideline is to "*provide internationally harmonised guidance on the use of selective safety data collection that may be applied in specific late-stage clinical trials that may be pre-approval or post-approval*."

The guideline details the appropriate types of data which would be used for selective safety data collection and data

that should generally be collected. They provide for protection of the safety and welfare of trial patients, and that routine patient care should not be compromised.

The guidelines further provide detailed explanation on general principles, implementation of selective safety data collection and practical considerations for selective safety data collection.

The guideline is intended to be read in conjunction with other ICH guidelines that are relevant to the conduct of clinical trials and clinical safety data management.

21. Highlights of fifth bilateral meeting between EMA and Medicines for Europe (here).

The EMA held their fifth bilateral meeting with Medicines for Europe on the 15 September 2022.

The following topics were discussed in the meeting:

- It was agreed by Medicines for Europe to gather supplementary feedback from its members in accessing the centralised procedure for generic medicines.
- A number of issues relating to Article 10 of Directive 2001/83/EC were raised by Medicines for Europe in respect of applications for authorisation to place medicinal products on the market.
- The importance of equal stakeholder representation, with emphasis on subject matter experts from the generic industry was highlighted.
- The development of the European Shortage Monitoring Platform ("**ESMP**") was mentioned. The EMA stated that they were working to have a functioning ESMP by Q1, 2025.

22. Positive Opinion issued by the EMA on second adapted Spikevax Vaccine (here).

The EMA issued a press release on 19 October 2022 which recommended authorisation of the second adapted Spikevax Covid-19 vaccine, targeting Omicron subvariants. The vaccine has been recommended for use for both adults and children, who are over the age of 12 and who have previously received their primary vaccination course against Covid-19.

The EMA's human medicines committee (the "**CHMP**") concluded that a booster dose of the second adapted Spikevax, produced a stronger immune response against the original strain and the Omicron subvariant BA.1, in comparison to the originally authorised Spikevax vaccine. The second adapted Spikevax vaccine is expected to be more effective in response to the BA.4 and BA.5 subvariants.

As the coronavirus evolves, the second adapted vaccine is expected to help maintain optimal protection against Covid-19.

It will be left to the national authorities in Member States to determine how the vaccine shall be rolled out to the public, whilst taking into account infection and hospitalisation rates, vulnerable populations, vaccination coverage and vaccination availability.

23. Cominarty and Spikevax vaccines recommended by EMA for children from six months (here).

A press release, published on 19 October 2022, by the EMA, concluding that their human medicines committee (the "CHMP") has recommended extending the use of Cominarty and Spikevax vaccines to include the use in children aged 6 months to 4 years for Cominarty, and children aged 6 months to 5 years for Spikevax.

Studies completed concluded that, a lower dose of Cominarty in children from 6 months to 4 years, showed a similar immune response to that of a greater dose in 16- to 25-year-olds. Further, the similar conclusion was reached for that of the Spikevax vaccines.

It was concluded by the CHMP that the benefits of both the Cominarty and Spikevax vaccines in children, outweigh the risk of them.

The EU pharmacovigilance system will assist in continuing to monitor the safety and efficacy of both vaccines across EU member states.

It will be up to the national authorities in the EU member states to determine the roll out of the vaccines, whilst taking into account the factors of infection and hospitalisation rates, vulnerable populations, vaccination coverage and vaccination availability.

24. CJEU makes preliminary ruling on M2Beautè

The Court of Justice of the European Union ("**CJEU**") ruled, on 13 October 2022, that a product which was intended to promote eyelash growth, was required to be classified as a medicinal product, rather than a cosmetic product. M2Beautè was the marketer for the product.

The ruling of the ECJ held that:

1) Article 1(2)(b) of Directive 2001/83, the "*Medicines Directive*", must be interpreted as meaning that a national authority may, for the purpose of classifying a product as a medicinal product, within the meaning of that provision, establish the pharmacological properties of that product by relying on scientific knowledge relating to a structural analogue of that substance.

2) Article 1(2)(b) of the Medicines Directive must be interpreted as meaning that a product which modifies physiological functions may be classified as a '*medicinal product*' within the meaning of that provision, only if it has specific health-promoting effects.

25. Updated guidance on applications for orphan designation published by the European Commission.

On 21 November 2022, the European Commission published updated guidance on the format and content of applications for designation as orphan medicinal products and on the transfer of designations from one sponsor to another.

The main change made in the updated guidance is in respect of the EMA's online platform on which orphan designation applications will now be submitted.

26. European Commission proposes new EU Global Health Strategy to improve global health security (here).

The European Commission adopted a new EU Global Health Strategy on 30 November. The Strategy is intended to improve global health security and deliver better health for all EU citizens. The Strategy offers an agenda for EU health policies leading up to 2030.

The Strategy builds on contributions received from a public consultation and is published alongside the first State of Health Preparedness Report.

The Strategy introduces three priorities when faced with dealing with global health challenges:

- Deliver better health and wellbeing of people across their life course;
- Strengthen health systems and advance universal health coverage; and
- Prevent and combat health threats, including pandemics, applying a One Health approach.

A "health-in-all-policies" approach is introduced to ensure a wide variety of policies genuinely contribute to health goals.

An improvement in global health security, protection of citizens from threats by stepping up prevention, preparedness and response, and early detection is sought with the introduction of the Strategy. To combat threats such as chemical, biological, nuclear or pandemic, the Strategy suggests actions such as:

- Strengthening local pharmaceutical systems and manufacturing capacities;
- Binding international rules on pandemic; and
- Stronger surveillance and detection of pathogens.

27. Joint European Commission and World Health Organisation announcement on global health co-operation (here).

The European Commission and the WHO issued a joint press release on 2 December 2022, on their co-operation to enhance global health security and architecture. The Commission and the WHO will further co-operate on the implementation of initiatives such as the EU Global Health Strategy, the European Health Union and WHO priorities for the 2022 – 2026 period.

Initiatives such as negotiations of a pandemic agreement and of amended International Health Regulations are referred to in the joint press release. The Commission and the WHO are expected to co-operate on these discussions to provide comprehensive health security for citizens around the world.

Further, both parties have also agreed to cooperate in the implementation of the EU's upcoming regulation on serious cross-border threats to health.

The Commission and the WHO are expected to begin development on a broad roadmap of digital collaboration in the first quarter of 2023.

28. Council Recommendation on a new EU approach on cancer screening published in Official Journal (here).

Further to updates provided in our previous Philip Lee Healthcare, Pharmaceuticals & Life Sciences newsletter, *Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 200 3/878/EC* was published by the European Commission on 13 December 2022. This follows the proposal adopted by the European Commission introducing a new EU approach for best practices to improve cancer screening.

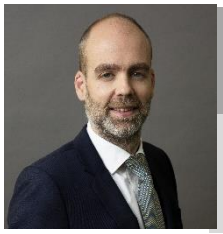
The Recommendation of 9 December 2022 supports the screening of cancer through the pathway of cancer care. This pathway is included in the framework of the European Commission's Europe's Beating Cancer Plan, which aims to improve the prevention, detection and treatment of cancer in the EU.

Regular monitoring of screening programmes, sharing of data on cancer screening, and updating of breast, cervical and colorectal cancer screening recommendations is proposed under the Recommendation.

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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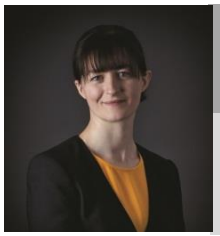

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