PHILIPLEE

Healthcare, Pharmaceuticals and Life Sciences Update

January 2024

WELCOME

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

1. GENERAL REGULATORY – EU

1. European Commission Work Programme 2024: life sciences aspects (here)

On 17 October 2023, the European Commission ("**EC**") adopted its Work Programme 2024 ("**WP**"), which includes items of potential interest to stakeholders in the life sciences sector.

Annex I to the WP, which sets out new initiatives, includes a biotech and biomanufacturing "*non-legislative initiative*". The WP states that the initiative "*will help realise the full benefits of biotechnologies and biomanufacturing*" as a means of increasing growth and labour productivity. Annex I also includes a non-legislative initiative on "*advanced materials for industrial leadership*". Both initiatives are scheduled to be delivered in the first quarter of 2024.

Annex II details proposals and initiatives to rationalise reporting requirements adopted by the EC since March 2023. This Annex references the Proposal for reform of the EU's general pharmaceutical legislation and notes that the proposed legislation will remove certain reporting requirements, including the yearly requirement for developers of medicinal products for rare diseases to submit a report to the European Medicines Agency on the state of development of those medicines.

2. Health and safety at work: informal trilogue agreement on final text of proposed Directive on exposure limit values for lead and diisocyanates (here)

On 14 November 2023, the Council of the EU, the European Parliament and the European Commission negotiators reached an informal trilogue (or provisional) agreement on the final text of the proposed Directive amending the carcinogens or mutagens at work Directive (98/24/EC) and the chemical agents at work Directive (2004/37/EC) as regards the limit values for lead and its inorganic compounds and diisocyanates.

Lead and its compounds are key occupational reprotoxicants that can affect sexual function, fertility and the development of the foetus. Diisocyanates are skin and respiratory sensitisers (asthmagens) that have the potential to cause allergic reactions such as occupational asthma and dermal occupational disease. The aim of the proposed Directive is to further improve the protection of workers from the health risks linked to exposure to these dangerous chemicals.

It is the first time in 40 years that the EU is revising the limit values for occupational exposure to lead, and the first time ever to introduce limit values for diisocyanates.

3. **Revised Product Liability Directive: Parliament and Council of the EU reach provisional agreement (here and here)**

On 14 December 2023, the European Parliament and the Council of the EU confirmed that they have reached provisional political agreement on the European Commission's proposal for a Revised Product Liability Directive. The proposed Directive will replace the Product Liability Directive (85/374/EEC). The revisions address the increase in online shopping (including from outside the EU) and new technologies (such as artificial intelligence), as well as seeking to ensure the transition to a circular economic model.

The press releases flag the areas on which a compromise was agreed, including:

- When a manufacturer of a product or a component is established outside the EU, as a last resort, the fulfilment service provider can be held liable for damages.
- Member states can provide compensation where there is no economic operator in the EU that can be held liable for damage caused by a defective product.
- Defectiveness may be presumed if the claimant faces excessive difficulties in proving it and the product is likely to be defective.
- Claimants can seek a court order requiring the business to disclose the "*necessary and proportionate*" evidence. Consumer protection authorities should assist consumers with compensation claims.
- Online platforms can be held liable for a defective product if an average consumer would believe that they (or a trader acting under their control) is providing the product.
- When a product is modified substantially, outside the original manufacturer's control, the person that made the substantial modification is liable as the manufacturer of the modified product.
- Although the definition of 'product' will be extended to digital manufacturing files and software, the rules will not apply to open-source software developed or supplied outside of a commercial activity.
- Claimants can recover non-material losses, including for psychological damage. They can also claim compensation following the destruction or corruption of data not used for professional purposes.
- In exceptional cases where symptoms are slow to emerge, there will be an extended liability period of 25 years.

The Directive is likely to be formally approved in early 2024 and will apply to products placed on the market 24 months after it enters into force (20 days after publication in the Official Journal of the EU).

4. **Statement from industry on the proposed EU Product Liability Directive (here)**

In advance of the European Parliament and Council of the EU issuing their provisional agreement on the revised Product Liability Directive, the European Federation of Pharmaceutical Industries and Associations, MedTech Europe, and others published, on 23 October, an industry statement calling for "*a major rethink*" on the European Commission's proposal for a revised EU Product Liability Directive ("**PLD**"). The industry states that as currently proposed, the PLD is unbalanced as it is too consumer friendly. For example, industry notes that the current draft disproportionately shifts the burden of proof onto defendants and could lead to abusive disclosure exercises. The industry also calls for compensation thresholds to be reintroduced and for further investigation into the effects of including software in the strict liability regime. Overall, the industry has

concerns that the PLD would lead to an increase in litigation, a reduction in innovation, and much more uncertainty for businesses.

5. **The future of Europe's medical technology regulations (here)**

   On 7 November 2023, MedTech Europe, the European trade association for the medical technology industry published a position paper proposing changes to the In-Vitro Diagnostic Medical Devices Regulation and Medical Devices Regulation. In the position paper, MedTech Europe outlines what it believes are the structural issues with the regulations, stressing that they are causing innovation to be hampered. The structural issues identified are:
   - The unpredictability and inefficiency of the certification processes regarding the information expected from companies, the requirements, and the timelines; and
   - The inefficiencies caused by the existing decentralised system of notified bodies.

6. **The MDCG issues revised position paper on compliance with the MDR and IVDR (here)**

   On 29 November 2023, the Medical Device Coordination Group ("**MDCG**") published a revised version of the notice to manufacturers and notified bodies to ensure timely compliance with the Medical Device Regulation ("**MDR**") and the In-Vitro Diagnostic Medical Devices Regulation ("**IVDR**") requirements that was published in June 2022. In the position paper, the MDCG calls on manufacturers to transition to the regulations and submit their certification applications as soon as possible, as delaying submissions could lead to a backlog of requests to notified bodies, resulting in delays and, ultimately, in product shortages. The call particularly urges manufacturers of class D IVD devices, which must transition to the IVDR by May 2025.

   In addition, and in line with some of the recommendations from industry above, the MDCG calls on notified bodies to make the certification process more efficient, transparent, and predictable, and highlights the importance of properly guiding and assisting manufacturers in the conformity assessment application. The MDCG also calls on the notified bodies to regularly provide data on the situation regarding the certifications, and to increase the transparency about their capacity and timelines, ideally on a common website compiling that of every other notified body in Europe.

7. **Chemicals safety: European Commission adopts "*one substance, one assessment*" package (here)**

   On 7 December 2023, the European Commission adopted the "*one substance, one assessment*" package, including three legislative proposals.

   The package (should it be adopted) will reform EU chemicals assessment with the aim of introducing faster, simpler and transparent processes. Under the package, regulatory tasks will be reallocated between four EU agencies, ensuring coherent and transparent safety assessments of chemicals used in products such as medical devices, toys, food, pesticides and biocides. It would also create a common data platform and introduce a "*one-stop shop*" access to data on chemicals held by the EU agencies and the Commission.

   The package also includes an evaluation report of the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (2011/65/EU).

8. **Health and safety: Amended Asbestos at Work Directive published in Official Journal of the EU (here)**

   On 30 November 2023, Directive (EU) 2023/2668 of the European Parliament and of the Council of 22

November 2023 amending Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work was published in the Official Journal of the EU.

Directive (EU) 2023/2668 updates existing rules in line with the latest scientific and technological developments. The new rules, among other things, significantly lower the current asbestos limits and provide for more accurate ways to measure exposure levels to asbestos based on electron microscopy, a more modern and sensitive method. They also provide for strengthened preventive and protective measures, such as obtaining special permits for asbestos removal and checking if there is asbestos in older buildings before starting demolition or maintenance work.

The Directive entered into force on 20 December 2023. Member states will have to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 21 December 2025.

2. GENERAL REGULATORY - IRELAND

9. Health Products Regulatory Authority publishes 2022 Annual Report (here)

On 15 November 2023, the Health Products Regulatory Authority ("**HPRA**") published its 2022 Annual Report, detailing its activities in regulating medicines, devices and other health products for the benefit of people and animals. The Report outlines the HPRA's programme of work in each of the health product areas it regulates, as well as highlighting how the national regulator responded effectively and rapidly during the year to new developments, as COVID-19 restrictions were widely relaxed and society reopened.

Dr. Lorraine Nolan, Chief Executive of the HPRA, said 2022 saw significant changes in the legislative landscape, including the implementation of the New Veterinary Regulation, Clinical Trials Regulation, Medical Devices Regulation, and In-Vitro Diagnostics Regulation.

10. New powers to be given to pharmacists (here)

From 1 March 2024, Irish pharmacists will have a power to extend prescriptions up to a maximum of 12 months for patients, if they feel it is appropriate.

Pharmacists may also decide, following assessment and the exercise of their clinical judgment, to refuse a patient's request for a prescription extension. In addition, there will be certain medications which will not be eligible for a prescription extension such as certain Controlled Drugs and medicines subject to the potential for misuse.

11. Public consultation on draft guide for health institutions who manufacture and use in-house in-vitro diagnostic medical devices in Ireland (here)

On 13 December 2023, the Health Products Regulatory Authority ("**HPRA**") announced that it is seeking input from health institutions and medical laboratories who manufacture and use in-house in-vitro diagnostic medical devices ("**IVDs**") in Ireland on the HPRA's draft guide on in-house devices. The guide aims to assist health institutions and medical laboratories that manufacture and use in-house IVDs to understand and implement the requirements of the IVDR.

The HPRA is inviting comments on this draft guide from health institutions and medical laboratories in Ireland. This consultation is being made available on the HPRA website and replies are welcome from all stakeholders.

The closing date of the consultation is 26 January 2024.

12. **Minister for Health bans the sale of nicotine inhaling products to children with immediate effect (here and here)**

Minister for Health Stephen Donnelly commenced, on 21 December 2023, section 28 of the Public Health (Tobacco Products and Nicotine Inhaling Products) Act to prohibit the sale of nicotine inhaling products such as e-cigarettes (commonly referred to as vapes) to persons under 18. The Act was signed into law on 13 December.

The new law came into effect on 22 December 2023. It is now an offence to sell a nicotine inhaling product to a child. The offence carries a penalty of a fine of up to €4,000 and/or a six-month term of imprisonment.

Minister Donnelly said: *"I committed to bringing this ban on the sale of vaping products to under 18s into law before Christmas and I am pleased that I have been able to do that by signing the commencement order. I thank colleagues in both Houses of the Oireachtas who understood the urgency for our children and who supported me to get this law enacted quickly. [...] In 2024 I will commence the remaining measures in the Act (such as around advertising, a licensing system and vending machines) and we will examine the results of our public consultation on the further regulation of e-cigarettes and on some innovative proposals in tobacco control."*

13. **Ministers for Health announce appointment of Chairperson of Commission on Care (here)**

On 14 December 2023, Minister for Health, Stephen Donnelly, and Minister for Mental Health and Older People, Mary Butler, announced the appointment of Professor Alan Barrett, Chief Executive Officer of the Economic and Social Research Institute, as the Chairperson of the Commission on Care for Older People. The independent Commission is due to be formally established in early 2024. It will examine the provision of health and social care services and supports for older people and make recommendations to the government for their strategic development. Subsequently, a cross-departmental group will be established under the auspices of the Commission to consider how best positive ageing can be supported across the life course across government departments.

3. GLOBAL INSIGHTS

14. **US Food and Drug Administration establishes Digital Health Advisory Committee (here)**

On 11 October 2023, the US Food and Drug Administration ("**FDA**") announced that it is establishing a Digital Health Advisory Committee ("**DHAC**") to provide advice on complex scientific and technical issues relating to digital health technologies ("**DHTs**"), including artificial intelligence/machine learning, augmented reality/virtual reality, digital therapeutics, wearables, remote patient monitoring, and cybersecurity. The DHAC's role will be to provide advice and recommendations on new approaches to develop and evaluate DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established FDA policy or regulation.

15. **Regulatory considerations on artificial intelligence for health of the World Health Organisation (here)**

The World Health Organisation ("**WHO**") published key principles for regulating artificial intelligence ("**AI**") for health on 19 October 2023. The document, entitled 'Regulatory Considerations on Artificial Intelligence for Health', is intended to guide governments and regulators in creating or updating policies on AI at national or regional levels. The

publication highlights the potential of AI in improving health outcomes, as well as the challenges and risks of using AI for health, such as ethical, legal, and human rights issues.

To manage the risks associated with AI systems, the publication highlights the following 6 topic areas that the WHO considers most important for regulation:

- Documentation and transparency;
- Risk management and artificial intelligence systems development lifecycle approach;
- Intended use and analytical and clinical validation;
- Data quality;
- Privacy and data protection; and
- Engagement and collaboration.

The WHO sees the main risk in the use of AI as the potential for bias arising from the data on which the AI has been trained. If an AI is trained only on data from a particular group, it will produce results that are only relevant to that group. This could have serious consequences for people who are not accurately represented in the training data. The WHO, therefore, suggests that the diversity of populations should be carefully and intentionally considered when developing an AI for health purposes. It calls on regulators to provide clear guidance on these processes.

16. **G7 agree on Guiding Principles and voluntary Code of Conduct for Artificial Intelligence Developers (here)**

On 30 October 2023, G7 leaders agreed on International Guiding Principles on AI and a voluntary Code of Conduct for AI developers under the Hiroshima AI process. These principles and the voluntary Code of Conduct will complement, at an international level, the legally binding rules that the EU co-legislators are currently finalising under the EU AI Act. The aim of the Code of Conduct and the Guiding Principles is to promote safe and trustworthy AI. The voluntary Code of Conduct will provide practical guidance and attempt to create a non-binding rulebook for AI developers. Both documents will be reviewed and updated as necessary, including through multistakeholder consultations, to ensure they remain fit for purpose and responsive to this rapidly evolving technology.

17. **US White House and Congress propose artificial intelligence legislation as Food and Drug Administration continues to act as artificial intelligence regulatory gatekeeper (here)**

As AI continues to be adopted by the pharmaceutical industry, regulatory bodies in the US and other countries are evolving to tackle challenges within the industry. These include data privacy, bias, accuracy and access, as well as appropriate uses of AI and incorporating checks and balances into its usage. On 30 October 2023, the White House's Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence instructed agencies to design plans for the appropriate and responsible use of AI across industries, including charging US Department of Health & Human Services with developing a safety program. The US Congress responded within weeks with an in-depth AI proposal (releasing the proposed Artificial Intelligence Research, Innovation, and Accountability Act of 2023, which is similar to the European approach to AI) while the US Food and Drug Administration has steadily been working to address AI.

18. **UK government announces funding to promote use of artificial intelligence in healthcare (here)**

On 29 October 2023, the UK government issued a press release reporting statements by the UK Prime Minister, Rishi Sunak, about the allocation of funding to promote the

use of AI in healthcare. The Prime Minister stated that £100 million will be provided to support the use of AI in aspects of medicine in which it will have the most potential impact.

The press release further explains that the £100 million will go towards funding the AI Life Sciences Accelerator Mission. This will facilitate research that considers how AI can be used in the eight critical healthcare missions contained within the UK government's Life Sciences Vision.

19. **New Amazon Prime benefit: unlimited doctor visits for $9 a month through One Medical (here)**

On 8 November 2023, Amazon announced it now offers 24/7 on-demand virtual care in the US as a Prime membership benefit for an additional $9 a month. The new benefit, available only to Amazon Prime members, will offer healthcare services for preventive care, immediate concerns, and chronic conditions like diabetes. $9 a month also allows Prime members access to in-person office visits at any of One Medical's hundreds of locations in the US, advertising "*longer appointments so you don't feel rushed*."

This announcement comes less than a year after Amazon first announced its $3.9 billion acquisition of the primary care provider One Medical, which had promising financials with $1 billion in revenue, but was not yet profitable at the time of the acquisition.

20. **Class action suit in US claims UnitedHealthcare used AI to wrongfully deny claims (here)**

On 14 November 2023, the estates of two deceased beneficiaries of UnitedHealthcare's Medicare Advantage plans filed a class action lawsuit against UnitedHealthcare ("**UHC**") for its alleged deployment of AI to make adverse coverage decisions about elderly patients.

According to the complaint, which was filed in the US District Court for the District of Minnesota, UHC knew that the AI model known as 'nH Predict' had a 90% error rate and that roughly 0.2% of policyholders would appeal denied claims while "*the vast majority [would] either pay out-of-pocket costs or forgo the remainder of their prescribed post-acute care*." According to the complaint, the nH Predict AI Model, as used by UHC, directs the insurer's medical review employees to cease covering care without considering an individual patient's needs. By "*eliminating the labour costs associated with paying doctors and other medical professionals for the time needed to conduct an individualised, manual review of each of its insured's claims*," the plaintiffs assert, UHC saves money by denying claims they otherwise would have paid. As alleged in the complaint, UHC's use of the tool to deny the members' post-acute coverage is "*systematic, illegal, malicious, and oppressive*."

21. **Biden - Harris administration announces new actions to lower healthcare and prescription drug costs by promoting competition (here)**

On 7 December 2023, the Biden Administration announced several new initiatives intended to "*promote competition*" in the healthcare sector. These initiatives reflect a broad range of concerns about rising costs in healthcare, including pointed references to "*price gouging*" and "*profiteering*" by private equity and big business. These initiatives build on the dozens of other regulatory efforts that President Biden ordered in his 2021 'Executive Order on Promoting Competition in the American Economy'. They also complement a number of enforcement actions, guidance statements, and rulemakings that the Federal Trade Commission ("**FTC**"), Department of Justice ("**DOJ**"), and Department of Health and Human Services ("**HHS**") have taken over the past three years to promote

competition in the healthcare sector, which those agencies highlighted in a press release issued at the same time as the White House's announcement.

The initiatives announced on December 7 include the following:

- HHS, FTC, and DOJ are taking steps to promote the sharing of data among themselves to identify so-called 'roll-up' acquisitions, such as mergers or acquisitions that may be too small to require reporting to the FTC or DOJ under the Hart-Scott-Rodino Antitrust Improvements Act, but which nevertheless can potentially create competitive issues.
- HHS and the Department of Commerce have released a new proposed framework for the exercise of 'march-in' rights under the Bayh-Dole Act. In short, for pharmaceuticals, medical devices, or other inventions whose development was funded by taxpayers, the Bayh-Dole Act allows the federal government under certain circumstances to license the invention to a third party. The new proposed framework would, for the first time, allow the government to consider pricing as a factor in determining whether to exercise these so-called 'march-in' rights.
- In the near future, the DOJ, FTC, and HHS will issue a joint Request for Information to the public, seeking information on the topic of "*corporate greed in health care*."
- HHS, FTC, and DOJ are creating new administrative roles within their respective organisations. HHS will appoint a new 'Chief Competition Officer'. And FTC and DOJ will both appoint 'Counsels for Health Care', with responsibility for leading antitrust enforcement efforts in healthcare.
- Finally, the Centres for Medicare & Medicaid Services ("**CMS**") is taking steps to increase the transparency of certain data it keeps about healthcare organisations. For the first time, CMS will publicise data about the ownership of Federal Qualified Health Centres and Rural Health Clinics. CMS will also explore ways to increase the transparency of data about Medicare Advantage plans and performance, starting with a request for information from the public on this topic to begin in early 2024.

22. Biocon Biologics Successfully Completes Integration of Viatris' Biosimilar Business in 31 Countries in Europe (here)

On 28 November 2023, Biocon Biologics, a subsidiary of Biocon Limited, announced that the integration of the Viatris' biosimilars business in 31 European countries has been successfully completed.

In Europe, Biocon Biologics portfolio includes 7 biosimilars: Insulin Aspart and Insulin Glargine, Bevacizumab, Pegfilgrastim, Trastuzumab, Adalimumab, and Etanercept. At a global level, Biocon Biologics states it has a robust pipeline of 20 assets for diabetology, oncology, immunology, ophthalmology, and bone health.

4. COMPETITION LAW

23. European Commission fines pharma companies in N-Butylbromide Scopolamine / Hyoscine cartel settlement (here)

The European Commission's (the "**EC**") investigation was triggered by an immunity application under the EC's 2006 Leniency Notice submitted by C2 PHARMA in April 2019. In September 2019, the EC conducted unannounced inspections. Following this, Transo-Pharm and Linnea applied for leniency.

The EC has decided that Alkaloids of Australia, Alkaloids Corporation,

Boehringer, C2 PHARMA, Linnea and Transo-Pharm have breached Article 101 of the Treaty on the Functioning of the EU by participating in a cartel concerning N-Butylbromide Scopolamine/Hyoscine ("**SNBB**"), which is an important input material to produce the abdominal antispasmodic drug Buscopan and its generic versions.

The EC found that the six companies co-ordinated and agreed to fix the minimum sales price of SNBB to customers (distributors and generic drug manufacturers) and to allocate quotas. In addition, the companies exchanged commercially sensitive information.

Alkaloids of Australia, Alkaloids Corporation, Boehringer, C2 PHARMA, Linnea and Transo-Pharm all agreed to settle the case under the EC's settlement procedure.

24. Judgment dismissing both appeal of fine calculation and European Commission request to remove co-operation reduction in relation to ethylene purchasing cartel (here)

On 14 July 2020, the European Commission announced its decision finding that, from December 2011 to March 2017, four ethylene purchasers (Westlake, Orbia, Clariant and Celanese) co-ordinated their price negotiation strategy against the ethylene sellers on the ethylene merchant market to influence the Monthly Contract Price ("**MCP**"), an element of the ethelyene price, to their advantage. The EC found that:

- Unlike in most cartels where companies conspire to increase their sales prices, the four companies colluded to lower the value of ethylene, to the detriment of ethylene sellers.
- The objective of the cartelists' conduct was to jointly influence the monthly MCP negotiations to their advantage, as this MCP input would lead to the lowest possible purchase price in their negotiations with ethylene sellers.
- The companies co-ordinated their price negotiation strategies before and during the bilateral MCP settlement negotiations with ethylene sellers by exchanging price-related information, which constituted the basis for establishing the MCP as an element of the ethylene price.

In November 2022, notice was published of a Clariant appeal before the General Court. The appeal sought annulment of the fine imposed in so far as it exceeded €94,405,800. Clariant also asked the General Court to reduce the fine of €155,769,000 imposed to a proportionate amount, in exercise of its unlimited jurisdiction under Article 31 of Regulation 1/2003.

Clariant claimed that:

- The EC breached Article 23(3) of Regulation 1/2003 and the principles of proportionality and sound administration by failing to exercise discretion, in so far as the EC mechanically applied a fine increase on the grounds of repeated infringement based on a set of (alleged) standard criteria without considering the circumstances of the present case. However, after dismissing each element of this first plea, the General Court held it must be dismissed in its entirety.
- The EC mechanically applied a fine increase under Point 37 of the Fining Guidelines without considering the circumstances of the present case and failed to exercise its discretion. However, the General Court held the EC had not erred in setting the level of deterrence uplift in fines. It also ruled that the fine was not disproportionate, that the fine for repeat infringement was not improperly assessed, and that the EC had clearly set out that the factors involved for general deterrence.

Finally, the General Court noted the EC's request to increase the fine by removing the 10% reduction for application co-operation, based on the existing appeal. However, the General Court also rejected the EC's counterclaim.

25. **Judgment upholding European Commission decision fining Teva and Cephalon for entering into unlawful "*pay-for-delay*" pharma patent settlement agreement (here)**

A patent settlement agreement whereby Cephalon induced Teva not to enter the market with a cheaper version of modafinil, in exchange for a package of commercial side-deals that were beneficial to Teva, infringed Article 101 of the Treaty on the Functioning of the EU ("**TFEU**") according to the European Commission. For several years, this "*pay-for-delay*" agreement eliminated Teva as a competitor and allowed Cephalon to continue charging high prices even though the main modafinil patent had long expired.

Teva and Cephalon (the applicants) brought an action before the General Court seeking the annulment of the contested decision or, alternatively, a reduction in the fines imposed.

The General Court held the following:

- The EC had not erred in the legal tests that it applied.
- The EC had not made are error of assessment in concluding that the purpose of each transaction was to serve as a transfer of value from Cephalon to Teva in consideration for Teva's commitment not to enter independently the market for generic medicines and not to compete with Cephalon on modafinil.
- The applicants' arguments were unfounded concerning the assertion that the EC erred in concluding that the settlement agreement could not produce pro-competitive effects that were demonstrated, relevant, sufficiently significant and not uncertain, which would be capable of casting reasonable doubt as to the anti-competitive object of that agreement.
- The argument that the EC did not substantiate its assertions in the contested decision with evidence relating to Teva's internal position was rejected.
- Also rejected was the argument that the EC had erred in finding that the scope of Teva's non-compete commitment exceeded the scope of Cephalon's patents.
- The applicants claimed that the EC wrongly concluded that the settlement agreement also constituted a restriction of competition by effect for the purposes of Article 101(1) TFEU. The General Court decided that it was appropriate to examine this plea, but rejected all of the applicants' arguments in this regard.
- The burden of showing that the settlement agreement met the conditions for exemption under Article 101(3) fell on the applicants. It concluded that the EC rightly found that the arguments and evidence put forward by the applicants fell short of showing that the settlement agreement, including its accompanying commercial transactions, involved sufficient efficiencies.
- Finally, the General Court rejected each of the applicants' arguments challenging the fines imposed.

26. **European Commission announces dawn raids in construction chemicals sector (here)**

On 17 October 2023, the European Commission announced that its officials have carried out unannounced antitrust inspections at the premises of companies active in the construction chemicals sector in several Member States.

The EC states that it has concerns that the inspected companies may have breached Article 101 of the Treaty on the Functioning of the EU. The construction chemicals that are the subject of the investigation are chemical additives for cement and chemical admixtures for concrete and mortar. These are ingredients that are added to cement, concrete and mortar to modify and improve their properties and provide them with specific qualities.

27. **Illumina appeals European Commission decision imposing fines for gun-jumping as a result of early implementation of Illumina/GRAIL merger (here)**

On 6 November 2023, details were published in the Official Journal of the EU of an action brought by Illumina, Inc to challenge the European Commission's ("**EC's**") decision of 12 July 2023 finding that Illumina and GRAIL breached Article 7(1) of the EU Merger Regulation (the standstill obligation) by implementing Illumina's acquisition of GRAIL while the EC's in-depth Phase II investigation into the proposed transaction was still ongoing.

Illumina, based in the US, is a global genomics company and a leading supplier of next generation sequencing systems for genetic and genomic analysis. GRAIL Inc is a US-based healthcare company that develops cancer detection tests relying on next generation sequencing systems.

The EC imposed a fine of €432,000,000 on Illumina, finding that the company strategically weighed up the risk of a gun-jumping fine against the risk of having to pay a high break-up fee if it failed to take over GRAIL. Illumina also considered the potential profits it could obtain by jumping the gun, even if it were ultimately forced to divest GRAIL. It then intentionally decided to proceed and to close the deal while the EC was still investigating.

Although GRAIL was fully aware of the standstill obligation and played an active role in the infringement, the EC decided to impose only a symbolic fine of €1,000 on the company as this was the first time it has imposed a fine for gun-jumping on a target company.

28. **Commission conditionally approves Novozymes/Christian Hansen merger (here)**

Novozymes A/S and Christian Hansen A/S are both Danish global bioscience companies. Novozymes is solely controlled by Novo Holdings A/S. Novozymes develops, manufactures and supplies industrial enzymes to multiple industries, such as agriculture, animal health food and beverage. Christian Hansen develops natural ingredients solutions for the food, nutritional, pharmaceutical and agricultural industries.

The European Commission found that the proposed merger between Novozymes and Christian Hansen, as initially notified, would have reduced competition in the market for the manufacture of one specific enzyme, lactase, using genetic modification technology.

In particular, the EC found that Christian Hansen had a project to start manufacturing this product and would very likely grow into an effective competitor within a short timeframe. The EC also found that post-merger there would not be sufficient potential competitors to exert sufficient competitive pressure on the merged entity.

To address the EC's concerns and avoid a Phase II investigation, the parties offered to divest:

- Christian Hansen's project to enter the market for the manufacture of lactase.
- Christian Hansen's lactase distribution business.
- Novozymes' lactase production facility.

On 12 December 2023, the EC released that it is satisfied that these commitments fully address its competition concerns, by paving the way for the creation of a divested business with the necessary production assets and research and development capabilities to grow as a viable competitive producer of lactase on a lasting basis.

5. DATA PROTECTION

29. Use of app to validate COVID certificate involves processing personal data (here)

On 5 October 2023, the Court of Justice of the European Union ("**CJEU**") has delivered its opinion on whether the General Data Protection Regulation ("**GDPR**") applies to the use of an app to check the authenticity of an individual's COVID-19 vaccination, test and recovery certificate (EU Digital COVID Certificate). The app was issued by the Czech Republic's Ministry of Health to help promote safe movement during the COVID-19 pandemic.

The CJEU found the app scanned the QR code on the EU Digital COVID Certificate and converted personal data from the code into a format readable by the person conducting the verification check. The conversion occurred automatically via the app, enabling the operator to consult the personal data displayed onscreen and assess whether the COVID status of the data subject being scanned complied with the certificate validation rules.

The CJEU ruled that the concept of 'processing' personal data as defined by Article 4(2) of the GDPR must be interpreted as including the use of an app issued by an EU member state for the verification of the validity of an EU Digital COVID Certificate.

30. Opinion from the European Data Protection Supervisor on Artificial Intelligence Liability Act (here)

On 11 October 2023, the European Data Protection Supervisor ("**EDPS**") adopted Opinion 42/2023 on the European Commission proposals for the revised EU Product Liability Directive and the Artificial Intelligence Liability Directive. The proposal for the AI Liability Directive aims to ensure victims of damage caused by AI can obtain equivalent protection to damage caused by other products. The EDPS fully endorses this aim and sets out a number of recommended changes to the proposal. These include:

- Ensuring individuals that suffer damage caused by AI systems produced or used by EU institutions enjoy the same protection as if the damage were caused by AI systems produced or used by private entities or national authorities.
- Extending the disclosure of evidence mechanism and the rebuttable presumption of a causal link to all AI systems, not just those defined as 'high-risk'.
- Stating that the proposal is without prejudice to EU GDPR, such that individuals can obtain redress through different avenues.

31. EU Data Act: Council of the EU adopts Regulation at first reading (here)

On 27 November 2023, the Council of the EU formally adopted, at first reading, a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act).

The Regulation aims to ensure fairness in the allocation of value from data among actors in the data economy and to foster access to and use of data. The proposal is expected to have significant impact on technology and data companies and the digital economy.

32. European Parliament agrees on text of the European Health Data Space Regulation (here)

On 28 November 2023, the members of the European Parliament working on the European Health Data Space ("**EHDS**") Regulation reached an agreement on the text for the Regulation. The agreed text aims to promote the use of aggregated health data for public interest reasons, but introduces limits on the use of these data, including bans to its use (e.g., in advertising or sharing with third parties), and making access subject to a request to national bodies.

The agreed text includes the need to obtain explicit permission from patients to use aggregated sensitive health data, provides patients with an opt-out mechanism for other health data, and the option to challenge a decision of a health data access body, either personally or through a non-profit organisation on their behalf. In addition, the agreed text underlines the importance of providing for sanctions in case of misuse of personal health data and includes the obligation to store health data in the EU. The text will have to be formally adopted by the European Parliament in a plenary vote in December and, if approved, will then need to be adopted by the Council.

33. European Health Data Space: Council agrees its position (here)

On 6 December 2023, EU Member State ambassadors agreed on the Council's mandate for a new law that will make it easier to exchange and access health data at EU level.

The EU Council presidency now has a mandate to begin negotiations with the European Parliament as soon as possible, with a view to reaching a provisional agreement on the proposed regulation.

34. CJEU judges that right of access to medical records is free of charge and unrestricted under EU's GDPR (here)

The Court of Justice of the European Union delivered, on 26 October 2023, its opinion in a case concerning the exercise of the right of access to a patient's records under Article 15 of the GDPR free of charge, where there is a right in German law which allows access to medical records subject to reimbursement of costs.

The CJEU found that the controller is under an obligation to provide the data subject, free of charge, with a first copy of their personal data undergoing processing, even where the reason for that request is not related to those referred to in recital 63. There is no provision in the GDPR for a controller to demand reasons for the request and recitals in EU law have no binding legal force and cannot be relied on either to derogate from the provisions in question or to interpret them in a manner clearly contrary to their wording. The right to access data relating to health guaranteed in Article 15 cannot be restricted, either by refusing to grant access or by requiring the payment of consideration and data subjects have the right to obtain a first copy free of charge. A piece of national legislation cannot make the data subject bear the costs.

In the context of a doctor-patient relationship, controllers are required to provide a faithful and intelligible reproduction of all the data undergoing processing, including a full copy of the documents included in their medical records (rather than summaries or compilations) where this is essential in order to enable the data subject to verify how accurate and exhaustive the data is, as well as to ensure it is intelligible. For example, this would include information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided.

6. HEALTHCARE

35. Medical Device Coordination Group publishes guidance on medical device software that works in combination with hardware (here)

On 18 October 2023, the Medical Device Coordination Group ("**MDCG**") released a guidance document on products that combine medical device software ("**MDSW**") with hardware or hardware components. The purpose of the guidance document is to provide advice on how developers of these products can demonstrate compliance with the applicable regulatory requirements under Regulation (EU) 2017/746 on medical devices ("**MDR**").

The guidance document notes that many MDSW applications require hardware or hardware components to fulfil their intended medical purpose. Most frequently, they need sensors or monitors to relay information back to the MDSW application. Manufacturers of MDSW applications that make use of such a system may also be the manufacturer of the hardware or hardware component, but the different parts of the system could alternatively be produced by different manufacturers.

The guidance document then sets out the three regulatory options that manufacturers in these various circumstances have in relation to such products:

- The hardware or hardware component can be marketed as an accessory to an MDSW;
- The hardware or hardware component can be marketed as a medical device. This would be as part of a 'system' under Article 22 MDR, as a combination with another medical device under Article 2(1) MDR, or as an integral part of a medical device; or
- The hardware or hardware component does not have an intended medical purpose and so is marketed as an integral element of a general consumer product or wearable digital product.

36. European Medicines Agency responds to European Ombudsman's questions on Policy 0070 concerning transparent publication of clinical data (here)

In a letter to the European Ombudsman, the European Medicines Agency ("**EMA**") addressed questions raised by the European Ombudsman when she opened a case seeking clarification on the relaunch of the EMA's policy on publication of clinical data for medicinal products for human use (Policy 0070). The letter to the European Ombudsman addresses how the EMA will deal with clinical trial data submitted under centralised marketing authorisation procedures completed while Policy 0070 was suspended (legacy procedures). It also addresses timelines for the relaunch.

37. European Medicines Agency adopts revised Clinical Trials Information System transparency rules (here)

On 6 October 2023, the European Medicines Agency issued a press release announcing the adoption of revised transparency rules for the publication of information on clinical trials submitted through the Clinical Trials Information System ("**CTIS**"). The revised rules will enable patients and healthcare professionals to access clinical trial information both faster and in a more efficient way whilst striking a balance between transparency of information on clinical trials and protection of commercially confidential information.

The revised rules were drafted following a public consultation in mid-2023. In the preamble to the revised rules, the EMA explains that stakeholder feedback during the consultation identified several areas for amendment. Based on that

feedback, the rules have been amended in the following ways:

- Clinical trials information will be published by reference to structured data fields and documents, relevant for the public and which correspond to the needs of patients and clinical researchers. Implemented changes will allow the public to easily identify what they are looking for by reducing complexity of information in CTIS. The information will also be more easily searchable through structured data fields.
- The number of documents that need to be published will be reduced to decrease the complexity and workload for users engaged in the necessary redactions.
- The deferral mechanism will be removed for every trial category. That mechanism permitted sponsors to delay the publication of certain data and documents for up to seven years after the end of a clinical trial to protect personal and commercially confidential information. This will result in key documents being published earlier.

38. **European Commission publishes factsheet on implementation of Health Technology Assessment Regulation (here)**

On 5 October 2023, the European Commission published a factsheet on Regulation (EU) 2021/2282 on health technology assessment ("**HTA Regulation**") summarising its governance and implementation in preparation for its application from 12 January 2025.

The factsheet sets out the following timeline for the HTA Regulation's implementation:

- 2023-2024 - Adoption of implementing acts and methodological and procedural guidance.
- 12 January 2025 - New oncology medicines and advanced therapy medicinal products will be assessed at EU level.
- 13 January 2028 - Orphan medicinal products to be added to the joint work.
- 13 January 2030 - All new medicines will come under the scope of the HTA Regulation.

39. **'Co-ordination Group for Mutual Recognition and Decentralised Procedures – human' revises position paper on use of mobile scanning technologies in medicines packaging (here)**

On 4 October 2023, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – human ("**CMDh**") published an updated version (dated January 2023) of its position paper on the use of mobile scanning and other technologies in medicines packaging and labelling.

40. **European Medicines Agency amends explanatory note on pharmacovigilance fees to take account of increases (here)**

On 4 October 2023, the European Medicines Agency published an updated version of its 'Explanatory Note on Pharmacovigilance Fees Payable to the European Medicines Agency'. The updates amend the Explanatory Note to take account of the increases in pharmacovigilance fees that were implemented by Commission Delegated Regulation (EU) 2023/1766. The new fees came into effect on 4 October 2023.

The pharmacovigilance fees were increased by 10.4%, which was in accordance with the level of inflation recorded by the Statistical Office of the EU for 2022. That increase is carried through to the discussion in the Explanatory Note, which sets out how pharmacovigilance fees are calculated and imposed. It also now states the new fee for each pharmacovigilance procedure.

41. **European Commission announces launch of Cancer Image Europe Platform prototype (here)**

On 29 October 2023, the European Commission issued a press release announcing that the first prototype of the digital infrastructure for the Cancer Image Europe Platform has gone live. The Platform is a key aspect of Europe's Beating Cancer Plan.

The press release explains that this first version of the Platform has been delivered by the project, which is part of the European Cancer Imaging Initiative. These initiatives aim to develop the infrastructure of the Platform so that it ultimately includes more than 100,000 cancer cases by 2025.

42. **European Medicines Agency publishes details on solidarity mechanism and toolkit for dealing with critical medicine shortages (here)**

On 24 October 2023, the European Medicines Agency issued a press release discussing the steps that it is taking to address shortages of critical medicines in the EU. The two measures that the press release focuses upon, and for which additional information is provided, are the solidarity mechanism and the toolkit. Both measures have been developed by the EMA Medicines Shortages Steering Group ("**MSSG**").

The solidarity mechanism is a voluntary arrangement by which an EU member state can request assistance in obtaining stocks of a medicine during a critical shortage. The mechanism should be used as a last resort when Member States have exhausted other possibilities.

The toolkit sets out the types of actions that the MSSG may consider recommending when critical medicines shortages have been escalated for its attention. In so doing, the toolkit supplements the communication that was published by the European Commission on 24 October 2023 in which such strategies were discussed.

43. **European Commission issues communication addressing medicine shortages in EU (here)**

On 24 October 2023, the European Commission published a communication entitled 'Addressing medicine shortages in the EU' together with a press release, fact sheet and Q&A. The Communication describes the measures that the EC is taking to address medicines shortages in the EU during winter 2023/2024 and beyond.

The Communication acknowledges that the EU remains vulnerable to the type of medicine shortages that occurred during winter 2022/2023 and discusses measures that have already been implemented. These include the drafting of the new pharmaceutical legislation which specifically seeks to enhance security of supply within the EU, dialogue with the pharmaceutical industry to ensure maintenance of supply, and joint procurement, stockpiling and monitoring initiatives.

44. **European Medicines Agency begins public consultation on draft three-year work plan for Methodology Working Party (here)**

On 30 October 2023, the European Medicines Agency released a draft revised consolidated three-year work plan for its Methodology Working Party ("**MWP**") to cover the period May 2022 to December 2024. The draft work plan sets out the strategic, operational and tactical objectives of the MWP, and how it intends to achieve those objectives, including through the publication of guidance documents and by engaging in other activities to facilitate the regulatory compliance of medicinal products.

The draft work plan describes the MWP's strategic goals, which are to provide methodological support to the

operational work of the European Medicines Regulatory Network and to promote the use of best methodological practice across the EU's regulatory frameworks for medicines. The draft work plan explains that the MWP will seek to achieve those goals in the short term and the long term through the publication of guidelines in the following areas:

- Clinical pharmacology;
- Modelling and simulation;
- Real world evidence;
- Clinical trial modernisation;
- Pharmacogenomics for precision medicine; and
- Data science and AI.

45. **Third Health Programme 2014-20: European Commission adopts Final Evaluation Report (here and here)**

On 15 November 2023, the European Commission adopted its Final Evaluation Report on the Third Health Programme 2014-20. It is supported by an external study carried out by a contractor of the EC between July 2021 and October 2022. Its purpose is to assess the management and implementation of the Third Health Programme, including the follow-up to recommendations of past health programmes' evaluations.

The Final Report concludes, among other things, that the Third Health Programme:

- Has been largely relevant in addressing the health needs expressed by European countries and citizens over the period of its implementation and has adapted to changes in health needs over time, being flexible enough to respond to emerging health needs such as the migrant/refugee crisis and the COVID-19 pandemic.
- Has been effective in achieving its objectives, as shown by the progress made on the indicators designed to measure the Programme's performance.
- Has been effective in enabling more co-operation and co-ordination among member states and overall improvements in health policy developments across the EU.

46. **European Medicines Agency announces publication of first harmonised electronic product information for medicines (here)**

On 8 November 2023, the European Medicines Agency issued a press release announcing that, together with the Heads of Medicines Agencies ("**HMA**") and the European Commission, it has published harmonised electronic product information ("**ePI**") for 25 selected human medicines on its Product Lifecycle Management Portal ("**PLMP**"). ePI is intended to increase the accessibility of product information and make it easier to update. As such, this initiative is an aspect of a pilot which is intended to facilitate the transition to the publication of ePI for medicines evaluated at both the EU and national level.

The press release explains that companies participating in the pilot submitted ePI in the course of their regulatory applications. Those applications have been evaluated by the EMA or the regulatory authorities of Denmark, the Netherlands, Spain or Sweden. The ePI for the medicinal products has accordingly been published on the PLMP in English (for centrally approved medicines) or in the language of the relevant national authority (for nationally approved medicines). ePI data can also be accessed via a public application programming interface.

47. **European Medicines Agency publishes draft concept paper on clinical development of vaccines for immunocompromised individuals (here)**

On 1 November 2023, the European Medicines Agency began a public consultation on a draft concept paper that discusses the need to

supplement the existing guideline on clinical evaluation of vaccines ("**Guideline**") with guidance on the specific needs of immunocompromised individuals.

The draft Concept Paper notes that immunocompromised individuals are often excluded from vaccine clinical trials because of concerns that their involvement may produce confounding data. As a result, such trials may yield results that lead to suboptimal dosing regimens and reduced vaccine coverage for such individuals, despite immunocompromised individuals being among those most in need of the protection afforded by vaccines.

The draft Concept Paper recognises that the Guideline currently provides little guidance on how the needs of immunocompromised individuals may be accommodated within the design of vaccine clinical trials. As such, the Vaccine Working Party and the Emergency Task Force recommend the development of an addendum to the Guideline, to address issues such as:

- Design of safety and immunogenicity studies in immunocompromised individuals and how efficacy could be inferred.
- Selection of immunocompromised subpopulations that are sufficiently large to be feasible for clinical trial conduct (and which could improve extrapolation of findings).
- Investigation of the need for alternative doses or dosing regimens for immunocompromised individuals, in studies intended to determine the effect of immunocompromised status on immune responses.
- Consideration of specific safety concerns and implications for the safety database.
- Definitions of and considerations for immunocompromised subpopulations in which to conduct studies, depending on the infectious agent and type of vaccine.

48. Standard of proof for therapeutic effect (European Patent Office) (here)

An appeals board of the European Patent Office ("**EPO**") has considered the standard of proof required in EPO proceedings to show the claimed therapeutic effect of a pharmaceutical. They stated that EPO proceedings applied the principle of free evaluation of evidence. This meant that the competent EPO body determined facts taking into account the evidence available in the proceedings and on the footing that one set of facts was more likely to be true than the other. There were no reasons not to apply this principle when deciding whether it was credible that a compound or composition induced a therapeutic effect.

In EPO proceedings, it was not necessary to perform a statistical analysis of the results and to determine a specific confidence interval, as compared to the usual requirement in biomedical research and by health authorities granting marketing authorisations for medicinal products.

49. European Medicines Agency fees: European Parliament adopts first reading position on proposed Regulation (here)

On 12 December 2023, the European Parliament plenary session adopted its first reading position on the proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 and repealing Council Regulation 297/95 and Regulation (EU) 658/2014 (EMA Fees Regulation).

The EMA Fees Regulation aims to provide a sound financial basis to support the EMA's operations and provide for fee and remuneration

amounts that are cost based. It also aims to simplify the legislative basis for the EMA's fees and charges by bringing together, in a single legal instrument, fee rules that are currently governed by two separate regulations. In addition, the proposal intends to make the fee system future proof by introducing regulatory flexibility in the way it is adjusted.

50. Data-based study quantifies adverse impact on innovation and market access of key aspects of EU Pharmaceutical Package (here)

In November 2023, the European Federation of Pharmaceutical Industries and Associations (EFPIA) published a study, prepared by the strategic market access consultancy Dolon, providing for a data-based impact assessment of the proposed Pharmaceutical Package of the European Commission.

The Study relies on risk-adjusted net present value ("**rNPV**") modelling to assess the potential impact of key aspects of the Proposal (changes to regulatory approval, modulation of regulatory data protection ("**RDP**"), introduction of an unmet medical need definition and of launch-and-supply conditionalities) on real-life investment and launch decisions by pharmaceutical companies. An rNPV model quantifies the strength of the economic proposition for investment or launch in a single figure. In doing so, it provides a conceptual framework for assessing the Proposal's impact.

The Study relies on two variations of the rNPV model. The first variation model quantitatively assesses the impact on innovation at the time of initiation of clinical development (phase I of R&D) of the Proposal's proposed modulation of the RDP duration (reduction of default RDP duration from eight to six years, with possibilities for extension) for medicines which rely on RDP as their last form of IP protection (i.e., more than one in three medicines – RDP products). The model relies on a mix of inputs, including Technopolis' impact assessment as prepared at the Commission's request, the published academic literature and EFPIA resources:

- While the Proposal imposes EU-wide market release and continuous supply within two years of marketing authorisation as a condition to regain two years of RDP, the Study's data show that this condition will not be satisfied by any product. This is because, to date, no RDP product has been successfully launched in all 27 EU Member States (the maximum number of countries is 20).
- The Study finds that one in five projects (22%) to research and develop RDP products will become economically inviable by 2035. This represents a loss of 50 medicines, which corresponds to up to 16 million Years of Life Lost and a loss of up to €2 billion of annual R&D activity within the EU. Thus, the EU's position as a global innovator will deteriorate further as compared to the USA, Japan and China. Germany (- €626 million), Belgium (- €381 million) and France (- €326) are set to be hit hardest.
- Within the pharmaceutical sector, SMEs will be most impacted by the Proposal. The Study estimates that only about one in ten SME-developed products will be economically viable.

The second variation model assesses the economic case for launch across EU Member States at the time of marketing authorisation. Despite being schematic in the absence of reliable public data, the Study's model finds that reducing RDP duration makes filing across all Member States even more challenging for industry than it already is today. Again, this holds especially true for SMEs, and is more pronounced for rare diseases than more prevalent conditions.

ABOUT

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