

### WELCOME

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

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.

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

### GENERAL REGULATORY – IRELAND

1. **The Windsor Framework and its Effect on Medicines** ([here](#)).

The Windsor Framework, as recently negotiated between the EU and the UK, provides clarity as to how a smooth supply chain for medicines will be ensured following the UK's departure from the EU.

The following measures relating to medicines has been agreed under the Windsor Framework:

- The UK's Medicines and Healthcare products Regulatory Agency will be responsible for approving all drugs for the whole UK market;
- Medicines approved by the European Medicines Agency (“EMA”) will no longer be placed on the NI market, but NI manufacturers can place medicines on the EU market;
- The Falsified Medicines Directive is disapplied for medicines supplied to Northern Ireland; and
- Northern Ireland will be reintegrated back into a UK-only regulatory environment for the provision of innovative drugs to patients, with the EMA removed from having any role.

### GENERAL REGULATORY – EU

2. **Extension of the MDR and IVDR Transitional Periods** ([here](#)).

*Regulation (EU) 2023/607* has amended the Medical Devices Regulation (the “MDR”) and the In Vitro Diagnostics Regulation (the “IVDR”) by extending the transitional period set out in both regulations.

The Regulation has the effect of extending the transitional period by which providers must adapt to the new rules for

medical devices and in-vitro diagnostic devices as follows:

- (i) For medical devices covered by a certificate or a declaration of conformity issued before 26 May 2021 – the transitional period will be extended until 31 December 2027 (for medium/lower risk devices) and until 31 December 2028 (for higher risk devices); and
- (ii) For class III implantable custom-made devices – the transitional period will be extended until 26 May 2026.

The Regulation has removed the “sell-off” date for devices too (*i.e.*, the end date after which devices that have already been placed on the market and remain available for purchase should be withdrawn).

### 3. Commission Q&A guidance on extended MDR and IVDR transitional periods ([here](#)).

The Commission published a Q&A guidance document on the extension of the MDR transitional period and removal of the ‘sell off’ period for medical and IVDR devices.

The guidance document provides answers on the practical aspects relating to the implementation of *Regulation (EU) 2023/607* which amended the transitional periods of the MDR and the IVDR.

Questions and answers on the following aspects are set out in the guidance document:

- The scope of the extension of the transitional period;
- The evidence of the extended transitional period;
- The conditions to be fulfilled to benefit from the extended transition period;

- The appropriate surveillance to be performed by notified bodies; and
- The deletion of the “sell-off date”.

### 4. Amendment of MDR and IVDR reassessment period ([here](#)).

*Commission Delegated Regulation (EU) 2023/502* and *Commission Delegated Regulation (EU) 2023/503* will amend the mandatory reassessment period required under the Medical Devices Regulation and the In Vitro Diagnostic Devices Regulation from five years to three years.

### 5. Scientific advice for high-risk medical devices launched by EMA ([here](#)).

The EMA has launched a pilot programme whereby advice will be provided on the intended clinical development strategy for certain high-risk medical devices.

Free advice will be given to ten selected applicants on the clinical development strategy to be adopted for such high-risk devices.

The pilot will prioritise advice for the following devices:

- Orphan devices and devices for paediatric use;
- Devices treating medical conditions that are life threatening or cause permanent impairment of a body function; and
- Novel devices with a possible major clinical or health impact.

The first five applicants for the pilot are due to be selected in April 2023.

### 6. Inquiry into reclassification of brain stimulation devices under MDR ([here](#)).

The European Ombudsman announced that an inquiry will be conducted into the reclassification of brain stimulation devices as Class III devices under the *Medical Devices Regulation (EU) 2017/745*.

The inquiry will be conducted on the back of a complaint regarding the failure of the Commission to take an evidence-based and participative approach in the development and adoption of the MDR and the classification of devices therein.

The Ombudsman has requested the following information from the Commission:

- The extent of data used for the reclassification of equipment intended for brain stimulation by the Commission;
- The actions carried out by the Commission to check the currency, completeness and accuracy of that data; and
- The consultation process that the Commission followed prior to making the Implementing Regulation.

The European Ombudsman is due to meet with the Commission to discuss the ongoing inquiry in April 2023.

#### **7. Use of CTIS now mandatory for new clinical trial applications ([here](#)).**

It is now obligatory for new clinical trial applications to be filed on the Clinical Trials Information System (CTIS).

This new obligation follows the one-year transitional period, where sponsors could choose whether to submit a new clinical trial application under the Clinical Trials Directive or under the new Clinical Trials Regulation - this optionality to submit applications under the Directive or the Regulation has now been removed.

#### **8. EMA mid-point report on regulatory science in the EU published ([here](#)).**

The EMA published their mid-point report in March 2023, summarising their mid-point achievements to date on their regulatory science strategy.

The EMA's Regulatory Science Strategy was first published in March 2020, with the EMA recognising that the pace of innovation had accelerated dramatically in recent years.

The report highlights some of the EMA's Regulatory Science Strategy's achievements:

- Fostering innovation in clinical trials;
- Promoting use of high-quality, real-world data in decision making;
- Reinforcing patient relevance in evidence generation;
- Contributing to health technology assessment bodies' preparedness and downstream decision making for innovative medicines; and
- Supporting developments in precision medicine, biomarkers and 'omics.

A final report setting out the EMA's achievements in the regulatory science strategy space is expected to be published in 2026.

#### **9. HERA, ECD and EMA sign agreements to cooperate on health emergency prepared-ness and response ([here](#)).**

The Commission's Health Emergency Preparedness and Response Authority (HERA) has signed agreements with the ECDC, and EMA, in order to promote co-operation and coordination between the organisations when dealing with public health emergencies.

The agreement between HERA and EMA states that they will collaborate on issues such as:

- The assessment of serious cross-border health;
- Identification of medical countermeasures;
- Identification of vulnerabilities related to the development, production and procurement of medical countermeasures;
- Coordination in the event of a recognised public health emergency;
- Contribution to reinforcing the global health emergency preparedness.

The areas which HERA and the ECDC will collaborate on include the following:

- Assessment of health threats relevant to medical countermeasures;
- Promoting research and development of medical countermeasures;
- Strengthen knowledge in preparedness and response to related medical countermeasures;
- Contribution to reinforcing the global health emergency preparedness.

#### 10. EESC opinion on proposed revision of Product Liability Directive ([here](#)).

The European Economic Social Committee (the “**EESC**”) has published their opinion on the European Commission’s proposal for a revision of the Directive on liability for defective products (the “**Directive**”).

The EESC, in its opinion, acknowledged the need to adapt the liability for defective products regime for future digital challenges. It further highlighted that the revision of the Directive addresses several consumer demands, including identification of those liable for defective

products, access to information and compensation, and extended coverage to cover digital and psychological damage caused by defective products.

Calls for greater consistency in the wording of identical obligations amongst different legislative instruments relating to defective products was emphasised in the EESC’s opinion as to the reason that the Directive should be revised.

### COMPETITION LAW

#### 11. Novartis fined for abuse of collective dominant position held.

The Belgian Competition Authority imposed a fine of €2.78m upon pharmaceutical firm Novartis Pharma SA and Novartis AG (“**Novartis**”) in January 2023 for abusing a collective dominant position that Novartis held with another pharmaceutical firm for a product relating to therapies for wet age-related macular degeneration.

The Belgian Competition Authority found that Novartis continued to warn ophthalmologists regarding the risks of off-label use of its product Avastin, following the release of studies that no longer allowed it to do so without qualification or reference to the scientific uncertainty created by the studies. Under precedent of the CJEU, the Belgian Competition Authority found these communications to be misleading. Notably the other party held to enjoy collective dominance was not fined in this instance.

### DATA PROTECTION

#### 12. Guidance published by the EMA on application of transparency principles to pilot evaluating raw data ([here](#)).

The EMA released its guidance on the application of its transparency principles to the raw data proof-of-concept pilot,

evaluating whether raw data assists in the assessment of marketing authorisation applications and post-authorisation applications, on 1 February 2023.

The guidance aims to clarify the application of the EMA's existing data transparency principles and its current practice and processes, with focus on:

- The EMA's policy on access to documents which describes the rules the Agency applies to access to documents requests; and
- The EMA's policy on the publication of clinical data for medicinal products for human use (Policy 0070).

## HEALTHCARE

### 13. CJEU judgment on the advertising of medicinal products ([here](#)).

The CJEU, in *EUROAPTIEKA SIA* (Case C-530/20), handed down judgment in response reference for a preliminary ruling on whether a Latvian ban on the advertising of medicinal products on the basis of price, special sales or bundled sales of medicinal products was compatible with EU law.

The CJEU held that the Latvian prohibition on the advertisement of medicinal products based on price was compatible with EU law given that the rationale being it was to discourage the irrational use of medicinal products which may derive from advertisements based on pricing.

### 14. CJEU judgment on medicinal products by presentation ([here](#)).

The CJEU has given a judgment on the application of EU laws on medicinal products and medical devices to products that have been “presented” as having properties for treating or preventing disease.

The Court ruled that *Article 2(2)* of *Directive 2001/83* applies to both ‘*medicinal products by presentation*’ as well as ‘*medical products by function*’, as referred to in *Article 19(2)(a)* and *1(2)(b)* of that Directive respectively.

It was further ruled that a product cannot fall within the definition of “medical device” under *Council Directive 93/42* or ‘*medicinal product by function*’ under *Directive 2001/83*, where its principal mode of action is not scientifically established. Scientific establishment of the mode of action and establishment as shall be assessed by national courts on a case-by-case basis.

### 15. CJEU judgment on national measures controlling prices of individual medicines ([here](#)).

The French Conseil d'État referred a question to the CJEU as to whether *Article 4(1)* of *Directive 89/105/EEC* is to be interpreted as meaning that the concept of a “*price freeze... on all medicinal products or on certain categories of medicinal products*” applies to a measure whose purpose is to control the prices of certain medicinal products, on an individual basis.

The CJEU concluded that *Article 4(1)* of the Directive does not apply to a measure, the purpose of which is to control the prices of certain medicinal products on an individual basis.

### 16. CJEU judgment on a reference for preliminary ruling regarding EU legislation on medicinal product safety features ([here](#)).

A judgment was handed down by the CJEU in response to a reference for a preliminary ruling which concerned the interpretation of certain articles of *Commission Delegated Regulation (EU) 2016/161* laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

The Spanish Courts posed the question to the CJEU as to whether the relevant EU provisions of the Regulation were compatible with national provisions that:

- Create an interface as a tool for use with the repository, which is owned and managed by the State administration.
- Require pharmacies to use that interface when they supply medicinal products financed by the national health system.
- Mandate that where no agreement is reached between the State administration and the entity managing the national repository in relation to integrating the interface concerned into the repository, integration may be required by ministerial order.

The CJEU held that the relevant articles must be interpreted as not precluding national legislation providing for the creation of an interface, as a tool for accessing the national repository, that is owned and managed by the public authorities.

The Court further found that the relevant articles were not precluding national legislation requiring pharmacies to use an interface owned and managed by the public authorities when they supply medicinal products financed by the national health system and requiring the entity managing the national repository to integrate that interface into the national repository.

#### **17. 2022 Human Medicine highlights published by EMA ([here](#)).**

The EMA published its Human Medicine Highlights 2022 on 16 February 2023, providing data on the number of medicines which were authorised throughout 2022.

The EMA recommended 89 medicines for marketing authorisation during 2022, 41 of which included a new substance that

had never before been authorised in the EU.

Public health emergencies were a key focus for the EMA in 2022. The document summarises the most important recommendations on vaccines and treatments for Covid-19.

Special initiatives introduced or maintained in 2022 are highlighted in the report, including accelerated assessment for medicines that address public health needs.

#### **18. Review of pseudoephedrine-containing medicines ([here](#)) .**

The EMA's Pharmacovigilance Risk Assessment Committee ("PRAC") announced that it has begun a review of pseudoephedrine-containing medicines, following the release of data suggesting the medicines possible association with posterior reversible encephalopathy syndrome and reversible cerebral vasoconstriction syndrome.

The PRAC is to review available evidence and determine whether the marketing authorisations for pseudoephedrine-containing medicines should be maintained, varied, suspended or withdrawn in the EU.

The announcement explains that pseudoephedrine-containing medicines are authorised in various EU Member States alone, or in combination with medicines to treat symptoms of a cold and flu.

Following the review, the PRAC will make a set of recommendations, which will then be forwarded to the Committee for Medicinal Products for Human Use ("CHMP"), who will then adopt an opinion.

The final stage of review is the adoption by the European Commission of a legally binding decision applicable in all Member States.

**19. Updated guidance on unforeseen variations to marketing authorisations released by EMA ([here](#)).**

The Court dismissed Polpharma's action and ordered Polpharma to pay the parties' costs.

The EMA has released an updated version of its guidance document on EMA Procedural Advice on Recommendations on unforeseen variations according to *Article 5 of Commission Regulation (EC) No 1234/2008*.

The updated guidance applies to medicinal products for human use that have been authorised through the centralised procedure.

A number of changes have been made to the guidance document, provided for in Annex 1 of the document, which include amendments to the process for requesting a recommendation for classification to reflect new EMA practices and format types, the applicable timeframe and the manner in which requests for recommendations for classification will be decided.

**20. CJEU judgment on global marketing authorisations ([here](#)).**

The CJEU has handed down judgment in *Commission v Pharmaceutical Works Polpharma SA and EMA* (Joined Cases C-438/21 P, C-439/21 P and C-440/21 P) regarding global marketing authorisations.













The Court, in upholding the Commission's decision, held that two products (*Fumaderm* and *Tecfidera*) marketed by Biogen Netherlands BV did not belong to the same marketing authorisation within the meaning of Article 6(1) of the *Medicines Directive*.

The CJEU set aside the judgment of the General Court which annulled the EMA's decision and concluded that *Fumaderm* contained another active substance with a different therapeutic moiety, in comparison to *Tecfidera*, and such difference could not be classified as a variation or extension under Article 6(1).

## 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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