MARIMÓN
ABOGADOS

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Dear all,

We hope this new edition of our Healthcare & Competition newsletter finds you well.

While the Covid-19 crisis is hopefully in definite retreat, European regulators and competition authorities are now very conscious of their vulnerability faced to global sanitary issues. European countries perceive the extent to which State intervention and State collaboration is necessary to ensure continuous and secure drugs' supply and fostering innovation in the healthcare sector.

From genomic sequencers to online pharmacies, several competition authorities are proving very active in this field, with a clear emphasis on consumers' welfare, identified with access to affordable medicines easily, rapidly and safely.

We will offer you an overview of the ongoing tendencies and close the Newsletter with se veral short highlights that may deserve a closer look in the near future.

We wish you a pleasant reading!

Competition law Team, Marimón Abogados

Revision of the EU general pharmaceuticals legislation

Following the sanitary crisis rooted in the Covid-19 pandemic, which revealed issues related to the shortages and disruptions in the supply of drugs and medical devices due to an excessive dependence on foreign sourcing, the European Union decided to draw lessons and change its legislation related to medication for human use.

In 2020, the Commission released a Communication on a Pharmaceutical Strategy for Europe[1]. It is made up of long-term projects aimed at making the European Pharmaceutical System more patient-centred, future-proof, and crisis-resistant, intended to complement other initiatives such as the European Health Data Space (EHDS)[2] and the EU Health Emergency Preparedness and Response Authority (HERA)[3].

Within this framework, in the last quarter of 2021, the EU launched a public consultation[4] on a Revision of the EU general pharmaceuticals legislation,[5] in order to support the evaluation of the existing general pharmaceutical legislation on medicines for human use, as well as the impact assessment of its revision to ensure a future-proof and crisis-resistant medicines regulatory system. The revision aims at ensuring access to affordable medicines, fostering innovation, improving security of supply, and adapt to new scientific and technological developments.

[1] Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Pharmaceutical Strategy for Europe, Brussels, 25.11.2020, COM(2020) 761 final.

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space_en

[3] HERA is already operational. It was launched on 16 September 2021 as a new European Commission Directorate-General, dependent on the EU Commissioner for Health and Food Safety. Its current annual work plan has a budget of €1.3 billion in 2022 to prevent, prepare for and rapidly respond to cross-border health emergencies. See https://ec.europa.eu/info/departments/health-emergency-preparedness-and-response-authority_en#department_plans

[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-de-la-legislacion-general-farmaceutica-de-la-Union/public-consultation_en

[5] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

As an overview of the responses to the public consultation different topics were raised by stakeholders. Regarding citizens, responses covered topics as supporting the sustainability of health systems especially as regards high medicine prices, a call for transparency in supply chains and pharmaceutical R&D costs, and the fact that EU regulatory framework should consider global health (i.e. distribution of medicines to low and middle income countries). The industry on its side was concerned about the importance of an attractive regulatory framework for global investment, the impact and importance of parallel trade for security of supply and the call for the digitalisation of medicines regulatory processes. The topics identified by public authorities and healthcare players were a better comparative safety assessment, incentives for increasing EU manufacturing of important drugs and APIs and transparency of medicinal product R&D and market launch costs.

Drawing from this feedback, the Commission is expected to adopt its new regulatory proposal in the fourth quarter of 2022.

As previously stated, establishing an EHDS is also a Commission priority. The aim is making the most of the potential of digital health to provide high-quality healthcare, reduce inequalities, and promote access to health data for research and innovation, while ensuring that citizens have control over their own personal data. Complex issues are at the core of the initiative, such as the exchange and access to health data, the fragmentation of digital standards and the limited interoperability between healthcare systems, as well as the use of digital services in health.

A public consultation regarding the EHDS also took place on 2021[6], and the Commission launched its regulatory proposal on 3 May 2022[7]. It provides a legal framework for primary and secondary use of electronic health data mainly for innovation purposes, so large amounts of high-quality health data will be available for the development of life-saving treatments, vaccines or other medical devices. The project is to ensure the free movement of healthcare data for the benefit of patients, researchers, businesses and public administrations. However, it will not constitute an unlimited right. The industry will be permitted to access and use the secondary health data when it´s granted permission by the national health data bodies, on an anonymised format, aligning with the GDPR[8].

Last quarter of 2022 may be therefore decisive for the regulatory landscape of the pharmaceutical sector in Europe. We will keep you duly informed.

In the spotlight: Illumina's acquisition of Grail still under EU scrutiny

Grail is a US company that defines itself as a *"healthcare company whose mission is focused on multi-cancer early detection"*. The company leverages genomic sequencing and data science tools to develop blood tests for early cancer detection, particularly based on genomic sequencing technology.

Illumina is an American company operating in the same market. It develops, manufactures and markets among other products, genomic sequencers that are essential for Grail and its competitors

[6] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/public-consultation_en

[7] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final.

[8] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

in the development and implementation of cancer screening tests. It was Illumina itself that founded Grail in 2016, which was later spun off in the same year.

In March 2021, the US Federal Trade Commission (FTC) challenged the proposed acquisition of Grail by Illumina. The FTC filed an administrative complaint[9] in order to block the proposed acquisition, alleging that Illumina was likely to restrain Grail's competitors access to essential input, potentially diminishing innovation in the US market for multi-cancer early detection. The case is still pending.[10]

In Europe, the French Competition Authority (AdC) considered that, if the transaction was accepted, there was a risk that Illumina would make access to its sequencers more complex for Grail's competitors in the sector, by increasing their price or by lowering their quality. Therefore, although the acquisition did not meet the regular turnover thresholds that trigger merger control, the AdC made use of the new and controversial interpretation of Article 22 of the EU Merger Regulation and referred the acquisition to the European Commission.[11] Several other national competition authorities adhered to the French referral, which was consequently challenged by Illumina before the General Court.[12]

Anyhow, Illumina decided to complete the acquisition of Grail in August 2021 while the EU merger control investigations were still ongoing, thereby allegedly violating their standstill obligation. The European Commission answered with the adoption of binding interim measures[13] to prevent the early merger to harm competition while continuing with their merger control investigation.

In detail, the EU measures focus on keeping both companies separate in practice despite the formal merger, e.g., forcing Grail to be run separately by a hold manager independent from Illumina, prohibiting both companies to share confidential business information with each other, prohibiting Illumina to favour Grail over its competitors in any way and strongly urging Illumina to prepare for divestment in case the merger were declared incompatible with the internal market.

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[9] https://www.ftc.gov/system/files/documents/cases/redacted_administrative_part_3_complaint_redacted.pdf

[10] https://www.ftc.gov/legal-library/browse/cases-proceedings/201-0144-illumina-inc-grail-inc-matter

[11] https://www.autoritedelaconcurrence.fr/en/press-release/european-commission-opens-review-illuminas-acquisition-grail-under-procedure-article

[12] Case T-227/21 (pending).

[13] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5661

These measures may be in force until the end of the investigation and compliance will be closely monitored by the Commission. For any infringement, the Commission may impose fines up to 5% of the party's average daily turnover and/or fines of up to 10% of their annual worldwide turnover. Furthermore, in case the Commission's investigation ultimately finds that the merger is incompatible with the internal, Illumina may be forced to undo the merger and be subject to additional fines for gun jumping.

As for the most recent developments, Illumina's recent offer of remedies to address competition concerns would not seem sufficient for the European watchdog.[14] New chapters of this intriguing show will surely follow…

Excursus on gun jumping and the new interpretation of article 22 EUMR

Gun jumping is understood in competition fora as the implementation of a concentration without awaiting approval from the relevant competition authority. It may entail very severe fines and it is an absolute enforcement priority for competition authorities as the following sample of recent cases demonstrate:

On 18 May 2022,[15] the General Court confirmed a European Commission € 28 million fine for gun jumping concerning Canon's acquisition of Toshiba Medical Systems Corporation (TMSC), both specialised in the manufacture of medical equipment. Very briefly, the GC considered that the first step of a two-stage acquisition was already a concentration that entailed a standstill obligation, inasmuch as that first step already gave Canon "some influence" over the target. Indeed, Canon "*had sole power to determine the identity of the ultimate purchaser of TMSC. Had it been prevented from acquiring it itself, the applicant could still have decided on the identity of the ultimate purchaser*".

In the Altice case, [16] the GC also confirmed recently that gun jumping infringements do not only consist in the acquisition of shares, but also in contractual provisions granting de facto decisive influence in the run-up to the acquisition of the shares. Indeed, contractual provisions providing for rights of veto and the appointment of managers and/or exchanges of information that are not directly related to the buyer's need to assess the real value of the company may qualify as infringements of the standstill obligation.

The Dutch Competition Authority (ACM) has recently imposed a fine of € 350,000 to a pharmacy association for gun jumping[17] as the operation exceeded the turnover thresholds laid down in the national legislation and was not notified to the authorities.

[14] https://www.reuters.com/business/exclusive-illumina-remedies-grail-bid-yet-convince-eu-antitrust-regulators-2022-03-03/

[15] Judgment of the General Court (Sixth Chamber) of 18 May 2022, case T-609/19 *Canon Inc. v European Commission.*

[16] Judgment of the General Court (Sixth Chamber) of 22 September 2021, case T-425/18 *Altice Europe NV v European Commission*.

[17] ACM/20/042068 – *VNA.*

The Spanish Competition Authority (CNMC) is also very active lately on prosecuting gun jumping. In 2021 at least three fines were imposed for failure to notify and during 2022 three transactions are being investigated for gun-jumping, and one fine has already been imposed.[18]

The risk of a gun jumping fine becomes even more present given the recent new interpretation of Article 22 EUMR,[19] already applied in the Grail/Illumina case. Just as a quick reminder, let us recall that even were no European or national threshold is met, the European Commission now understands that any national authority may refer a case that does not have an EU dimension but affects trade between Member States and threatens to significantly affect competition within the territory of the Member State or States making the request. This covers concentrations of companies that play or will in the future play a significant role in the market despite having a turnover that does not reflect their current or future competitive potential and does not fall within the notification thresholds.

This new interpretation is particularly relevant in the pharmaceutical and digital sectors, where innovation plays an important role and there are companies with great potential that have not yet been able to commercially exploit the results of their innovative activities (and, therefore, they do not have any (relevant) turnover or market shares yet.

Attentive to Servier's judicial outcome…

On 9 July 2014, the European Commission (EC) fined Servier[20], a French pharmaceutical company, and five other producers of generic medicines for so-called pay-for-delay agreements, intended to exclude competitors and delay the entrance of cheaper generic medicines. Servier was also fined for abuse of dominance for implementing a strategy to delay generics entry in the market for perindopril. All the companies involved appealed the decision.

In 2018 the EU General Court partially revoked the EC decision on Servier[21]. It confirmed that the generics were potential competitors of Servier and that five patent settlement agreements were restrictive of competition. However, one pay-for-delay agreement (the one with Krka´s) was not anti-competitive as the existence of a reverse payment was not proven and thus the EC was not entitled to find a restriction of competition by object. Moreover, the GC concluded that the EC was wrong in establishing that Servier held a dominant position in the market, as it did not sufficiently assess the substitutability of perindopril and other ACE inhibitors in terms of their therapeutic use, underestimated the propensity of patients treated with perindopril to be switched to another ACE inhibitor, and gave too much importance to the price factor. A reduction of the fine was the consequence of such findings.

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[18] SNC/DC/048/21: *DGTF/PARPÚBLICA/TAP;* DNC/DC/045/21: *ALBIA/TANATORIOS MOSTOLES;* SNC/DC/014/21: *FUENSPAÑA/ALIANZA CANARIA.*

[19] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings and Commission Guidance on application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases.

[20] Case AT.39612-Perindopril (Servier).

[21] Judgment of the General Court (Ninth Chamber, Extended Composition) of 12 December 2018, case T-691/14 *Servier and Others v. Commission.*

The GC ruling was appealed before the ECJ[22]. Last 20 October 2021, the ECJ heard the appeals by the EC, Servier and generic drug makers of the GC´s 2018 judgment. On one side, Servier argued that the GC wrongly concluded that they faced potential competition from generic drug makers with whom they signed pay-for-delay agreements, as they did not take into account the regulatory and technical obstacles that generics faced in entering the market, and consequently wrongly assessed the legal and economic context of the agreement.

On the other side, the EC argued that potential competition may exist even before an originator´s patent expiration; proof of it was that Servier willingness to pay for settling disputes. Regarding the pay-for-delay agreements, the question put to the EC was whether the harm came from the reverse payment or from the delay of entry. To which the EC replied that the essential element is the payment, which aligned the generic drug makers incentives with Servier´s ones.

Additionally, the EC argued that the GC´s market definition was wrong and went against the settled case law, as it did not take into account the dynamics of the market or the substitutability of perindopril nor the real market conditions. Servier explained that the reasons to conclude agreements with the generics companies and not with others that the GC also considered competitors was that there were no patent disputes with those other companies.

This is not the first time the ECJ has ruled on patent settlements. The Lundbeck Judgment,[23] which also involved pay-for-delay agreements with generics, could shed some light on the forthcoming conclusion of the ECJ. While we wait, the non-binding opinion of the Advocate General has been postponed to 30 June.

[22] Cases C-201/19 P, Servier and Others v. Commission; C-176/19 P, Commission v. Servier and Others; C-198/19 P, Teva UK and Others v. Commission; C-151/19 P, Commission v. Krka; C-144/19 P, Lupin v. Commission; C-164/19 P, Niche Generics v. Commission; C-166/19 P, Unichem Laboratories v. Commission; C-197/19 P, Mylan Laboratories and Mylan v. Commission

[23] Judgment of the Court (Fourth Chamber) of 25 March 2021, case C-591/16 *Lundbeck v. Commission*.

Competitive risks in the German hospital sector highlighted by the Bundeskartellamt's sector inquiry

Background

The Bundeskartellamt launched a sector inquiry into hospitals in 2016 in order to analyse the competitive conditions for hospitals in Germany. A wide range of hospitals across all Germany from Saarland to Saxony were surveyed, covering approximately 22 percent of all hospitals in Germany. In addition, a large number of physicians were interviewed as well, resulting in a detailed insight into the German hospital sector.

Main findings

1. The regulatory framework makes the hospital sector different

The hospital sector in Germany is characterised by a regulatory framework that has an impact on market and competitive processes. Generally, German hospitals require authorization to treat patients with statutory health insurance (roughly 86% of the population). As part of their operations, hospitals must comply with various federal and state regulatory minimum standards on quality.

2. The decisive competitive factor is quality, not prices

Patients choose themselves between different hospitals and their choice is not always the nearest hospital to their homes. Generally, this gives hospitals an economic incentive to innovate and invest, as well as to make efficient use of the scarce resources of the solidarity-based statutory health insurance.

- In the area of inpatient hospital treatment, price itself is surprisingly not a significant competitive parameter for hospitals. Around 98% of all inpatient hospital cases are part of the so-called standard care. These treatments are reimbursed with standard rates covered by the mandatory health insurance, meaning that patients do not pay hospital bills directly and prices are therefore not relevant in the patient's hospital choice. The decisive competitive factor for patients is the quality

of treatment, besides personal criteria like distance or their doctors' recommendations for a specific hospital. German hospitals therefore do not compete by offering lower prices, but by offering more attractive and higher-quality treatment options.

- Hospitals mostly decide themselves what range of inpatient services they actually offer and in which area they specialise in order to optimise their treatment offer. Hospital planning authorities do exist, but they do not assign specific treatment services to hospitals and do not restrict hospitals in their ability to develop their own treatment priorities and where to concentrate their capacities. German hospitals are therefore free to specialise according to their own economic (and competitive) considerations.

- Federal and state hospital quality regulations do not preclude quality competition among hospitals, but set minimum standards that all hospitals must at least meet. However, each hospital operator is free to set higher quality standards for competitive differentiation.

- Competition between hospitals ensures high quality and efficient use of scarce resources: If hospitals reduce their services or quality, they risk patient outflows to competing hospitals and loss of revenue and profit. In a less competitive environment (i.e. less operators present), patients would migrate mainly to hospitals of the same group, thereby decreasing incentives for high quality of care and competitiveness.

3. M&A as the largest competitive risk

Hospitals compete with one another for treatment cases, or in other words: for patients. Each hospital strives to offer a better quality of treatment than competitors and to exceed the mandatory minimum standards.

However, if all local hospitals are operated by the same company, quality competition will most likely suffer as the hospitals will no longer face the risk of patients choosing a competing hospital. In this case, there would be a greater financial incentive for the hospitals to save money by reducing the quality of treatment, i.e., the number of staff or the quality of medical equipment.

In general, most mergers in the hospital sector would however not raise any competition concerns, as Andreas Mundt, the Bundeskartellamt president, emphasized recently. Nonetheless, critical cases may require a close look to ensure sufficient competition in Germany's hospital sector, as "*[t]he consequences of extensive concentration processes are irreversible. Once local operator diversity is eliminated, competition is harmed permanently and patients have less choice*".[24]

[24] https://www.bundeskartellamt.de/SharedDocs/Meldung/EN/Pressemitteilungen/2021/02_09_2021_SU_Krankenhaus.html

Joint Nordic Report (2021) – Online Pharmacy Markets in the Nordics

The Nordic Competition Authorities jointly analysed and compared the size and regulation of online pharmacy markets among the Nordic countries: Finland, Sweden, Norway, Denmark and Iceland.

Background

Overall, the online retail market has been one of the fastest growing sectors during the last two decades and the Nordic countries have an especially well-developed e-commerce sector.

Adding to this, the demand for online services of pharmacies has increased significantly since the Covid-19 pandemic in many countries and may have also changed preferences for some consumers permanently. Demand should therefore remain at a higher level in the future.

However, the regulation of pharmacies differs between the Nordic countries, and this has created different market conditions for online pharmacies to operate in these countries.

Findings

Although the Nordic countries are all highly-developed and digitalized societies with closely related cultures, the role of online pharmacies in each country is not as similar as one might assume at first sight. In particular, the competition authorities came to the following conclusions:

1. Regulations hinder the development of the online pharmacy market in some markets

Regulations are very different between the Nordic countries. This especially applies to online-only pharmacies. For example, in Finland, Norway and Iceland, pharmacies operating online only are not allowed whatsoever whereas offline pharmacies are able to simultaneously offer their products on the internet. The size of the Finnish online pharmacy market for example is therefore quite limited, accounting for roughly 1% of the overall e-commerce market.

In comparison in Sweden and Denmark, online pharmacies contribute around 5-6 % to the e-commerce market, because more liberal regulations apply.

2. Pharmacy markets consist of different players

In Sweden and Norway, OTC pharmaceuticals can be sold by outlets other than licensed pharmacies. In Sweden, the outlets are even free to set the prices of all kinds of OTC medicines by themselves, leading to a higher price competition and lower prices beneficial for consumers.

However, in Denmark, Norway and Iceland, non-pharmacy outlets may only sell a narrow selection of OTC medicines themselves and only after acquiring a special licence from the respective medicine

agency. Pharmacies in these countries therefore face less additional competition from non-pharmacy outlets in comparison to the market in Sweden and Norway.

Furthermore, due to differing regulations online pharmacy markets are still relatively nationally segmented as there are no cross-border actors, thereby limiting price competition.

3. Further liberalisation needed

The competition authorities believe that online pharmacies offer great potential in organising pharmacy services more efficiently. In general, all Nordic countries are among the most digital countries in the world and already have a well-developed e-commerce sector, making the countries well-equipped to develop online pharmacy markets further.

The Nordic countries may learn from each other about best practices for developing the regulation of pharmacy markets. For example, the experiences of Sweden with a more liberal approach leading to price competition can be valuable for other countries that are considering reforming their pharmacy markets.

According to the joint report, a (further) liberalisation of the pharmacy markets across the Nordic countries would have the following advantages for consumers: (i) increase price competition and thus reduce overall healthcare expenditure; (ii) increase accessibility to pharmaceutical products. However, regulatory reform to this aim shall require political negotiations and lies out of the scope of competition authorities' powers.

Other HIGHLIGHTS and FOLLOW-UPs…

Spanish authority rejected complaint alleging AstraZeneca inhaler abuse

On 20 April 2021 the CNMC closed its file against AstraZeneca, triggered by a complaint from TEVA concerning abusive predatory pricing over Symbicort. Other than not finding evidence of predation, the case is also interesting for the challenge of former dawn raids, where the validity of subsequent judicial authorizations and consent is discussed.

Farmacia Spagnoletti- Price Increase of masks and antibacterial gel (AGCM)

Excessive pricing being always a hard case to make for antitrust authorities, this case demonstrates that advantageous profit from the pandemic triggers particular sensitivity.

CAT upholds infringement decision for pay for delay pharma deals

In 2016, the Competition and Markets Authority in the UK (CMA) determined, among other things, that GlaxoSmithKline (GSK) had abused its dominant position for pay-for-delay deals. GlaxoSmithKline plc (GSK) was found to have made payments totaling £50 million to other generic suppliers of paroxetine, including Generics (UK) Limited (GUK) and Alpharma Limited (Alpharma), as part of a patent settlement.

The companies brought an appeal to the UK Competition Appeal Tribunal (CAT). Based on ECJ answers given in the Generics (UK) case, the CAT decided to uphold the CMA decision that GlaxoSmithKline and some generic suppliers of the paroxetine broke competition law. However, it decided to reduce the fines, GSK having to pay £22.2 million.

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Marimón Abogados is a law firm founded in 1931 that offers legal services in all fields of law and has offices in Barcelona, Madrid and Seville. Our firm has adapted to the changes that have taken place in the legal market, creating specialised departments with extensive experience that accompanying our clients in their daily activities.

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