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Pharma & Competition

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Dear all,

We are happy to start 2021 with a new issue of our Pharma & Competition newsletter. Many antitrust decisions and ongoing investigations deserve a close look. They are full of new approaches and adaptations to new realities: direct compensation to the National Health Service was accepted as a commitment in UK antitrust proceedings; withdrawing a medicine may no longer be a possibility for a dominant company; and pay-for-delay settlements are still very much the target of antitrust enforcers.

We try to give you a hint on those ongoing investigations and also finish the Newsletter with several short highlights that may deserve a closer look in the near future. The CNMC public consultation, the possible revision of the EU legislative framework for medicines and cross-border cooperation among different authorities (see Lediant case) are certainly the main highlights.

Enjoy!

Competition law Team, Marimón Abogados

Damages compensation to the NHS accepted as a commitment in CMA's antitrust settlement proceedings

The British Competition and Markets Authority ('CMA') accepted compensation payments to the National Health Service ('NHS') as binding commitments in two settlement proceedings. Those payments do not preclude the NHS from claiming any further damages from the company involved in the anticompetitive practice.

In the first case, the CMA fined four pharmaceutical companies (Auden McKenzie, King, Lexon and Alissa) almost £3.4 million for anticompetitive practices in the supply of nortriptyline drug; a prescription medicine used to relieve symptoms of depression. The unlawful practices consisted of:

(i) **Market sharing:** between September 2014 and May 2015 King and Auden McKenzie agreed that the first would supply only 25mg and the second only 10mg tablets. The firms also fixed output and prices.

(ii) **Information exchange:** King, Lexon and Alissa shared commercially sensitive information to keep prices up. Between 2015 and 2017, when the cost of the drug fell, these pharmaceutical companies shared information on prices and volumes, alongside strategic information on Alissa's plans to enter the market. Public spending on this medicine reached £38 million in 2015.

In addition to fines, the CMA secured a payment of £1 million to the NHS.

In the second case, the CMA fined three pharma companies (Aspen, Tiofarma and Amilco) up to £2.3 million for anticompetitive agreements concerning the supply of fludrocortisone; a prescription drug used to treat primary and secondary adrenal insufficiency (Addison's Disease). This drug is paid by the NHS and ultimately by UK taxpayers.

As it turned out, the companies agreed that **Tiofarma and Amilco would withdraw from the market** in order for Aspen to maintain its position as the sole supplier of the drug in the UK. In return, **Amilco received a 30% share of the drug price increase** and **Tiofarma the exclusive direct marketing right** of the drug in the UK. Following the agreement, the price increased by up to 1800%.

As part of the commitments' package, Aspen proposed compensating the NHS for damages with £8 million.

These cases are definitely worth a close look since payments of this nature are largely unprecedented and the transposition of the ECN+ Directive will introduce settlement proceedings across

all Member States' jurisdictions [see Article 14(2) ECN+ Directive in conjunction with Article 18(3) Damages Directive]. Will this kind of upfront compensation extend to other ongoing antitrust investigations in the pharma sector? Will it also extend to other sectors and/or private operators? Would this help reduce or shorten damages litigation?

The withdrawal of medicines as an abuse of a dominant position

The CMA consulted on Essential Pharma's proposed commitments to address competition concerns involving the possible withdrawal of Priadel, a medicine that treats bipolar disorder.

Background of the case

In April 2020, Essential Pharma notified the Department for Health and Social Care ('DHSC') that it intended to discontinue the supply of Priadel from October 2020 in the UK, because such supply was loss-making. Alternative drugs for patients were far more expensive –the closest alternative is Camcolit, also supplied by Essential Pharma– and the process of changing drugs itself could cause significant harm to patients.

In order to prevent withdrawal, the DHSC engaged in price negotiations with the company given (i) a compelling clinical need to ensure the supply of Priadel in the UK; (ii) significant concerns raised by the DHSC and medical practitioners regarding patient welfare; and (iii) significant material, financial and administrative implications for the NHS if many patients switched drugs. After failed negotiation attempts the DHSC approached the CMA in June 2020.

In October 2020, the CMA opened a formal investigation into whether Essential Pharma (i) held a dominant position in the market for the supply of lithium carbonate medicines; and (ii) abused such position by a strategy to withdraw Priadel, directly or indirectly impose unfair prices for the supply of lithium carbonate medication and force patients to switch to another product.

Material discussion

The key issue here is determining to what extent a dominant undertaking is obliged to market a drug when it is inefficient and/or loss-making.

The mere opening of antitrust proceedings may be an indication that such conduct could constitute an abuse. Nevertheless, the CMA seems provisionally receptive to the proposed commitments and may not have to rule on the nature or gravity of the infringement, if any.

Commitments under consideration

Following the opening of the file, Essential Pharma suspended the withdrawal of the drug and concluded an agreement with the DHSC to review the price of Priadel, which thereafter increased but remained lower than the price of alternative drugs. Essential Pharma also offered to maintain the supply of Priadel for five years and to refrain from withdrawing the drug from the market in the future.

This case is relevant for several reasons, namely for:

(i) the swift action taken by the CMA in the investigation of the facts and the rapid change of Essential Pharma's conduct and business strategy, reversing its decision to withdraw Priadel and offering commitments to address competition concerns;
(ii) the involvement of both Essential Pharma and the DHSC in collaborating with the CMA to resolve an issue of general interest; and
(iii) following the CMA trend to accept commitments that anticipate third-party claims or interests.

To sum up, the price renegotiation itself would seek a fair balance between guaranteeing a medicine's supply -which may be a matter of public interest- and ensuring a reasonable return on investment, thereby avoiding excessive hindrance on innovation incentives.

European Commission fines Teva and Cephalon for delaying market entry of a cheaper generic drug

The European Commission fined Teva and Cephalon €60.5 million for agreeing to delay the market entry of a cheaper generic version of modafinil, Cephalon's blockbuster drug for sleep disorders, after its main patents had expired.

Cephalon's modafinil was marketed under the 'Provigil' brand and accounted for more than 40% of its worldwide sales. While the main patents on the drug in Europe expired in 2005, Cephalon had secondary patents which provided additional protection for the marketing of the drug. Therefore, when Teva launched its generic version of modafinil in the UK in 2005, Cephalon brought legal actions arguing an infringement of its secondary patents.

It was precisely in 2005 when the two pharmaceutical **companies concluded a patent settlement agreement whereby Cephalon induced Teva not to introduce its generic drug into the market**

and not to challenge Cephalon's allegedly weak secondary patents. In return, Teva received cash payments and certain commercial side-deals (i.e. a distribution agreement, the acquisition of a licence on certain Teva modafinil patents by Cephalon, purchases of raw materials from Teva and access to clinical data for the development of a different medicine).

The delayed entry of Teva's generic drug was detrimental to competition on the market and ultimately harmed consumers, in so far as:

(i) Cephalon did not face competition from cheaper drugs, which could have lowered prices for modafinil, e.g. when Teva entered the UK market, its price was 50% lower than the price of Provigil; and

(ii) pay-for-delay agreements serve as a disincentive to innovation, because generics stimulate pharmaceutical companies to focus their efforts on innovating rather than on maximising income by preserving market exclusivity of their old drugs.

The pharmaceutical company Teva is also being investigated by the European Commission for a possible abuse of dominant position concerning the marketing of its drug for treating multiple sclerosis, Copaxone. The European Commission raided Teva twice, as part of this investigation.

Other HIGHLIGHTS and FOLLOW-UPs…

- Upcoming investigations in the pharmaceutical sector

Following investigations into Big Techs, a US top Democrat stated that the next target should be Big Pharma companies. Any comments being premature, we will follow up.

The CNMC opened abuse proceedings against Leadiant Biosciences Spa and Leadiant Biosciences Ltd for possible abuses in the market for the manufacture and supply of the orphan drug CDCA-Leadiant, used for the treatment of patients with cerebrotendinous xanthomatosis, an ultrarare disease. According to the public information on the file, the case could have some connections with the current Italian investigation against the same company concerning excessive pricing.

- A Pharmaceutical Strategy for Europe

The European Commission adopted a Pharmaceutical Strategy as part of the project to build a stronger European Health Union to promote (i) access to affordable medicines for patients and addressing unmet medical needs; (ii) competitiveness, innovation and sustainability of the EU's pharmaceutical industry; (iii) crisis preparedness and response mechanisms and addressing security of supply; and (iv) a high level of quality, efficacy and safety standards. As remarkable flagship actions, a revision of the basic pharmaceutical legislation is envisaged for 2022; and the creation of a EU Health Emergency Response Authority may be proposed in the second semester of 2021.

- The ECJ confirms the exceptionality of refusing access to European Medicines Agency (EMA) files

The ECJ backed the General Court and confirmed that access to EMA files on marketing authorisations may be restricted to third parties only when it is (i) necessary to protect judicial proceedings, in which case only documents drawn up in the context of specific court proceedings are protected; and (ii) indispensable to protect the applicant's commercial interests.

- Spain opens medicines wholesale distribution consultation

In March 2017, the CNMC Advocacy Directorate launched a study on competition conditions for marketing and wholesale distribution of prescription medicines, commercialised through pharmacies. It has now opened a public consultation targeting the main market players, including economic operators, public institutions, associations, academics, consumers and patients and other experts and stakeholders in the sector to express their views on the study. Responses may be sent until 12 February 2021.

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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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