GETTING THE DEAL THROUGH

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Pharmaceutical Antitrust 2013

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs?

The regulatory framework for the marketing, authorisation and pricing of pharmaceutical products as currently in force in Greece comprises two main legislative acts: Inter-ministerial Decision No. 3(a)/82161 of 24 August 2012 on the harmonisation of Greek legislation with the Community legislation on the production and marketing of pharmaceutical products for human use (Inter-ministerial Decision No. 3(a)/82161) – following Directive 2001/83 on the Community code relating to medicinal products for human use (Law 311 of 28 November 2001), as in force and amended by Directive 2010/84, on pharmacovigilance (Law 348 of 31 December 2010) – read together with Legislative Decree 96/1973, as in force; and Inter-ministerial Decision No. 3(a)/7789 of 23 January 2013 on the setting of pharmaceutical prices (Inter-ministerial Decision No. 3(a)/7789).

Inter-ministerial Decision No. 3(a)/82161 sets out the main requirements relating to the granting of marketing authorisations of pharmaceutical products, the labelling and packaging of medicinal products, their wholesale distribution and advertising, pharmacovigilance requirements, etc. It also provides the legal basis for approval of generic products via an abridged procedure in light of the provisions of Directive 2001/83. On the other hand, pricing and reimbursement of pharmaceutical products fall within the scope of Inter-ministerial Decision No. 3(a)/7789.

2 Which bodies are entrusted with enforcing these regulatory rules?

The National Drug Organisation (EOF) constitutes the competent regulatory body for the authorisation of pharmaceutical products. Its primary task is to review applications for pharmaceutical products in the course of the national marketing authorisation procedures. It is also the competent authority for monitoring pharmaceutical products already on the market for pharmacovigilance purposes. Additionally, EOF is entrusted with the task of monitoring manufacturing facilities and seizing potentially dangerous products.

EOF and the Ministry of Health and Social Solidarity work together on setting the prices for pharmaceutical products. The prices of pharmaceutical products are uploaded to the website of the Ministry of Health and Social Solidarity in the form of a price bulletin comprising prices both for products that are reimbursed by the Greek health insurance system and those that are not. The Ministry notes that 'the current Greek pricing system is based on the exceptional and harsh economic, social and medical factors that are specific to Greece. The Greek Ministry of Health asks competent authorities in other countries not to refer to those prices in their national pricing and reimbursement decision-making process.'

3 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

There are two sets of national rules that are most directly relevant to the application of competition law to the pharmaceutical sector: those affecting marketing of generic pharmaceutical products and those affecting marketing of parallel-traded pharmaceutical products.

Rules for the marketing of generic pharmaceutical products are generally contained in Inter-ministerial Decision No. 3(a)/82161 detailing Directive 2001/8. On the other hand, parallel trade of pharmaceuticals products is specifically connected with the public service obligation of all pharmaceutical producers, importers, industry outlets, sub-agencies and pharmaceutical wholesalers operating on the national market, that is, the obligation to ensure appropriate and continuous supplies of medicinal products to the market, namely to pharmacies and people authorised to engage in pharmaceutical retail distribution, so that national needs are met at all times (article 81 of Inter-ministerial Decision No. 3(a)/82161). Greek law further provides specifically for the quantitative dimension of the public service obligation not only of pharmaceutical companies but also of wholesalers, that being, 'the national needs'. Greek law provides that the notion of 'national needs' under the public service obligation of both pharmaceutical companies and wholesalers is understood as the prescription rate on the Greek market of the said medicine, as calculated by Intercontinental Medical Statistics (IMS), plus a 25 per cent safety minimum (EOF Circular No. 50262 of 27 November 2001). The obligation is not to have an IMS level +25 per cent of each medicine stocked in Greece but to put on the Greek market quantities of each medicine that are at least equal to the current prescription number of each medicine (IMS data) plus a 25 per cent surplus for emergencies. The 25 per cent surplus shall be allocated to the market throughout the year, while taking into account any seasonal and emergency needs (EOF Circulars No. 50262 of 27 November 2001 and No. 66429 of 8 November 2005).

Competition legislation and regulation

4 Which legislation sets out competition law?

At national level, competition law matters are treated by both free-competition and unfair competition rules. More specifically, antitrust issues are governed by Law 3959/2011 on free competition as well as articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU), whereas Law 146/1914, governs unfair practices and abusive conduct such as misleading statements and advertising or purposefully preventing competition.

In more detail, article 1(1) of Law 3959/2011, echoing article 101(1) TFEU, prohibits anti-competitive agreements and concerted practices that prevent, restrict or distort competition. Undertakings caught within the scope of article 1(1) may be exempted under article 1(3) of Law 3959/2011, as any prohibition may be declared inapplicable to agreements and concerted practices that contribute to improving the production or distribution of goods, or to promoting

technical and economic progress, provided that they also allow consumers a fair share of the resulting benefit, only impose restrictions indispensable to achieving those objectives and do not permit the elimination of competition. Likewise, article 2 of Law 3959/2011, echoing article 102 TFEU, prohibits an undertaking holding a dominant position from abusing it through either exclusionary practices (predatory pricing, price discrimination, fidelity rebates, tying, bundling, refusal to supply, margin squeeze, etc) or exploitative practices (excessive pricing, unfair trading conditions, etc). Articles 5–10 of Law 3959/2011 provide for the merger control rules.

In Greece there is also a provision under Law 146/1914 imposing an obligation on undertakings, whether dominant or not, to supply customers that are in a position of economic dependency towards the company or provider (article 18 (a), formerly article 2 (a) of Law 703/77 on free competition). This provision covers cases where the behaviour of the company does not constitute either an agreement within the meaning of article 1, paragraph 1 of Law 3959/2011 (and article 101 TFEU) or an abuse of dominance by a dominant undertaking within the meaning of article 2 of Law 3959/2011 (and article 102 TFEU). More specifically, it provides that: 'a company's abusive behaviour is prohibited towards economically dependent undertakings, which act as its customers, and may relate even to a single product or service with lack of alternative solutions on the part of the dependent undertaking. This abuse takes place through the imposition of unfair terms, discriminating treatment and the sudden and unjustifiable termination of long commercial relationships'.

There are no competition rules relating specifically to pharmaceutical products; any relevant practice shall fall within the ambit of these same general rules.

5 Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

Even though there are no pharmaceutical-specific guidelines, there are certain rules that are directly relevant to the application of competition law to the pharmaceutical sector, namely the European Commission Block Exemption Regulations, accompanied by explanatory guidelines, which are directly applicable at national level (Regulation No. 772/2004 of 27 April 2004 on Technology Transfer Agreements and Related Guidelines; Regulation No. 1217/2010 of 14 December 2010 on Research and Development (R&D) Agreements; and Regulation No. 1218/2010, of 14 December 2010 on Specialisation Agreements and Related Guidelines on Horizontal Restraints and Regulation No. 330/2010 of 20 April 2010 on Vertical Agreements and Related Guidelines; the Hellenic Competition Commission's (HCC) Leniency Programme (Decision No. 526/VI/2011); the HCC's Guidelines on setting of fines (notice dated 12 March 2006 and updated on 17 July 2009); and the HCC's de minimis notice dated 2 March 2006.

6 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive effect of conduct or agreements in the pharmaceutical sector?

The HCC is solely responsible for investigating and deciding on pharmaceutical mergers provided that they do not meet the turnover thresholds set forth in article 1(2) and article 1(3) of the European Community Merger Regulation ('Community dimension'). Likewise, the Commission and the national courts share responsibility for reviewing or investigating agreements between companies or unilateral conduct by one or more dominant companies that have as their object or effect the distortion of competition within the meaning of articles 1 and 2 of Law 3959/2011, and articles 101 and 102 of the TFEU.

7 What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

According to article 25 of Law 3959/2011 in case of violation of articles 1, 2 and 11 of the law, and articles 101 and 102 TFEU, the HCC by relevant decision may either cumulatively or separately impose:

- cease-and-desist orders with a view to bringing an infringement to an end;
- behavioural or structural remedies;
- pecuniary sanctions for companies or their individual representatives for breaching competition law or decisions of the HCC, which may reach up to 10 per cent of their turnover in the preceding business year, whereas fines for individuals may range from €200,000 to €2 million;
- daily pecuniary sanctions up to €10,000 to secure compliance with a cease-and-desist order or (behavioural or structural) commitments imposed on the company concerned;
- criminal sanctions on individuals which represent companies breaching competition law. Such criminal sanctions may involve a fine of up to €1 million and imprisonment of at least two years for a cartel infringement, or a fine of up to €300,000 for an infringement of abuse of dominant position; and
- interim measures which are similar to cease-and-desist orders but reserved to cases where there is an urgent need to prevent an imminent risk of irreparable harm to competition.

In 2006 the HCC found violation of article 2 of Law 703/77 (now 3959/2011) on the part of a pharmaceutical company for a period of three months for an anti-competitive refusal to supply wholesalers. Given that no actual results were effected in the relevant market, the HCC issued an order that the company not repeat the conduct in the future otherwise a fine of up to 3 per cent of the company's turnover in the business year preceding the violation would be payable.

8 Can private parties obtain competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Private parties may seek interim measures or a cease-and-desist order or damages by bringing an action before the civil courts under tort rules (ie, article 914 of the Greek Civil Code) in connection with an alleged infringement of applicable competition rules (follow-on or stand-alone claims). According to prevailing legal theory, the decision of the HCC on the violation of competition law provisions does not create in itself a binding legal precedent for the civil court; the same does not apply in relation to the decisions of the administrative courts issued on appeal of the HCC's decision.

Civil courts in Greece are yet to produce a final decision on such a case even though many have been referred to national courts.

9 May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

According to article 11 of Law 3959/2011, the HCC may initiate a sector-wide investigation on its own initiative or following a request by the minister for development, competitiveness and shipping. Quite recently (January 2013) the HCC initiated a sector-wide investigation in the market of HD medical devices (haemodialysis). As yet, the results of the investigation are not known.

10 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation of competition distinct from the general competition rules?

In Greece, the HCC is the only authority responsible for applying and enforcing competition rules.

11 Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

Industrial-policy type arguments may be used in the pharmaceutical sector as in any other industry sector for justifying restrictions of competition under article 1, paragraph 3 of Law 3959/2011.

12 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?

Associations of undertakings and consumer associations may submit complaints before the HCC for the enforcement of competition law rules provided that they show that they (or their members) are directly and adversely affected by the alleged infringement. Moreover, these associations may express their views in sector inquiries launched by the HCC. Finally, these associations may file actions for damages in tort before national civil courts provided that they can substantiate the existence of an unlawful act; the occurrence of damage; and a causal link between the unlawful act and the damage caused.

Review of mergers

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

The general competition rules apply and there are no special rules applicable to mergers in the pharmaceutical industry.

14 How are product markets and geographic markets typically defined in the pharmaceutical sector?

When defining the relevant product market in cases involving the pharmaceutical sector, the HCC shall rely on the product classification developed by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by it and by IMS. The relevant market assessment thus entails an analysis of the substitutability of medicines at level 3 of this classification system, thereby grouping medicines with similar therapeutic indications. The HCC shall thus accept that these medicines belong to the same product market because they have a similar 'intended use'. On the other hand, the relevant geographic market is considered to be national, especially given the lack of harmonisation of member state legislation in the field of pricing and reimbursement.

The HCC has examined few cases involving a merger between pharmaceutical companies. The market definition assessment adopted is as follows: first, with regard to the relevant product market, the HCC has based its conclusion on demand substitutability with reference to the product's characteristics, intended use and price. The HCC has also found that the market for the production and marketing of pharmaceutical products may be further segmented on the basis of the therapeutic category to which the product belongs (see HCC Decision 378/V/2008, Acquisition by Alapis of KP Marinopoulos). Second, with regard to the relevant geographical market, the HCC has found that the market for the production and marketing of pharmaceutical products is national in scope because the merging parties as well as their competitors operated under sufficiently homogenous competitive conditions (eg, price regulation) (see HCC Decision 378/V/2008, acquisition by Alapis of KP Marinopoulos, HCC Decision 31/V/2009 acquisition by Alapis of PGN Gerolymatos, HCC Decision 445/2009 acquisition by Alapis of MENTIMEK).

15 In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

Since there are no merger cases where the HCC found a problematic product and geographic overlap as a result of a pharmaceutical merger, it can only be assumed that the HCC will follow the European Commission's line in this respect (namely, when the aggregate market share of the merging firms exceeds 40 per cent, provided that the increment caused by the merger is not negligible. In this regard, potential competition should also be taken into account).

16 When is an overlap with respect to products that are being developed likely to be problematic?

As indicated above, there have been no relevant cases before the HCC as yet.

17 Which remedies will typically be required to resolve any issues that have been identified?

According to article 8 of Law 3959/2011, a merger can be granted clearance subject to conditions or obligations to prevent the establishment or a strengthening of a dominant position, or ensure a predominant improvement of the competitive environment. In case of breach of such conditions, the HCC may impose pecuniary sanctions of up to 10 per cent of the combined aggregate turnover of the participating undertakings. In the event that the participating undertakings do not comply following such a fine, the HCC may order the unwinding of the merger.

There have been no decisions by the HCC imposing remedies for the clearance of pharmaceutical mergers as yet. However, it is only natural to assume that the HCC shall follow the line adopted in relevant cases of other industry sectors, that is, accept structural remedies, for instance divestments of overlapping products to suitable purchasers or licensing arrangements on suitable terms with a view to clearing the merger (by way of example, by Decision 562/VII/2013 the HCC accepted quite recently (February 2013) the merger of Ethniki Bank of Greece and Eurobank Ergasias Bank SA on the condition that Eurobank Ergasias shall divest part of its business (in the merchant acquiring market) to a third party).

18 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

According to the European Commission's 2007 Consolidated Jurisdictional Notice on the Control of Concentrations between Undertakings, the acquisition of intangible assets such as patents may be considered to be a concentration if those assets constitute a business with a market turnover. This is also the case for the transfer of a patent licence, if it is an exclusive licence on a lasting basis and if this will enable the acquirer to take over the turnover-generating activity relating to this licence. Given the lack of specific case law in the pharmaceutical sector, it is expected that the HCC, should there be such a case, will follow the same line of reasoning.

Anti-competitive agreements

19 What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

According to article 1, paragraph l of Law 3959/2011, all agreements between undertakings, decisions by associations of undertakings and concerted practices that have as their object or effect the prevention, restriction or distortion of competition on the national market are prohibited. Agreements and concerted practices caught by paragraph 1 are automatically null and void under paragraph 2 of the same article, unless they qualify for an individual or block exemption under paragraph 3. Therefore, the prohibition of article 1, paragraph 1 may be declared inapplicable where any agreement or category of agreements between undertakings, any decision or category of decisions by associations of undertakings or any concerted practice or category of concerted practices contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and

does not: impose on the undertakings concerned restrictions that are not indispensable to the attainment of these objectives; or afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question. Anti-competitive agreements or practices may also take advantage of the block exemptions under the EU Block Exemption Regulations, which also apply at national level according to the excplicit wording of paragraph 4 of article 1, Law 3959/2011.

In this sense, assessment of an agreement or practice under competition rules shall entail a two-tier analysis.

20 Describe the nature and main ramifications of any cartel investigations in the pharmaceutical sector.

Quite recently (January 2013) the HCC initiated a sector-wide investigation in the market of HD medical devices (haemodialysis) following allegations of a cartel in the market. No actual results have been published as yet. There have been no previous cartel investigations in the pharmaceutical sector in Greece.

21 To what extent are technology licensing agreements considered anti-competitive?

There have been no relevant cases in the pharmaceutical sector in Greece.

Nevertheless, presumably the HCC would apply the EU Block Exemption Regulation 772/2004 as well as the basic principles entrusted by the European case law in the said matter. According to Regulation 772/2004, a technology licensing agreement will be exempted if the parties to the agreement hold a combined market share in the product or technology market not exceeding 20 per cent, if they are competitors (ie, licensee and licensor), or 30 per cent, if they are not competitors, and the agreement does not contain 'hard-core restrictions' (eg, output restrictions, market allocation).

22 To what extent are co-promotion and co-marketing agreements considered anti-competitive?

So far the HCC has not addressed competition issues in relation to co-promotion or co-marketing agreements, even if the contracting parties are competitors and these agreements imply some degree of joint activity at the level of commercialisation (commercialisation agreements between competitors can only have restrictive effects on competition if the parties have some degree of market power; it is unlikely that market power exists if the parties to the agreement have a combined market share not exceeding 15 per cent). In addition, since such agreements are likely to arise in the context of R&D cooperation between pharmaceutical companies, EU Block Exemption Regulation 1217/2010 on R&D cooperation would also be applicable.

Notwithstanding competition law concerns, according to article 98, paragraph 3 of Inter-ministerial Decision No. 3(a)/82161, co-promotion agreements cannot be excluded by the EOF.

23 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

Agreements between competitors (actual or potential) that have as their object restraints in competition shall be regarded as anti-competitive in themselves. Such practices exist in price fixing agreements, quota cartels, output restrictions, exchange of commercially sensitive information and market sharing. In contrast, other agreements, such as R&D or production joint ventures, will be subject to an effects-based analysis.

Agreements between competitors (actual or potential) can be exempted pursuant to the European Block Exemption Regulations, the European De Minimis Notice or the national De Minimis Notice of the HCC (it is noted that restrictions that are anti-competitive by object, that is, fixing prices, allocation of markets and allocation of output or sales do not fall within the ambit of the said regulations).

Confidentiality provisions will have no bearing on whether an agreement is anti-competitive.

24 Which aspects of vertical agreements are most likely to raise antitrust concerns?

There have been no relevant cases in the pharmaceutical sector in Greece. However, the European Block Exemption Regulations on vertical agreements and the corresponding Commission Guidelines on vertical agreements would apply. Vertical agreements, that is, agreements between operators at different market levels, are usually considered anti-competitive to the extent that they have as an effect the restriction, distortion or prevention of competition. In this sense, exclusivity clauses, export or import bans, market sharing, IP licensing agreements and supply quota systems are some examples of potentially anti-competitive vertical agreements. It is further noted that during the last 50 years, most of the cases on vertical agreements in the pharmaceutical sector have concerned attempts by pharmaceutical companies in collusion with their distributors to restrict in one way or another parallel trade.

25 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

There is no HCC precedent in this respect. By way of reference it is noted that in its 2004 Guidelines on Technology Transfer Agreements, the European Commission accepts that licensing agreements that serve as a means to settle an intellectual property rights dispute or to prevent one party from asserting its intellectual property rights against the other party, are 'not as such restrictive of competition' but the 'individual terms and conditions of such agreements may be caught by competition rules' (paragraph 204).

Anti-competitive unilateral conduct

26 In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

According to article 2 of Law 3959/2011, any abuse by one or more undertakings of a dominant position within the Greek market or a substantial part of it shall be prohibited. Such abuse may, in particular, consist in:

- directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- limiting production, markets or technical development to the prejudice of consumers;
- applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

Specifically in respect to the pharmaceutical sector, the HCC found in its decision 318/V/2006 following a complaint against GlaxoSmith-Kline Plc and its Greek subsidiary GlaxoWellcome AEBE (Glaxo), that Glaxo was dominant in the relevant market of one of its products and breached article 2 of Law 703/77 (now 3959/2011) by refusing to supply its customers/wholesalers.

27 When is a party likely to be considered dominant or jointly dominant?

According to settled case law, dominance is a position of economic strength enjoyed by an undertaking that enables it to prevent effective

competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers. A company's high market share (at the very least 40 per cent), combined with much lower shares held by its competitors and the absence of countervailing buying power in the hands of its customers, will be indicative of dominance if it can be shown that the company has held its high market share for some time and is likely to do so for the foreseeable future.

It is within this context of settled case law and community law principles that HCC and national civil courts assess dominance in the pharmaceutical sector. By way of example, it is noted that in its decisions 318/V/2006 and 229/III/2003, HCC defined the relevant market on the basis of the product's therapeutic ingredient, thus defining relevant product market as the market for one pharmaceutical product. In this sense, the HCC naturally concluded that Glaxo held a monopolistic position in this product market in Greece.

28 Can a patent holder be dominant simply on account of the patent that it holds?

Even though there has been no relevant case before the HCC, it would presumably follow the well-established Community principle that intellectual property rights do not confer in themselves a dominant position on the right-holder (in this respect, Commission Communication Guidance on the Commission's enforcement priorities in applying article 102 TFEU to abusive exclusionary conduct by dominant undertakings.)

29 To what extent can an application for the grant of a patent expose the patent owner to liability for an antitrust violation?

There is no HCC precedent in this respect. However, it would presumably follow the European Commission's decision in *AstraZeneca* holding that patent applications may give rise to antitrust liability in exceptional circumstances, should the applicant be found dominant within article 2 TFEU (in this sense, it is not the existence of a patent but the misuse of the right by a dominant undertaking that may give rise to anti-competitive concerns).

30 To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

Enforcement of a patent may constitute an abuse of a dominant position and thus fall foul of article 102 TFEU and article 2 of Law 3959/2011 if the patent holder misuses the rights conferred by the patent at the expense of competitors, that is, where other undertakings depend on the use of the patent for their business activities and the patent holder denies the licensing of the patent without any justification or where patent enforcement leads to vexatious litigation on the part of the patent holder.

There is no HCC precedent in this respect.

31 To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

As it is the position of the European Commission, life-cycle management strategies that aim at exploiting the patent system do not as such raise antitrust concerns, even if they prevent or delay market entry by potential competitors, in particular generics companies. For antitrust concerns to arise, the Commission recognises three cumulative grounds: first, the companies that apply such strategies must be dominant; second, their strategy must create substantial foreclosure effects on the market and; third, there must be no objective justification for that strategy other than the aim to prevent or delay market entry by potential competitors. There is no HCC precedent in this respect.

Update and trends

During the last three years, due to the austerity measures taken to combat the extreme financial crisis, the Greek legislature has been very active amending pharmaceutical regulation to control public expenditure for health care. Quite recently, Law 4052/2012, as amended by Law 4093/2012, introduced a number of changes affecting predominantly the pricing and reimbursement of pharmaceutical products (both original and generics): promotion of generics via compulsory prescription by active substance; e-prescription for almost all medicines; a clawback and a rebate mechanism with retrospective effect; consecutive reductions in the maximum prices for both original and generic pharmaceuticals; reductions in profit margins for pharmacists; e-procurement for the supply of medicines to public hospitals; a one-off special payment by marketing authorisation holders for the inclusion of prescription medicines in the positive list, among other charges. All these measures, coupled with the considerable 'haircut' of the state bonds the pharmaceutical companies had acquired in settlement of overdue hospital debts have taken their toll in the national pharmaceutical market. Great concerns have arisen in terms of the availability of products in the market and an emerging explosion in parallel exports as prices got lower. In light of all these developments, it will be very interesting to see how a national judge or the HCC could escape addressing the particular current features of the pharmaceutical market in Greece as possible objective justification grounds when assessing a conduct that could otherwise infringe antitrust rules.

32 Do authorised generics raise issues under the competition law?

Even if the European Commission examines in detail the said issue in its pharmaceutical sector inquiry report, there has been no clear position on the said matter. There is no HCC precedent of such practice in the pharmaceutical sector in this respect either.

33 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

The issue of whether sector-specific features can justify anti-competitive conduct of an allegedly dominant company in the pharmaceutical market arose in the *Syfait* case (C-53/03) and, more recently, in *Lelos* cases (C-468 to 478/06). In particular, the European Court of Justice (ECJ) was asked whether Glaxo's refusal to meet all orders put by its wholesalers in Greece constituted an abuse of dominance as it intended to restrict parallel trade of the Glaxo's products at hand. An argument was presented by Glaxo highlighting the special legal framework surrounding pricing and reimbursement of pharmaceutical products. The ECJ while assessing the argument went on to hold that 'the degree of regulation regarding the price of medicines cannot prevent any refusal by a pharmaceuticals company in a dominant position to meet orders sent to it by wholesalers involved in parallel exports from constituting an abuse' but, on the other hand, that 'such a company must nevertheless be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests'. All in all, even if there are indeed special characteristics to the pharmaceutical sector, both the ECJ and the European Commission have declined to justify on these grounds any deviation from the general competition principles.

34 Has there been an increase in antitrust enforcement in the pharmaceutical sector in your jurisdiction? If so, please give an indication of the number of cases opened or pending and their subject matters.

There has been no noticeable increase in antitrust enforcement in the pharmaceutical sector in Greece. However, it is noted that there are a number of cases for damage claims following violation of antitrust law (ie, abuse of dominance) pending before civil courts.

35 Is follow-on litigation a feature of pharmaceutical antitrust enforcement in your jurisdiction? If so, please briefly explain the nature and frequency of such litigation.

Actions for damages before national courts have increased in recent years in Greece. However, follow-on litigation is not a particular feature of pharmaceutical antitrust enforcement in Greece.

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