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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?

Greece has recently adopted new laws and regulations with a view to introducing significant amendments into its regulatory framework on pharmaceutical products. Such amendments aim in principle at keeping public expenditure for health care under control and promoting generics market entry. In this respect, Law 4052/2012 has introduced a number of changes in pharmaceutical legislation including changes on pricing of original and generics pharmaceutical products, the promotion of the use of generics (via compulsory prescription by active substance), e-prescription and rebates.

In respect of marketing and authorisation of pharmaceutical products, Ministerial Decision DYC3(a)/83657/2006 transposing into Greece EU Directive 2001/83/EC on the Community Code relating to medicinal products for human use as in force (Ministerial Decision) and Legislative Decree 96/1973 on the trading of pharmaceutical and cosmetic products (Legislative Decree) apply. The Ministerial Decision and the Legislative Decree lay down the requirements for the granting of a marketing authorisation licence, wholesale distribution, classification of the various medicinal products, pricing, labelling, advertising, pharmacovigilance, exports, etc.

In relation to pricing of pharmaceutical products, the prices of original pharmaceutical products in Greece are regulated by the Department of Prices of Pharmaceutical Products (Ministry of Health and Social Solidarity, Directorate for Pharmaceutical Products and Pharmacies) following a proposal by the National Organisation for Medicines (EOF). The prices of pharmaceutical products are determined for the packages that are approved by EOF and the European Medicines Agency (EMA). In particular, there are three prices: the manufacturer price, the wholesale price and the pharmacy retail price. The wholesale price and the pharmacy retail price are determined on the basis of the manufacturer price. According to the applicable pricing system (the so-called '2+1 system'), the manufacturer price is calculated on the basis of the average of the three lowest European manufacturer prices (two reference prices must be from the EU-15 and Switzerland and one reference price from the new EU member states). The prices for generics are also based on the manufacturer price (ie, the maximum price of the generic equals 60 per cent of the price of the branded medicine).

Law 3816/2010 reintroduced the list of prescription pharmaceutical products and Law 3918/2010 governs inter alia the supply of pharmaceutical products to the public sector.

2 Which bodies are entrusted with enforcing these regulatory rules?

The Ministry of Health and Social Solidarity (MOH) is the supervising authority in Greece responsible for pharmaceutical products, health care professionals and the provision of health-care services in general. EOF (supervised by MOH) is responsible inter alia for issuing market authorisations, classifying pharmaceutical products according to their prescription status as well as for setting the prices of pharmaceutical products. EOF may also impose sanctions including fines or other remedies in case of a breach of the applicable regulatory rules.

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

The aspects of the pharmaceutical legislation which are most directly relevant to the application of competition law are those relating to market access for generics pharmaceutical products (authorisation and pricing), competition conditions between generics companies and originators companies as well as parallel trade.

Competition legislation and regulation

4 Which legislation sets out competition law?

Law 3959/2011 ('Competition Law') provides for the Greek competition rules on anti-competitive agreements and concerted practices, abuse of dominance and merger control. In particular:

- article 1(1) of Competition Law mirroring the equivalent provision of article 101(1) of the Treaty on the Functioning of the European Union (TFEU) prohibits anti-competitive agreements and concerted practices which prevent, restrict or distort competition. However, undertakings caught by article 1(1) may be exempted under article 1(3)(mirroring the equivalent provision of article 101(3) TFEU), which provides that the prohibition may be declared inapplicable to agreements and concerted practices which 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 indispensible to achieving those objectives and do not permit the elimination of competition. Article 1(4) of the Competition Law provides that the EU Regulations on the application of article 101(3) TFEU are applicable by the Greek competition authorities and courts for the application of article 1(3) of the Competition Law;
- article 2 of the Competition Law (which contains the equivalent provision of article 102 TFEU) prohibits an undertaking holding a dominant position from abusing it through either exclusionary practices (eg, predatory pricing, price discrimination, fidelity rebates, tying, bundling, refusal to supply, margin squeeze, etc) or exploitative practices (eg, excessive pricing, unfair trading conditions etc); and
- articles 5-10 of the Competition Law provide for the merger control rules.

In respect of state aid rules, article 107(1) TFEU applies which prohibits member states from granting aid provided through state

resources which distorts, or threatens to distort, competition and trade between member states by favouring certain undertakings or the production of certain goods.

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

There are no specific guidelines by the Greek authorities on the application of competition law in respect of pharmaceutical sector. However, there are certain EU block exemption regulations accompanied by the relevant explanatory guidelines which are relevant for the pharmaceutical sector and are also applicable under Greek rules (article 1(4) of the Competition Law): Regulation No. 772/2004 on technology transfer agreements (OJ [2004] L123/11); Regulation No. 1217/2010 on research and development (R&D) agreements (OJ [2010] L335/36); Regulation No. 1218/2010 on specialisation agreements (OJ [2010] L335/43); and Regulation No. 330/2010 on vertical agreements (OJ [2010] L102/1).

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

Mergers (including pharmaceutical mergers which are not subject to different treatment) are investigated by the Hellenic Competition Commission (HCC) under Greek merger control rules provided that they fulfil the turnover thresholds laid down in article 6(1) of the Competition Law and they do not have an EU dimension (ie, they do not meet the turnover thresholds under the European Union Merger Regulation (EUMR), in which case they would be subject to clearance by the European Commission (Commission)).

According to article 6(1) of the Competition Law, a concentration shall be notified to the HCC for clearance before it is completed (pre-merger notification) where the combined aggregate worldwide turnover of the participating undertakings amounts to at least €150 million and each of at least two of the participating undertakings has an aggregate turnover exceeding €15 million in Greece. Mergers affecting the Greek market which meet the thresholds laid down in the EUMR will be assessed by the Commission, unless the latter consents to a referral of the case to the HCC pursuant to an application by the HCC or the parties to the merger.

Anti-competitive conducts are investigated by the HCC under article 1 or article 2 of the Competition Law. Anti-competitive conduct which may affect trade between EU member states may be investigated by either the HCC or the Commission.

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

In the event of an infringement of article 1 or article 2 of the Competition Law, the following remedies may be imposed by the HCC:

- cease-and-desist orders with a view to bringing an infringement to en end;
- behaviour or structural remedies;
- fines to companies or their individual representatives for breaching competition law or decisions of the HCC. Fines to companies may reach up to 10 per cent of their turnover in the preceding business year, whereas fines to individuals may range from €200,000 to €2 million;
- daily fines up to €10,000 in order to secure compliance with a cease-and-desist order or (behavioural or structural) commitments imposed to the company concerned;
- criminal sanctions to 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-orders but imposed where there is an urgent need to prevent an imminent risk of irreparable harm to public interest.

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 Greek civil courts under Greek tort rules (ie, 914 Greek Civil Code) in connection with an alleged infringement of applicable competition rules. It is noted that pursuant to EU Regulation 1/2003 (OJ [2003] L1/1) and the Competition Law, Greek civil and criminal courts may directly apply articles 101 and 102 TFEU and articles 1 and 2 of the Competition Law. Such actions may be brought regardless of whether the HCC has found an infringement under competition law.

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?

The HCC may initiate a sector-wide investigation on its own initiative or following a request by the minister for development, competitiveness and shipping. So far, the HCC has not initiated such a sector-wide investigation in the pharmaceutical sector.

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

The HCC is the only authority responsible for applying competition rules in the pharmaceutical sector.

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 only in the context of the application of article 1(3) of the Competition Law, setting out the conditions under which conduct caught by article 1(1) of the Competition Law may be exempted.

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

Non-government groups (NGOs) including trade associations, consumer associations, patient associations, may play an important role in the application of competition law in the pharmaceutical sector, since they may submit complaints and intervene in the proceedings of the HCC. In addition, NGOs have the right to express their views in sector inquiries launched by the HCC.

In addition, consumer associations may take actions for damages before civil courts under Greek consumer protection law and Greek tort law provided that they can substantiate the existence of: an unlawful act; 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?

Pharmaceutical mergers are not subject to specific rules or distinct analytical framework, thus, they are treated in the same way as other mergers. In addition, the HCC case law to date does not indicate that the HCC has taken into account sector-specific features of the pharmaceutical industry in the context of its merger assessment.

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

There are limited cases where the HCC has examined a merger involving overlaps between pharmaceutical products. The approach followed by the HCC in respect of the market definition is as follows:

- Product market: The HCC has defined the market based 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 therapeutical category to which the product belongs (see HCC decision 378/V/2008, *Acquisition by Alapis of KP Marinopoulos*); and
- 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 431/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?

Overlaps between product and geographical markets in Greece will be considered as problematic, if a merger results in a substantial impediment, distortion or restriction of competition in the relevant market. In this respect, the HCC will assess whether the merger will have adverse effects to actual or potential competition (including pipeline products which are close to the marketing stage).

As there are no merger cases where the HCC found a problematic product and geographic overlap as a result of the pharmaceutical merger, it can be assumed that the HCC will follow the Commission's approach in this respect. Thus, it appears that horizontal mergers between undertakings might be considered as problematic when the combined aggregate market shares of the merging parties exceed 40 per cent, provided that the increment caused by the merger is not negligible. In case the combined aggregate market shares of the merging parties do not exceed 25 per cent, no competition concerns are likely to arise.

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

Please see the answer to question 15.

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

The HCC may approve a concentration subject to conditions (ie, structural or behaviour remedies) which are imposed to ensure that the concentration (in its initial form or as it may have been modified) does not result in significant restriction on competition or produce coordinated issues. In case of breach of such conditions, the HCC may impose fines which may reach 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 concentration.

There have been to date no decisions by the HCC imposing remedies for the clearance of pharmaceutical mergers. However, we consider that, in such a case, the HCC would most likely accept structural remedies, for instance divestments of overlapping products to suitable purchasers or licensing arrangements on suitable terms with a view to clearing a pharmaceutical merger.

It is noted that the HCC has to date imposed behaviour remedies in certain cases, whereas in October 2009 the HCC issued its first clearance decision subject to divestment (see *Hellenic Petroleum/BP Hellas* transaction).

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?

In merger control cases, the HCC applies the Commission's Consolidated Jurisdictional Notice on the control of concentrations between undertakings (OJ [2008] C95/1) (Jurisdictional Notice). According to the Jurisdictional Notice, an acquisition of intangible assets such as patents may be deemed as a concentration if such assets constitute a business activity generating turnover (see paragraph 24). In this respect, the transfer of licences for patents will qualify as a concentration if the licence is exclusive and the transfer of such licence results in the transferring of the turnover-generating activity on a lasting basis. On the contrary, the transfer of a non-exclusive licence may not constitute on its own a business to which a market turnover is attached and therefore would not qualify as a concentration.

Anti-competitive agreements

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

Article 1(1) of the Competition Law prohibits any agreements or concerted practices between undertakings or associations of undertakings which have as their object or effect the prevention, restriction or distortion of competition in Greece. Anti-competitive agreements under article 1(1) of the Competition Law include the so-called 'hard-core restriction' which restrict competition by their object, ie, price fixing, market sharing, quotas, collective exclusive dealing, output restriction, resale price maintenance, export bans.

Agreements and concerted practices caught by article 1(1) of the Competition Law are automatically null and void under article 1(2) of the Competition Law unless they qualify for an individual or block exemption under article 1(3) of the Competition Law.

Under article 1(3) of the Competition Law, the prohibition under article 1(1) of the Competition Law may be declared inapplicable in case the four conditions laid down therein are cumulatively met, ie, the agreement:

- contributes to improving the production or distribution of goods or promoting technical or economic progress;
- allows consumers a fair share of the resulting benefit;
- does not impose on undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
- does not afford such undertakings the possibility of eliminating competition in a substantial part of the product in question.

'Hardcore restrictions' are not usually exempted under article 1(3) of the Competition Law.

Anti-competitive agreements or practices other than 'hardcore restrictions' are also subject to a block exemption under the EU Block Exemption Regulations which also apply under article 1(4) of the Competition Law.

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

To date, there have been no cartel investigations in the pharmaceutical sector in Greece.

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

The HCC has to date not addressed this issue. In any event, in case of such a technology licensing agreement, EU Block Exemption Regulation No. 772/2004 on technology transfer agreements will apply. According to this Regulation, 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, etc).

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

Article 111(8) of the Ministerial Decision permits the co-promotion and co-marketing agreements. From a competition law perspective, notwithstanding implying a degree of joint activity between competitors, co-promotion and co-marketing agreements are considered as likely to generate efficiencies in the pharmaceutical sector.

So far, the HCC has not assessed co-promotion or co-marketing agreements in the pharmaceutical sector. If HCC had to address co-promotion and co-marketing agreements, it would assess them in light of general competition law. In addition, since such agreements are likely to arise in the context of R&D cooperation between pharmaceutical companies, EU Block Exemption Regulation No. 1217/2010 on R&D cooperation will be also applicable.

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 (actual or potential) competitors – unless falling subject to the de minimis rules – having as their object or effect the prevention, restriction or distortion of competition are prohibited by competition rules whatever the form they assume and regardless of whether they are actually implemented. In this respect, hard-core cartels (eg, price fixing, market sharing and collusive tendering between competitors) and tacit collusion in oligopolistic markets will be prohibited.

However, some agreements between (actual or potential) competitors may not be prohibited provided that they do not entail unnecessary restrictions of competition and they produce benefits for consumers and efficiency gains, which are sufficient to outweigh any restrictions to competition. In this respect, agreements between (actual or potential) competitors such as R&D agreements and joint production agreements may escape the prohibition under article 1(1) of the Competition Law subject to an effect-based analysis (such effect-based analysis will need to take into account all market features, such as market shares, competitive environment, etc). It cannot be excluded that the HCC may require certain internal arrangements to ensure that the exchange of information between the cooperating parties does not go beyond what is necessary for the performance of such cooperation agreement.

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

Vertical agreements (ie, agreements between undertakings operating at different levels of the market chain) may be deemed anticompetitive if they aim at or have as their effect the prevention, restriction, or distortion of competition.

The HCC jurisprudence is not illustrative on this issue with regard to pharmaceuticals. However, exclusivity clauses, import or export bans, market sharing, and non-compete clauses, rebate practices agreed by undertakings operating in the pharmaceutical sector might raise competition concerns under article 1(1) of Competition Law.

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

This issue has not to date been considered by the HCC. However, a patent settlement agreement resolving a dispute will be assessed as any other arrangement under applicable competition rules. In this respect, the Commission Guidelines on technology transfer agreements provide that agreements serving as a means to settle a dispute over intellectual property rights against the other party are not themselves restrictive but the 'individual terms and conditions of such agreements' may be caught by article 101(1) TFEU (OJ [2004] C101/2, paragraph 204). For instance, settlement agreements limiting generic entry or including a value transfer from an originator company to a generic company are likely to be deemed anti-competitive agreements especially if such agreements are entered into with a view to establishing a profit sharing mechanism through payments from the originator company to a generic company to the detriment of patients and public health expenditure.

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?

Article 2 of the Competition Law prohibits undertakings holding a dominant position from abusing it. Article 2 of the Competition Law provides examples of practices caught by its prohibition including charging of unfair prices, limiting production, markets or technical development, discrimination practices, tying and bundling. In general, conduct which is prohibited under article 2 of the Competition includes: exclusionary abuses, ie, practices which have the effect of impeding competition on the relevant market (by forcing out or marginalising existing competitors or raising barriers to entry for potential competitors) and exploitative abuses, ie, practices which are unfair or unreasonable towards those persons which depend on the dominant firm for the supply of goods or services on the relevant market.

With respect to the pharmaceutical sector, the HCC found in its decisions 318/V/2006 in respect of the complaint against GlaxoSmithKline Plc and its Greek subsidiary GlaxoWellcome (Glaxo), that Glaxo was holding a dominant position in the relevant market and breached article 2 of the Competition Law by unjustifiably refusing to supply wholesalers.

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

The HCC and the Greek courts follow the Commission's and EU court's approach in relation to the finding of dominance under article 102 TFEU when considering whether an undertaking has a dominant position, or whether two or more undertakings are 'collectively dominant' in a relevant market. Dominance is defined as a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained in the relevant market by affording it the power to behave to an appreciable extent independently of most of its competitors, its customers and ultimately of its consumers. The assessment of whether a firm has a dominant position takes into account a number of indicators including market shares, the number of competitors, barriers to entry and expansion, potential competition, countervailing buyer power, product differentiation, etc.

A guide on the definition of dominance in the pharmaceutical market lays in the decisions of HCC 318/V/2006 and 229/III/2003 in respect of the complaint against Glaxo for a breach of article 2 of the Competition Law and article 102 TFEU. In this case, the HCC first defined the relevant market based on the principle therapeutical ingredient of the pharmaceutical product (thus defining relevant product market as the market for one pharmaceutical product), and then found that Glaxo has a quasi-monopolistic position in this market since it is the only pharmaceutical company offering such product in Greece.

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

There is no case law on this issue so far. The HCC however is likely to follow the Commission's Communication Guidance on article 102 TFEU which provides that intellectual property rights (IPR) do not themselves confer dominant position on the IPR holder (see

Update and trends

Greece is currently amending its regulatory framework on pharmaceuticals with a view to bringing pharmaceutical spending closer to levels in other EU countries. In this respect, Greece has taken key actions including the promotion of use of generics (eg, via compulsory prescription by active substance), reduction in the maximum price of generics relative to branded medicines (60 per cent), reduction in profit margins of pharmacists and extension of the coverage of copayments. In addition, Greece has recently undertaken efforts to increase tendering procedures for the supply of pharmaceutical products by hospitals as well as to implement e-prescribing across all social security funds.

Commission Communication Guidance on the Commission's enforcement priorities in applying article 102 TFEU to abusive exclusionary conduct by dominant undertakings, OJ [2009] C45/7).

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

The HCC has to date not addressed this issue. In this respect, it is assumed that the HCC will follow the principles which the Commission and the EU General Court applied in *AstraZeneca*, where it was found that the misuse of a patent application by a dominant undertaking may result in antitrust liability.

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

Patent enforcement may raise competition concerns under article 2 of the Competition Law (or article 102 TFEU) if it qualifies as vexatious litigation by the patent holder which holds a dominant position in the relevant market (as to the test for assessing whether vexatious litigation exists see *ITT Promedia NV*).

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

Life-cycle management strategies with a view to taking full advantage of the patent system do not as such raise competition concerns. However, life-cycle strategies will be likely to raise competition issues if they are applied by dominant undertakings, have foreclosure effects (eg, preventing or delaying generics market entry) and cannot be objectively justified. So far, the HCC has not assessed such strategies in the pharmaceutical sector.

32 Do authorised generics raise issues under the competition law?

Generics companies offering authorised generics might be involved in anti-competitive practices if they enter into arrangements which restrict or distort competition between generics companies. In addition, anti-competitive issues may also arise in the case of mergers between originators and generics companies if they result in launching generic versions of the originators' products prior to the expiry of the patent and the market entry of the generic versions, capturing as a result the market and impeding generics companies from gaining a significant share of the market. So far, the HCC has not addressed similar concerns.

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

Dominant undertakings accused of abuse can rely on objective justifications to excuse their conduct. In this regard, EU Court AG Colomer opined in the *Lelos* case that in order to justify its abusive behaviour, a dominant undertaking may rely on features relating to the particular market (see Cases C-468 and 478/06, two cases where the EU Court was asked to give its preliminary ruling inter alia on which grounds Glaxo may rely on to justify its breach of article 2 of Competition Law by refusing to supply all its wholesalers based in Greece (see above HCC decision 318/V/2006)).

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 particular increase in antitrust enforcement in the pharmaceutical sector in Greece. Based on the schedule of upcoming hearings of the HCC, there are no opened or pending cases relating to pharmaceuticals.

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.

Follow-on litigation has not to date been a feature of pharmaceutical enforcement in Greece.

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