GETTING THE DEAL THROUGH

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Pharmaceutical Antitrust

The application of competition regulation in 29 jurisdictions worldwide

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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 marketing and authorisation of pharmaceutical products are governed by Ministerial Decision DYG3(a)/83657/30.12.2005 (published in Governmental Gazette No. B/No.59/24.01.2006).

Pharmaceutical price regulation is centralised and price setting remains a national health policy issue. It is regulated by chapter 27 of Greek Market Regulation Code. The price regulation process is based on an agreement between the country's health authorities and the pharmaceutical industry. The purpose of the agreement is usually to approve safe and effective medicines at reasonable prices, encouraging investment and competitive economic policies. The responsibility for pricing lies with the Ministry of Development, which issues official prices subject to the consent of the Ministry of Health. Such prices are regularly published in a price bulletin, which is distributed to all pharmacies.

Price determination process takes into account various factors, including:

- wholesale prices of imported products – these are fixed at the lowest ex-factory European price to which import expenses and other charges that apply are added;
- wholesale prices of locally manufactured or packaged products – these are defined by taking into account production and distribution costs, adding the profit margin of the producer and other charges that may apply; and
- the retail price is the wholesale price plus the pharmacist's profit margin and VAT. The retail price is uniform all over the country, except for some districts where reduced VAT rates apply, etc.

The prices of over-the-counter products are also regulated, in the same way as prescription medicines.

Pharmaceutical companies are required to prepare an application dossier to start a procedure for a drug authorisation. The application dossier is submitted to the National Drug Organisation (EOF). The Price Committee at the Ministry of Development deals with price process. A pre-requisite for price setting is the marketing of the product in at least one European country.

Generic products are regulated by article 11 of the above-mentioned Ministerial Decision DYG3(a)/83657/30.12.2005. Also, the EOF, in its Circular No. 34193/11.10.1999, has adopted the guidelines of the EC 368/96 Decision (Generics). The prices of generic products are set at 80 per cent of the retail price of the respective branded medicine.

2 Which bodies are entrusted with enforcing these regulatory rules?

The EOF, the Ministry of Health and Social Solidarity and the Ministry of Development enforce the above-mentioned regulatory rules.

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

A lot of aspects (as mentioned above) of the existing regulatory regime directly affect competition rules, for example:

- prices are not freely set by market forces (as is the case for the majority of products) but are fixed by public bodies;
- such state intervention, on the basis of protection of the national health budget, supersedes the principles of free competition;
- also in the distribution chain, wholesale margins are also fixed, again 'eliminating' competition; and
- the obligation imposed on firms to maintain sufficient stocks to satisfy national demand is another strong indication that the pharmaceutical sector does not function under conditions of normal competition.

Competition legislation and regulation

4 Which legislation sets out competition law?

Greek Competition Law is set out by Law 703/77 'On the control of monopolies and oligopolies and the protection of free competition', as amended by Laws 1934/1991, 2000/1991, 2296/1995, 2323/1995, 2741/1999, 2837/2000, 2941/2001, 3105/2003, 3260/2004, 3373/2005, 3419/2005, 3438/2006, 3604/2007 and 3592/2007. Also, specific decisions, issued by the Hellenic Competition Committee (HCC), of regulatory power, apply (eg, Decision No. 299/V/2006 on Leniency, Announcement of 2 March 2006 on 'De minimis').

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

No. The Competition Law applies to all business sectors.

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

Pharmaceutical mergers, as well as the anti-competitive effect of conduct or agreements in the pharmaceutical sector, are subject to common regulations that apply to all sectors. The HCC is the competent body to decide on both.

If a merger has not been approved by the HCC, the Ministry of Development and the Ministry of Finance have the authority (arti-

cle 4c of Law 703/77), under specific conditions, to approve such a merger, if for example such merger has general economic benefits, setting-off any distortion of competition, or for reasons of national economy, or if such merger attracts investments in Greece.

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

Again, there are no specific remedies for the pharmaceutical sector, so the common competition remedies apply. The HCC may:

- prohibit the concentration of undertakings, in cases where the concentration may significantly restrict competition;
- allow an exemption from the obligation to suspend mergers, in cases where the law so permits;
- impose fines, pecuniary penalties or other sanctions mentioned in the law;
- order injunctive measures;
- express its concurrent opinion on the issuance of a decision by the minister of development which allows the exemption of certain categories of cooperative ventures; and
- express its concurrent opinion on the issuance of a decision by the minister of development specifying categories of ventures that are not prohibited.

For example, on 3 August 2001 the HCC ordered GSK to supply three medicines to Greek wholesalers in unlimited quantities. The order came as a surprise, since never before had a competition authority ordered the supply of unlimited quantities, not even from a public utility company.

In its Decision No. 318/V/2006 the HCC decided that GlaxoSmithKline AEVE (a subsidiary of GlaxoSmithKline Plc) had violated article 2 of Law 703/77. Refusal to supply was considered as abusive exploitation of a dominant position. No fine was imposed. The HCC ordered the company to abstain from such behaviour in the future, otherwise a fine of 3 per cent on gross revenue would be imposed.

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 can lodge a complaint before the HCC or request interim measures. Regarding any possible damages, civil courts have competence, although establishing damage is always a crucial issue.

The HCC Decision No. 318/V/2006 was issued following a complaint lodged by various pharmaceutical wholesalers and associations. Before such decision, Decision No. 193/III/2001 ordered interim measures, obliging the company to execute the orders for the medicines under question, up to final decision.

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?

By virtue of article 5 of Law 703/77, the HCC has the authority either on its own initiative or following an order by the Ministry of Development to conduct sector-wide inquires. If it finds out that competition conditions are not sufficient, it can impose specific measures (of a regulatory character).

No such official investigations have been published on 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?

No. The EOF or the Ministry of Health and Social Solidarity have no authority over antitrust rules. As an expert body, however, EOF can be invited to participate before the HCC in a pending case (eg, in the *GlaxoSmithKline* case, EOF was invited by a specific decision of the HCC, as well as the director of the Pharmaceutical & Pharmacies Direction of the Ministry of Health).

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

Competition rules do not apply to privatisations of Greek enterprises. Also article 1, paragraph 3 of Law 703/77 provides that exemption could be granted to an anti-competitive (prima facie) agreement for reasons of technical or financial progress.

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

NGOs do play a role, as experts in the field, but there is no specific provision applying to them as far as procedure before the HCC is concerned. They have the powers any third party could have to lodge complaints and intervene (by lodging an official application) in a pending case. As already explained, the HCC also invites them, on its own initiative, to participate in a pending case and testify.

Consumer associations can initiate actions for damages only in civil courts (on the basis of Law 2251/1994, the Consumer Protection Law). The legal basis for such actions would be, as for all actions for damages, article 914 of the Greek Civil Code establishing tort liability. The cumulative substantive conditions for claiming damages are: unlawful act, damage and the existence of a causal link between the unlawful act and the damage. Damages are assessed on the basis of injury suffered by the plaintiff. No economic models exist under Greek law for the calculation of damages.

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?

There are no specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed. As mentioned above, however, the Ministry of Development and the Ministry of Finance have the authority (article 4c of Law 703/77), under specific conditions, to approve a merger prohibited by the HCC, if for example such merger has general economic benefits, setting-off any distortion of competition, or for reasons of national economy, or if such merger attracts investments in Greece.

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

There is no specific provision on this. Through various decisions of the HCC on mergers in the pharmaceutical industry, the following definitions have been followed.

Product market: test of substitutability has been applied. In certain cases, wholesalers' market (ie, wholesales from wholesalers' storage to pharmacies) has been deemed to be the relevant product market (Decision No. 378/V/2008). In others, (Decision No./148/

II/2000) production and trade of pharmaceutical products has been defined as relevant product market, which was further sub-divided in categories according to specific use of product, characteristics of products, therapeutic classes (eg, TNP solutions, basic intravenous solutions, colloids – Decision No. 14/II/1998). Also, prescribed and non-prescribed pharmaceutical products also have been defined as the relevant market (Decision No. 189/III/2001).

Geographic market: the Greek national market has been traditionally defined as a relevant geographic market, although, in various cases companies have claimed that European market should be the relevant market when lodging the notification.

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

According to Greek law, a merger control filing (pre-merger notification) is required where the combined aggregate turnover of the participating undertakings amounts to at least €150 million worldwide and each of at least two of the participating undertakings have a turnover of more than €15 million in the Greek market. The obligation to make a post-merger notification applies for concentrations where the combined market share of the participating entities in the product market represents at least 10 per cent of the total market of the products or services concerned, or where the aggregate turnover of at least two of the participating undertakings in Greece amounts to €15 million. The HCC will prohibit all concentrations of undertakings that are subject to pre-merger notification and that would significantly impede competition in the national market or in a substantial part thereof, in relation to the characteristics of the products or the services concerned, and in particular by the creation or strengthening of a dominant position. The test is in accordance with the EU merger control guidelines.

To evaluate whether a merger would significantly impede competition the criteria are:

- the structure of the relevant markets;
- the actual or potential competition by virtue of the businesses established in or outside Greece;
- the existence of legal or actual barriers to enter the market;
- the position of the parties concerned in the market and their financial and economic power;
- the alternatives available to suppliers and consumers to the parties concerned and to other existing or potential competitors;
- their access to suppliers or product markets;
- the trend of supply and demand of the relevant products and services; and
- the interests of intermediate and final consumers and their contribution to technical and economic progress, provided that this progress is to the benefit of the consumer and does not impede competition.

In its Decision No. 378/V/2008 (approval of the acquisition of 51 per cent of the company Marinopoulos by Alapis), the HCC, after assessing all data in the case, as well as the specific structure of the market and the market shares of the companies concerned, found that the said concentration 'does not create or strengthens any dominant position […] and raises no doubt as to the possibility to restrict significantly competition in the relevant markets, which the concentration concerns'.

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

There is no case law whereby a potential overlap of pipeline products has been examined. Theoretically, it would be examined in the context of 'the actual or potential competition'.

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

There is no case law on this issue. Still, as discussed above, the Ministry of Finance and Development could overcome any difficulties identified and permit a merger for specific reasons.

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?

Acquisition of assets fall within the meaning of 'control'. In particular, article 4(c) of Law 703/77 states that control derives from rights, contracts or other means that, either separately or in combination and taking into account the relevant factual and legal circumstances, provide the capacity to decisively control the activities of an undertaking and especially by: ownership or the right of use in respect of the whole or a part of the assets of an undertaking; or rights or contracts that provide the capacity to control decisively the composition, voting or decisions of the organs of an undertaking.

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 of Law 703/77, all agreements between undertakings, all decisions, by associations of undertakings and concerted practices that have as their object or effect the prevention, restriction or distortion of competition, shall be prohibited and, in particular, those that:

- directly or indirectly fix purchase or selling prices or any other trading conditions;
- limit or control production, markets, technical development or investment;
- share markets or sources of supply;
- apply dissimilar conditions to equivalent transactions with other trading parties, thereby impeding competition, in particular by refusing, without valid justification, to sell, purchase or conclude any other transaction; or
- make the conclusion of contracts subject to acceptance by other parties of supplementary obligations that, by their nature or according to commercial usage, have no connection with the object of such contracts.

20 Have there been cartel investigations in the pharmaceutical sector?

There is no official decision published by HCC.

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

Technology licensing agreements could merit an exemption under article 1, paragraph 3 of Law 703/77. The HCC, could exempt such agreement, which restrict competition but:

- contribute to improving the production or distribution of goods or to promoting technical or economic progress;
- allow consumers a fair share of the resultant benefit;

- do not impose any restrictions which are not indispensable to the attainment of the aforementioned objectives; or
- do not afford the parties concerned the possibility of eliminating competition in a substantial part of the relevant market.

However, since the said provision resembles article 81 EC, the HCC tends to follow guidelines issued by EC and interpretation by EC courts.

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

Any agreement between competitors raises suspicions of illegal collusion, such as price fixing, which belongs in the core of anti-competitive behaviour.

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

R&D agreements, joint ventures and any other form of collaboration with a competitor raises the suspicion of anti-competitive behaviour, which – of course – has to be proved on the specific facts of each case.

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

Usually, vertical agreements will raise antitrust concerns if they include hard-core restrictions, such as price fixing affecting the end-user. There is no case law in the pharmaceutical sector on this matter, however.

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

Any agreement between competitors raises suspicions of illegal collusion, such as price fixing, which belongs in the core of anti-competitive behaviour.

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 703/77, abusive behaviour by a dominant firm can include:

- directly or indirectly imposing fixed purchase or selling prices or other unfair trading conditions;
- limiting production, consumption or technical development to the disadvantage of consumers;
- applying dissimilar conditions to equivalent transactions with other trading parties, in particular by refusing, without valid justification, to sell, purchase or conclude any other transactions, thereby placing certain undertakings at a competitive disadvantage; or
- making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations or supplementary contracts that, by their nature or according to commercial usage, have no connection with the subject of such contracts.

The HCC ruled in *GlaxoSmithKline* that the decision to stop supplying the wholesalers and distribute the pharmaceuticals itself did not constitute per se an abuse of dominant position. It is important to mention that in this case the HCC referred questions to the ECJ in January 2003 based on how and when a dominant company is allowed to refuse fully to meet wholesalers' orders to limit parallel trade. Advocate General Jacobs issued a positive opinion on the questions in October 2004, indicating that GlaxoSmithKline's conduct in failing to meet orders was fully justified. According to the advocate general, 'restricting the supply of products does not automatically constitute an abuse of a dominant position merely because the dominant undertaking intends to restrict parallel trade.' He went on to note that a dominant company 'is not obliged to meet orders which are out of the ordinary' and is entitled to take reasonable steps 'in order to defend its commercial interests.' Despite the positive opinion, which is usually adopted by the European Court of Justice (ECJ), the ECJ referred the case back to the HCC in May 2005 without issuing a decision, because the HCC, not being a court or a tribunal, nor a legal body, cannot refer questions to the ECJ.

Also, the Athens Appeal Court, in its Decision No. 7770/2007 ruled that a refusal to supply was not abusive, since the behaviour of the company was due to 'its attempt to prevent the reduction of its profit, arising out of the different prices of the said pharmaceutical product in the various EU member states' and therefore justified.

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

There is no legal definition of a dominant position. According to the HCC's case law, the dominant firm is the one that is in a position to behave independently of its competitors, customers and consumers.

A crucial indicator for dominance is high market share; other factors include:

- the existence of other competitors in the market, having the same vertical integration;
- the range of products offered by competitors;
- entry of new competitors in the same market and assessment of distribution channels; and
- financial and technological power.

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

Not by itself. Other conditions have also to be fulfilled, such as the substitutability test.

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

Not necessarily an abuse of dominance.

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

There is no precedent available concerning the issue of whether the enforcement of a patent could raise issues under antitrust law.

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

Patents are granted for 20 years. An extension for five more years could be awarded by the issuance of a Supplementary Protection Certificate. At the expiry of the patent-covered period, antitrust issues could theoretically be raised, if, for example, the patent holder tries artificially to extend their monopoly (by adopting 'defensive' mechanisms and trying to register new products to restrict competition by companies producing generic products). Patent litigation is very often seen in Greek civil courts, usually between big multinational companies (holding a patent) and Greek companies (producers of generics). There is no case law as per antitrust implications so far.

Update and trends

Regarding the judicial civil cases between patent holders and generic producers, Greek courts are very reluctant to order interim measures; therefore civil cases take a long time to reach a final decision. Such delay favours generics producers, who are usually Greek companies, since they are free to sell.

At the time of writing (April 2009), a draft law amending Law 703/77 has been given to the public (1 April 2009) by the Ministry of Development. The new draft law imposes severe criminal penalties on individuals for breaching competition rules, strengthens the investigation powers and the forces of the HCC, and provides for an Internal Audit Division in the HCC, among other measures.

32 Do authorised generics raise issues under the competition law?

The state's interest is to increase the market share of generic drugs, so as to reduce health insurance expenses. Defence strategies by patent holders to impede their competitors in developing generics are currently a subject of investigation by the EC; in this context it is very likely that the EC will collaborate with the HCC and request data about the Greek market. There is no precedent case on this issue.

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

Public health issues prevail over principles protected by antitrust rules. Public health is being seen as more important than free competition; therefore, competition is being restricted by legislative and administrative rules, which for other products would be considered as contrary to the basic principles of antitrust rules and would be incompatible with the constitutional and community legal regimes (Athens Appeal Court Decision 7770/2007 confirms such principle).

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