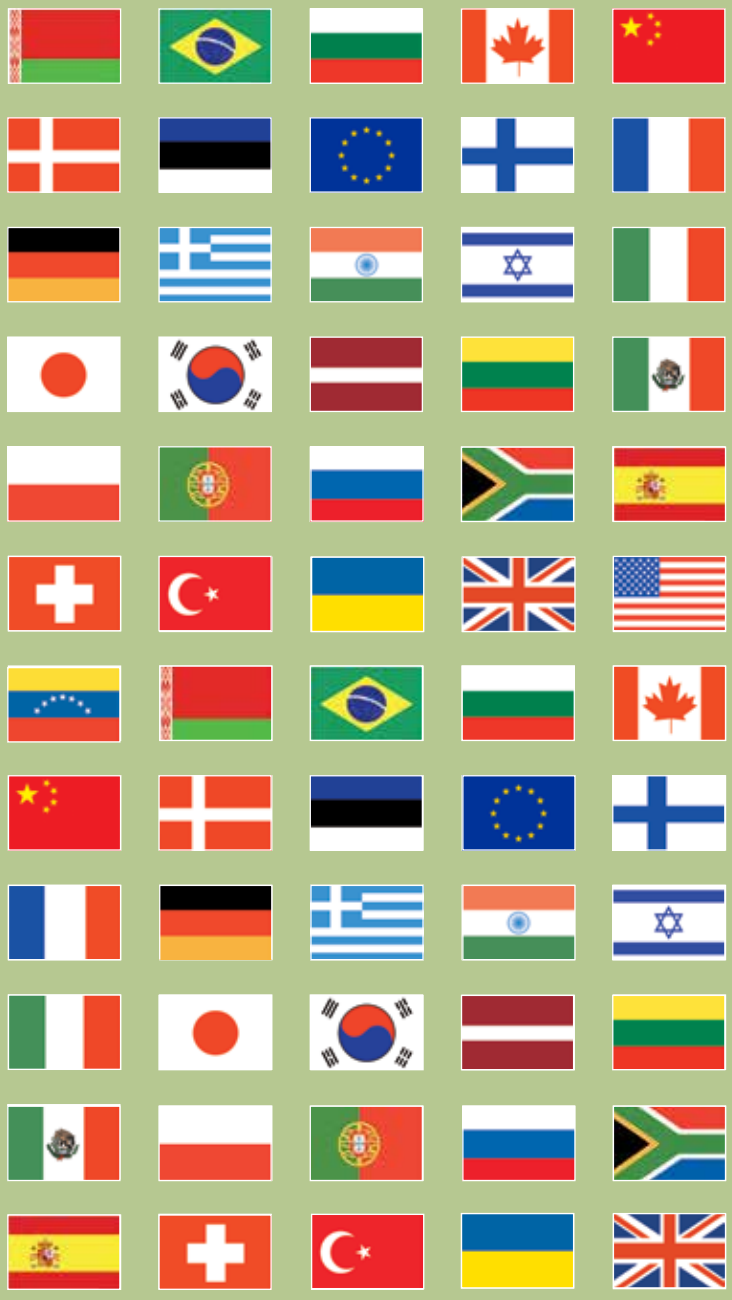
GETTING THE DEAL THROUGH

# Pharmaceutical Antitrust

## in 31 jurisdictions worldwide

## 2014

**Contributing editor: Marleen Van Kerckhove**



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### Contributing editor: Marleen Van Kerckhove Arnold & Porter LLP

*Getting the Deal Through* is delighted to publish the fully revised and updated seventh edition of *Pharmaceutical Antitrust*, a volume in our series of annual reports, which provide international analysis in key areas of law and policy for corporate counsel, cross-border legal practitioners and business people.

Following the format adopted throughout the series, the same key questions are answered by leading practitioners in each of the 31 jurisdictions featured. New jurisdictions this year include Israel, Poland and Spain.

Every effort has been made to ensure that matters of concern to readers are covered. However, specific legal advice should always be sought from experienced local advisers. *Getting the Deal Through* publications are updated annually in print. Please ensure you are always referring to the latest print edition or to the online version at www.GettingTheDealThrough.com.

*Getting the Deal Through* gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. Getting the Deal Through would also like to extend special thanks to contributing editor Marleen Van Kerckhove at Arnold & Porter LLP for her continued assistance with this volume.

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## CONTENTS

# Bulgaria

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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 Medicinal Products in Human Medicine Act of 2007 (the 2007 Medicinal Products Act), as amended, provides the regulatory framework for marketing, authorisation and pricing of pharmaceutical products in Bulgaria. A number of secondary legislative acts further detail the specific tenets and requirements in these areas.

**2** Which bodies are entrusted with enforcing these regulatory rules?

The Bulgarian Drug Agency is responsible for enforcing the regulations regarding authorisation and marketing of pharmaceutical products in Bulgaria. At a regional level, the Drug Agency exerts control of manufacturing, storage, marketing (including wholesale and retail trade) of pharmaceutical products in close coordination with the regional health inspectorates.

The National Council for Pricing and Reimbursement, a body formed and operating under the auspices of the Minister of Health, is responsible for pricing. It sets and amends prices of reimbursed products, and includes or excludes such products from the reimbursement lists.

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

Marketing authorisation, pricing regulations and public supply obligations are the aspects most directly relevant to the application of competition law to the pharmaceutical sector in Bulgaria.

## Competition legislation and regulation

**4** Which legislation sets out competition law?

The Act on Protection of Competition of 2008 (the 2008 APC), as amended, sets out the principles and rules of competition law in Bulgaria.

Chapter 3 of the 2008 APC introduces the ban on anti-competitive agreements and concerted practices between undertakings, and decisions of associations of undertakings. A set of conditions for individual exemption and de minimis thresholds are provided for as well.

Chapter 4 of the 2008 APC sets out the rules for establishing dominance and the prohibition of its abuse (including a non-exhaustive list of possible forms of abuse).

Chapter 5 of the 2008 APC details the requirements for merger control review of transactions that qualify as concentrations and the turnover thresholds that trigger a review.

The rules on sector inquiries are provided for in Chapter 6. Chapters 8 et seq flesh out the procedural rules, as well as sanctions imposed when Bulgarian competition law is breached.

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

No specific guidelines on the application of competition law to the pharmaceutical sector have been adopted in Bulgaria. However, general block exemption guidelines with respect to horizontal, vertical, research and development, specialisation and technology transfer agreements exist and could be of relevance to interactions between competitors, suppliers or distributors in the sector.

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

The Commission for the Protection of Competition is the agency entrusted with the enforcement of competition law in Bulgaria. The authority investigates and rules on mergers, anti-competitive agreements and abuse of dominance in the pharmaceutical sector. Its decisions are subject to appeal before the Bulgarian Supreme Administrative Court, which renders a final decision in the case.

Bulgarian civil and administrative courts may also act as national competition authorities under Regulation 1/2003 and adjudicate on cases of anti-competitive agreements in the pharmaceutical sector to which EU antitrust rules apply. Under Bulgarian law, private damages claims may be heard in civil courts.

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

The Commission for the Protection of Competition may:

- impose interim measures in cases of urgency when a risk of serious and irreparable damage exists. The interim measure may take the form of termination of the infringement or other actions;
- order the termination of the infringements (a cease-and-desist order), including the adoption of behavioural or structural measures for restoring effective competition;
- impose a sanction of up to 10 per cent of the pharmaceutical company's Bulgarian turnover in the last full financial year. For example, a local wholesaler, Sanita Trading, was fined approximately €35,000 in 2005 for refusal to supply insulin to pharmacies; or
- approve commitments proposed by the pharmaceutical company under investigation. In this case, the investigation is closed without formally establishing an infringement. Commitments may not be adopted in cases of serious infringements (eg, cartels).

**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 in principle seek interim measures, a cease-and-desist order or other behavioural or structural measures for restoring competition, or redress for damages incurred as a result of the antitrust infringement. Private damages actions have not yet gained traction in Bulgaria.

**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 Commission for the Protection of Competitions has the powers to conduct sector-wide inquiries and does so on a regular basis, mainly in industries close to end-consumers.

The authority completed a sector inquiry in the pharmaceutical sector in 2006. Back then, it was concluded that the market environment at the three levels of the supply chain – manufacturing and imports, wholesale and distribution, and retail sale – was relatively competitive. At the level of manufacturing and imports, and retail sale, the markets were fragmented, whereas the wholesale and distribution segment was more concentrated. The cause for greatest concern was the vertical integration between manufacturers, wholesalers and distributors on the one hand, and chains of pharmacies on the other. The Commission for the Protection of Competition opened two follow-on probes on the basis of the findings from the sector inquiry. One investigation – Higia EAD – related to alleged anti-competitive vertical arrangements between a wholesaler and pharmacies. No infringement was established. The second probe concerned the alleged refusal of three wholesalers (Sting, Sanita Trade and National Commercial League) to supply medicinal products to a certain chain of pharmacies. No infringement was established in this case either.

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

The Bulgarian Drug Agency, the regional health inspectorates and the National Council for Pricing and Reimbursement are not responsible for sector-specific regulation of competition as distinct from the general 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 have been less likely to gain ground in an antitrust investigation before the Commission for the Protection of Competition since Bulgaria joined the European Union. Recently, the authority has tended to consider more case-specific objective justifications and efficiency gains.

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

Non-government groups play a role in the application of competition rules to the pharmaceutical sector mainly through participation in market-testing exercises. Apart from that, their role in the enforcement process is not particularly prominent for the time being.

## 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 sector-specific features of the pharmaceutical industry are taken into account in merger reviews only when specific to the case.

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

Product markets are defined by reference to the ATC classification (predominantly, to ATC 3 level). The geographic dimensions are by and large considered to be national because of the national regulatory specificities.

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

A product and geographical overlap between two merging parties would in principle be considered as worth further, in-depth scrutiny when the parties' combined market share exceeds 15 per cent and, based on the Commission for the Protection of Competition's decisional practice so far, the increment is larger than 1 per cent. Though not formally set as a 'rule of thumb' threshold, a combined market share of 40 per cent or more is likely to be considered problematic if no sufficient competition constraints can be established.

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

No specific soft law or case law authority to that effect exists to date.

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

Remedies are not typically required in pharmaceutical mergers in Bulgaria.

**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?

The acquisition of one or more patents or licences is subject to merger notification if:

- the patent or patents represent a part of an undertaking;
- turnover from activities in Bulgaria can be clearly allocated to the patent and this turnover exceeds approximately €1.53 million in the last full financial year; and
- the acquirer's and the target's combined Bulgarian turnover in the last full financial year exceeded €12.7 million.

## Anti-competitive agreements

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

The general framework for assessing agreements and practices for their compatibility with Bulgarian antitrust law is provided for in Chapter 1 of the 2008 APC. Anti-competitive acts are considered to be agreements or practices whose object or effect is to prevent, restrict or distort competition on a given market, such as:

- direct or indirect fixing of prices or other commercial conditions;
- allocation of markets or sources of supply;
- limitation to or control of production, trade, technical development or investment;
- application of dissimilar conditions to equivalent transactions with trading parties whereby one of them is put at a competitive disadvantage in relation to its competitors; and

- making the conclusion of a contract conditional upon the acceptance by the other party of additional obligations that by their nature or according to commercial custom have no connection with the subject of the main contract or with its performance.

Anti-competitive agreements are deemed null and void by operation of law.

Agreements or practices that could restrict competition may escape competition law sanction should their effect be de minimis or they merit individual exemption.

The effects of an agreement or a practice are considered to be de minimis provided that:

- in cases of horizontal agreements, the parties' combined market share does not exceed 10 per cent; and
- in cases of vertical arrangements, each party's market share on the relevant upstream or downstream market does not exceed 15 per cent.

An agreement or a practice qualifies for an individual exemption provided that it:

- contributes to improvement of production, distribution or technical progress, and allows consumers a fair share of the resulting benefit; and
- does not impose restrictions on competition, possibly eliminating it.

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

One investigation in an alleged hard-core (cartel) agreement in the pharmaceutical sector in Bulgaria has been conducted so far. It related to suspected bid rigging for local public procurement contracts for the supply of antianæmic preparations and methadone to hospitals in the period 2005–2010. Identical or similar prices were to be observed in several bidders' quotes for both products. In the course of the investigation, the Bulgarian Commission for the Protection of Competition conducted an extensive correlation analysis of input and bidding prices per defined daily dose for each product group during the relevant period. Although certain symmetries in pricing appear to have been established, the authority considered them as mere indicia that would not stand as sufficient evidence. As no tangible proof of price coordination between bidders was available, the Commission for the Protection of Competition considered that it was not in a position to draw firm conclusions on that point. Furthermore, the authority recognised the transparency-enhancing effects of certain regulatory requirements for pricing (eg, price ceilings) and eligibility to bid (eg, the need to provide a pharmaceuticals manufacturer's confirmation of quantities and prices in bids).

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

To date, the Bulgarian Commission for the Protection of Competition has not raised objections of principle against technology licensing agreements. Technology transfer agreements may in principle merit group exemption if the conditions under the Bulgarian Group Block Exemption Rules with respect to technology transfer are met. These conditions are identical to the ones provided for in Commission Regulation No. 772/2004. It can be reasonably expected that unsettled issues under Bulgarian law will be resolved in the light of Regulation No. 772/2004 and the relevant guidelines.

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

The Bulgarian Commission for the Protection of Competition has not dealt with co-promotion and co-marketing agreements in its enforcement practice so far and thus has not taken a stance on these concepts and their possible effects on competition. However, based on the authority's soft law guidelines and decisional practice in other industries, co-promotion and co-marketing agreements are likely to be considered anti-competitive if they bring about exchange of sensitive commercial information, significant commonalities of cost, or outright or tacit coordination.

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

Under Bulgarian law, hard-core agreements are considered anti-competitive and per se illegal.

Research and development, specialisation and commercialisation are likely to raise concerns upfront if they result in collusion. Otherwise, their conformity with competition law would be assessed against the Bulgarian Group Block Exemption Rules, which are identical to those under the relevant European Commission's block exemption regulation, or after weighting their anti and pro-competitive effects under the Bulgarian individual exemption rules.

Exchange of sensitive commercial information (especially contemporaneous and future pricing, output and sales data) would also raise competition concerns under Bulgarian law.

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

Hard-core arrangements under vertical agreements are most likely to raise antitrust concerns. Arrangements that could possibly result in foreclosure on a downstream market, such as exclusive supply or distribution agreements, are also likely to be seen by the Bulgarian Commission for the Protection of Competition as problematic.

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

To date, the Bulgarian Commission for the Protection of Competition has not raised objections of principle against patent settlements. Should a patent settlement in the pharmaceutical sector be brought for review by the authority, its views are likely to be shaped by findings and conclusions reached in the European Commission's sector inquiry and reports on the monitoring of patent settlements.

## 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?

The conduct of a firm with monopoly or market power would be considered to be anti-competitive if it prevents, restricts or distorts competition and harms consumers by foreclosing competitors or exploiting customers or suppliers. Forms of abusive behaviour include:

- predatory pricing;
- margin squeeze;
- direct or indirect imposition of unfair prices, or other unfair trading conditions;
- application of dissimilar conditions to equivalent transactions with different trading parties thereby placing them at a competitive disadvantage;
- making the conclusion of an agreement conditional upon the other party undertaking additional obligations or entering into other agreements that – by their nature or according to the settled trade practice – have no link to the main agreement or its performance;
- refusal to sell goods or provide services to an actual or a potential

customer and thus hindering the activities carried out by the customer, which may prevent, distort or eliminate competition; and
- limitation of production, marketing and technical development to the detriment of consumers.

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

A party is considered dominant when – on the basis of its market share, financial resources, access to markets, technology sophistication and relations with other parties – it is in a position to act independently from its customers, suppliers and competitors. An undertaking with a market share of less than 40 per cent is unlikely to be considered dominant. In its decisional practice, the Bulgarian Commission for the Protection of Competition has considered the undertaking's substantial financial resources (eg, operating profit of a few hundred million euros, a two-digit revenue growth in a previous financial year, and assets of tens of millions of euros on a consolidated basis), vertical integration, a web of exclusive distribution arrangements, first-mover advantage and a strong brand as indications of significant market power.

Two or more parties are likely to be considered jointly dominant when they are linked in such a manner that they carry out – even only in certain respects – joint conduct on the market, namely they tacitly coordinate their market policies.

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

In its decisional practice with respect to other industries, the Bulgarian Commission for the Protection of Competition has held that exclusive rights may render an undertaking dominant. By the same token, it could be reasonably expected that a patent holder could be found to be dominant on account of the patents that it holds.

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

The Bulgarian Commission for the Protection of Competition has not dealt with such a hypothesis in its decisional practice so far. As a matter of principle, an application for the grant of a patent could expose the applicant to antitrust liability should the applicant be found to have abused the procedure in a way that leads to an unjustified grant of patent rights and foreclosure of further market entries.

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

Possible abusive enforcement of patent rights has not been subject to antitrust scrutiny in Bulgaria. It can be expected to cause competition law concerns if it artificially raises barriers to entry or results in market allocation.

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

Life-cycle management strategies have not triggered the Bulgarian Commission for the Protection of Competition's investigative attention so far. They may be expected to invite scrutiny to the extent that they impair innovation and fend off market (especially generic) entries.

**32** Do authorised generics raise issues under the competition law?

To date, authorised generics have not raised competition concerns under Bulgarian law.

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

Features of the pharmaceutical industry are likely to be considered as objective justification only if specific to the factual background of a given case.

**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.

Over the past five years, the number of antitrust investigations in the pharmaceutical sector in Bulgaria has been decreasing. The majority of the cases concerned the role of the National Health Insurance Fund (eg, pricing and reimbursement policies) in shaping the competitive environment on the markets for wholesale and retail trade in medicinal products.

**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.

No. Follow-on litigation has not yet gained momentum in Bulgaria despite the attempts of the Bulgarian Commission for the Protection of Competition to promote it.


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