Pharmaceutical Antitrust

Contributing editors
Marta Giner Asins and Yann Anselin

2018

GETTING THE DEAL THROUGH

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Norton Rose Fulbright LLP

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Preface

Pharmaceutical Antitrust 2018

Eleventh edition

Getting the Deal Through is delighted to publish the eleventh edition of *Pharmaceutical Antitrust*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Bulgaria, Canada and Romania.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Marta Giner Asins and Yann Anselin of Norton Rose Fulbright LLP, for their continued assistance with this volume.

GETTING THE DEAL THROUGH

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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? Which bodies are entrusted with enforcing these rules?

Regulation of the marketing, authorisation and pricing of pharmaceutical products in Bulgaria is contained in the Medicinal Products in Human Medicine Act, as well as in several secondary legislative acts that further elaborate upon specific aspects of those areas.

The regulatory rules in relation to the marketing and authorisation of medicinal products are enforced by the Executive Drug Agency, while the pricing of medicinal products is regulated and enforced by the National Council for Pricing and Reimbursement.

2 Are drug prices subject to regulatory control?

Drug prices are heavily regulated at all levels of the supply chain and at no point do they stop being regulated. The National Council for Pricing and Reimbursement compiles a positive drug list that determines which drugs are covered by national health insurance and the state budget. The positive drug list comprises four groups of medicinal products defined in article 262 of the Medicinal Products in Human Medicine Act:

- outpatient drugs reimbursed by the National Health Insurance Fund (NHIF) as stipulated by the Health Insurance Act;
- pharmaceuticals purchased by public hospitals, centres for emergency care, inpatient psychiatric facilities, medico-social care centres for children and centres for transfusion haematology, which are not included in the basic benefit package;
- pharmaceuticals for oncological and rare diseases as well as for dialysis and transplant patients, which were financed by the Ministry of Health through the state budget until 2011 and are now funded by the NHIF; and
- pharmaceuticals for AIDS and infectious diseases financed by the Ministry of Health through the state budget.

As regards the pricing of medicinal products, article 261a of the Medicinal Products in Human Medicine Act sets out four categories of medicinal products and the type of control the National Council for Pricing and Reimbursement exerts:

(i) regulation of the prices of medicinal products included in the positive drug list under article 262, paragraph 1 (outpatient drugs reimbursed by the NHIF as stipulated by the Health Insurance Act) and paid by public funds in accordance with the lowest reference prices in the member states;
(ii) regulation of the price limits of prescription drugs, apart from those under (i), in accordance with the lowest reference prices of the drug in the other member states;
(iii) registration of maximum selling prices for the retail sale of non-prescription drugs; and
(iv) ensuring the retail sale prices of the drugs included in the positive drug list do not exceed those paid with public funds under (i).

3 Is there specific legislation on the distribution of pharmaceutical products?

The regulatory framework on the distribution of pharmaceutical products, for both wholesale and retail sale, is contained in the Medicinal Products in Human Medicine Act.

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

Market access and authorisation, wholesale and retail distribution, as well as regulation on pricing are all directly relevant to the application of competition law.

Competition legislation and regulation

5 Which legislation sets out competition law?

The regulatory regime of competition is set out in the Bulgarian Competition Protection Act of 2008 (CPA) (most recently amended on 3 January 2018), as well as in the directly applicable Treaty on the Functioning of the European Union (TFEU) (articles 101 and 102) and the respective EU regulations.

With the latest regulatory changes to the CPA, the national legislator implemented the Damages Directive (Directive 2014/104/EU). The amendments to the CPA largely follow the structure of the Damages Directive and entered into force on 7 January 2018. They apply to both breaches of articles 101 and 102 TFEU and of the national provisions of article 15 (prohibited agreements) and article 21 (abuse of dominance) of the CPA. The new provisions will not apply to infringements of other provisions of Bulgarian competition law specific to Bulgaria, such as the abuse of a stronger bargaining power and unfair competition practices.

The Bulgarian Commission for the Protection of Competition (CPC) has also adopted a methodology for determining sanctions under the CPA (Decision No. 71 of 3 February 2009).

6 Which authorities investigate and decide on pharmaceutical mergers and the anticompetitive nature of conduct or agreements in the pharmaceutical sector?

There is no special body dealing with the violations of competition law specifically in the pharmaceutical sector, thus pharmaceutical mergers and anticompetitive conduct or agreements in the pharmaceutical sector are subject to the general regulatory regime and to investigation by the CPC.

When rendering its decisions, the CPC acts as a law-enforcement authority. Its decisions are subject to appeal before the Bulgarian Supreme Administrative Court.

7 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

If an infringement of the rules for protection of competition is established, the CPC usually imposes a sanction of up to 10 per cent of the company's turnover in the previous financial year. For example, in July 2017, the CPC fined a local wholesaler, Pharmnet, with a sanction of 0.1 per cent of its turnover (which was around 494 million leva in 2016) for the infringement of the general prohibition on unfair

competition. The sanctioned wholesaler, which is in vertical integration with a large chain of pharmacies, had threatened other pharmacies to open one of its own pharmacies nearby, if the former did not purchase medicines from said wholesaler.

Other remedies available under Bulgarian law, which can be cumulatively or separately imposed, are:

- interim measures in cases of serious and irreparable damages that are likely to occur;
- order for termination of the infringement; and
- order for adoption of behavioural or structural measures for restoring competition.

If the investigated pharmaceutical company undertakes to seize its anticompetitive practices, the CPC has the discretion to terminate the investigation without establishing infringement or imposing sanctions.

The implementation of the Damages Directive in the national legislation (see question 5) also opens the doors to private enforcement claims seeking compensation for damages caused by anticompetitive behaviour.

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

Private parties, whose rights and interests have been affected in a negative way by the anticompetitive practices of their competitors, may ask the CPC to launch proceedings against the alleged violator and seek the imposition of all the measures envisaged in question 7.

With the latest regulatory changes, private parties are now also able to file for private damages actions. As these changes have just entered into force (7 January 2018), no such claims have yet been dealt with by Bulgarian 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?

The CPC is empowered by law to conduct inquiries upon its sole discretion in different sectors or types of arrangements. State bodies, natural and legal persons are strictly obliged to cooperate and provide precise and reliable information. The last two thorough sector-wide inquiries in the pharmaceutical sector were published in 2006 and in December 2016.

The 2016 analysis of the CPC encompasses the period between 2010 and 2015 and states that there are no particular anticompetitive concerns on the Bulgarian pharmaceutical market despite there being partial vertical and horizontal integration. In comparison with previous years, for the inspected period, the horizontal integration between pharmacies has declined as chain pharmacies comprised of only 20 per cent of all 3,794 pharmacies in the country. On the other hand, the market share for reimbursed medicines of chain pharmacies has increased from 48 per cent in 2011 to 54 per cent in 2015.

In terms of horizontal integration, the CPC noted that some chain pharmacies are integrated with wholesalers and distributors, which contributes to greater financial stability, but should be treated with caution. At the time of the inquiry, no cases of unfair treatment or unfair market conditions have been registered.

The CPC also observed that, since 2012, parallel exports of medicines to countries like Germany, Romania and Poland show a steadily increasing trend; however, this has not yet become an anticompetitive concern.

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

Non-government groups that can prove 'legitimate interest' (ie, infringement of their rights and interests) are entitled to bring a formal complaint before the CPC; however, to date, no such complaints have been filed in the pharmaceutical sector. NGOs, trade associations and consumer groups are often consulted by the CPC in the course of competition proceedings regarding the factual circumstances and the effects of the alleged anticompetitive behaviour.

Review of mergers

11 Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

Bulgarian competition law does not provide for any specific rules applicable to mergers between pharmaceutical companies.

However, it is practice for the CPC to take into account the sector specifics when reviewing mergers. For example, in October 2017, the CPC allowed for the acquisition by Sopharma Trading (one of the largest medicines distributor) of the Pharmastore pharmacies chain, taking into account the interchangeability of the medicinal products distributed by Sopharma and by its direct competitors, as well as the specific legal and structural barriers to entry into the pharmaceutical market.

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

The product market definition is aligned to that employed by the European Commission – the active pharmaceutical ingredient and the ready-to-use product form two separate markets. This has recently been reiterated by the CPC in its sector-wide analysis of 2016 mentioned in question 9. The market of active pharmaceutical ingredients is generally defined in accordance with the anatomical therapeutic chemical (ATC) classification (generally the ATC level 3). However, each case must be examined separately. For example, the CPC defined the relevant product market in its Decision No. 988 of 11 November 2008 by reference to ATC level 5; that is, products with the same international non-proprietary names.

The geographic market encompasses the territory of Bulgaria, as the legislation applies throughout the country and no specific regulation exists in separate areas of the country.

13 Is it possible to invoke before the authorities the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

This argument can only be invoked in relation to anticompetitive agreements, decisions and practices – these are not prohibited if they contribute 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 which do 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.

14 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market be considered problematic?

If the combined market share of participating undertakings exceeds 15 per cent the merger will be further investigated by the CPC. In the merger between Sopharma trading and Medica in 2015, the CPC concluded that no concern arose, as their combined market share did not exceed the threshold of 15 per cent established in the CPC's practice.

15 When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?

The CPC has not yet dealt with cases of overlap with respect to products that are being developed. Neither is this issue addressed in the legislation.

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

The legislation does not provide for any remedies in relation to problematic issues in mergers.

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

Reporting obligations arise for an undertaking acquiring a patent or licence where:

Update and trends

A specific area of interest is the implementation of the Damages Directive into the CPA on 7 January 2018, which allows for private actions for damages. Unusual for Bulgarian law, the new regime provides for a rebuttable presumption that cartel infringements, unlike abuses of a dominant position, always cause harm. Another novelty is that from now on judges may seek the assistance of the CPC for assessment of damages caused.

In its 2016 sector-wide inquiry, the CPC expressed concerns regarding the observed increase in parallel exports of medicines to countries like Germany, Romania and Poland, which may harm the adequacy of supply of certain medicines and thus induce anticompetitive behaviour and practice.

- the turnover of the undertaking that owns the patent generated in Bulgaria in relation to that patent exceeds 3 million leva in the previous financial year; and
- the combined turnover of the merging undertakings exceeds 25 million leva in the previous financial year.

Anticompetitive agreements

18 What is the general framework for assessing whether an agreement or practice can be considered anticompetitive?

The CPA generally reiterates article 101 TFEU and prohibits all types of 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 within the relevant market, and in particular those which:

- directly or indirectly fix purchase or selling prices or any other trading conditions;
- share markets or sources of supply;
- limit or control production, markets, technical development or investment;
- apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; or
- make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations that, by their nature or according to commercial usage, have no connection with the subject of such contracts.

The law provides for an exemption from the prohibition for agreements of minor importance, which applies where the total share of the undertakings or participants on the market of commodities and services, subject to the agreement, the decision or the concerted practice does not exceed:

- 10 per cent of the respective market if the participants are competitors; or
- 15 per cent of each of the respective markets, if participants are not competitors.

However, the exemption will not apply in the event that the agreements, decisions or concerted practice have as their objective or result:

- direct or indirect fixing of prices;
- allocation of markets or clients, or both; and
- restriction on production and sales.

19 To what extent are technology licensing agreements considered anticompetitive?

Technology licensing agreements and the effect they may have on competition in the pharmaceuticals sector have not yet been considered by the CPC.

20 To what extent are co-promotion and co-marketing agreements considered anticompetitive?

There are no precedents of co-promotion and co-marketing agreements examined by the CPC in the pharmaceuticals sector.

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

Agreements with actual or potential competitors are likely to raise issues if they impose hard-core restrictions, such as limiting output, allocating either customers or markets or fixing prices, as well as if they concern the sharing of commercially sensitive information (trade secrets of any kind).

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

Hard-core restrictions in vertical agreements are generally considered anticompetitive. In 2014, the CPC considered whether standard clauses in contracts of Abbott Products and Sting, as well as their trade practice, could constitute a restriction on parallel exports and distort competition. The CPC, however, concluded that, based on the facts, no violation existed.

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

The CPC has not yet considered the implications of settling patent disputes in terms of competition, but should a case arise, it will probably follow the European Commission's Technology Transfer Guidelines. Antitrust violations may arise where:

- 'pay-for-restriction' or 'pay-for-delay'-type settlement agreements are involved, whereby a value transfer from one party in return for a limitation on the entry or expansion on the market of the other party exists;
- the entry of a competing generic product has been delayed as a result of the settlement and, in return for the delay in entry, the generic manufacturer obtains some form of consideration from the incumbent originator (value transfer);
- parties cross-license each other and impose restrictions on the use of their patents, including restrictions on their licensing to third parties; and
- restriction of the freedom to challenge an intellectual property right is not part of the specific subject matter of an intellectual property right and may restrict competition.

24 To what extent can joint communications or lobbying actions be anticompetitive?

The CPC has not reviewed joint communications or lobbying actions; it is therefore difficult to predict the stance it will take. In addition, lobbying is not regulated in Bulgarian law.

25 To what extent may public communications constitute an infringement?

If public communications contain misleading statements about the characteristics of the medicinal products or misleading and comparative advertising, these will infringe competition rules. See question 33.

26 Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, etc?

Whether exchange of information in the pharmaceutical sector is more likely to occur remains to be seen. However, the CPC has published guidelines on the sharing of information between competitors, which adopt a case-by-case approach to sharing of information. To fall within the scope of antitrust law, it is necessary to establish that there is an agreement between undertakings, a decision of an association of undertakings or a concerted practice between undertakings on the grounds of which the undertakings exchange information or transfer it to an association that has as its objective the centralisation, structuring and processing of the information prior to providing it to the undertakings.

Anticompetitive unilateral conduct

27 In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

Unlawful anticompetitive conduct by firms with monopoly or market power is present when they:

- directly or indirectly impose purchase or selling prices or other unfair trading conditions;
- limit production, trade and technical development to the prejudice of consumers;
- apply dissimilar conditions to equivalent transactions with certain partners, thereby placing them in a disadvantaged position;
- make the conclusion of contracts subject to the assumption of additional obligations or the conclusion of additional contracts that, by their nature or according to customary commercial practice, are not related to the subject matter of the main contract or to its implementation;
- unjustifiably refuse to deliver a good or to provide a service to a real or potential client in order to prevent their business from being carried on; or
- any other form of the firm's conduct, which is likely to prevent, restrict or distort competition and affect the interests of consumers.

Monopoly market position can be established only by law, otherwise it is illegal.

28 Is there any de minimis threshold for a conduct to be found abusive?

There is no appreciability (de minimis) threshold for a conduct to be found abusive under Bulgarian law or court practice. In general, the CPC usually desists from enforcement action in cases where there are no significant anticompetitive effects.

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

In determining the notion of 'dominant position', Bulgarian authorities and courts apply and refer directly to the definition provided for in the *F Hoffmann–La Roche and Others* case (C-179/16). Relevant in this regard is the market share of the undertaking (especially if over 40 per cent in the relevant market), substantial financial resources (assets or operating profit of tens of millions of euros), and barriers to entry on the relevant market by other undertakings (legal, structural and others), if they allow the undertaking to behave to an appreciable extent independently of its competitors and customers.

Two or more undertakings may have a joint dominant position without the need for each of them to be individually dominant, if in the light of the characteristics of the relevant market, it can be established that each of the undertakings considers it possible and economically rational to adopt common market behaviour.

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

Holding a patent does not automatically confer dominance. Only if the patent is enforced to the detriment of competitors and grants the undertaking an appreciable extent of independence to competitors and customers, will dominant position be present.

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

Patent enforcement may engage the liability of the undertaking for anticompetitive behaviour where it is used, or is likely, to infringe competition (see question 27). The Bulgarian competition authorities have not had the occasion to review patent-related complaints.

32 When would life-cycle management strategies expose a patent owner to antitrust liability?

Life-cycle management (LCM) in the pharmaceutical sector is common, but on a stand-alone basis unlikely to engage the antitrust liability of the patent holder. Under Bulgarian law, patent protection for medicines is limited to a period of 10 years. LCM strategies will be viewed as particularly problematic if they impede or prevent the entry of generic medicines to the market. The Bulgarian authorities, for the time being, have not ruled on the lawfulness of LCM strategies, but they will likely follow the *AstraZeneca* judgment (C-457/10) of 2012.

33 Can communications or recommendations aimed at the public or HCPs trigger antitrust liability?

If communications or recommendations aimed at the public or HCPs contain misleading statements about the characteristics of the medicinal products or misleading and comparative advertising, these will constitute violations of the Bulgarian competition law. For example, in the 2016 case against Walmark Bulgaria, the CPC found that the advertisement of its product was misleading and caused damages to the reputation of its competitors by suggesting that the other products would have lower positive effects on patients. However, in 2017, the Supreme Administrative Court annulled the CPC's decision.

34 May a patent holder market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?

The holder of the authorisation for use of the generic product may not place it on the market until 10 years have elapsed since the date of the first authorisation of the reference medicinal product. The consent of the patent holder is irrelevant. Before the expiry of the 10-year period, the generic drug may be marketed only for purposes and uses unrelated to the scope of the patent protection.

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35 Can actions taken by a patent holder to limit off-label use trigger antitrust liability?

If such actions fall under the general scope of application of the prohibited anticompetitive practices and arrangements, there might be instances in which these will trigger antitrust liability. However, to date, the CPC has not ruled on such case.

36 When does pricing conduct raise antitrust risks? Can high prices be abusive?

Predatory pricing is considered by the CPC as one of the gravest forms of prohibited anticompetitive behaviour. Selling at unreasonably high prices when in a dominant position on the market may also trigger the antitrust liability of the undertaking (eg, when the dominant undertaking tries to justify the high price with the related costs for production, which are already covered and included in the price of a similar product or related service). However, owing to specifics of the Bulgarian market and the heavy regulation of prescribed medicines and those included in the positive drug list, it is unlikely that the CPC will have to deal with abusive pricing of medicines by single undertakings.

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

In its practice, the CPC takes into account the specific features of the pharmaceutical sector. In the 2016 sector-wide inquiry, the CPC identified ensuring adequacy of supply of medicines as an area of concern, especially given the increased volumes of parallel export since 2012, and urged the government to take appropriate steps to address the issue. Thus, for example, ensuring adequate market supply could be used as an objective justification, alongside other well-grounded examples.

38 Has national enforcement activity in relation to life-cycle management and settlement agreements with generics increased following the EU Sector Inquiry?

To date, the Bulgarian antitrust authorities have not dealt with complaints in this regard, but judging from their enforcement practice, it could be expected that they will follow the EU Sector Inquiry.

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