Pharmaceutical Antitrust 2021

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Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the fourteenth edition of *Pharmaceutical Antitrust*, which is available in print and online at www.lexology.com/gtdt.

Lexology 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.

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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.

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Romania

Lucian Bondoc, Raluca Voinescu and Andreea Lungu

Bondoc & Asociatii

PHARMACEUTICAL REGULATORY LAW

Regulatory framework

1 | What is the applicable regulatory framework for the authorisation, pricing and marketing of pharmaceutical products, including generic drugs?

The applicable regulatory framework is mainly represented by Healthcare Reform Law No. 95/2006 (the Healthcare Law), as further amended and supplemented, and also by the secondary legislation issued by the Ministry of Health (MOH) and comprising a multitude of orders, norms and regulations issued on the implementation of the Healthcare Law.

Key pieces of secondary legislation relevant for the authorisation and pricing of pharmaceutical products include the following:

- authorisation of medicinal products (MOH Order No. 895/2006);
- pricing methodology (MOH Order No. 368/2017);
- health technology assessment (HTA): criteria and methodology for inclusion in the list of reimbursed products in the social healthcare security system (MOH Order No. 861/2014);
- cost control by the government: clawback, cost volume agreements/cost volume result agreements – Government Emergency Ordinance No. 77/2011, MOH Order No. 735/976/2018; and
- Government Decision No. 720/2008 for the approval of the list of reimbursed international non-proprietary names, corresponding to the medicinal products that patients benefit from, with or without personal contribution, in the social healthcare security system.

The marketing of pharmaceutical products is mainly regulated under the Healthcare Law, and also under the secondary legislation issued by the National Agency for Medicines and Medical Devices (NAMMD).

In essence, a pharmaceutical product may be commercialised in Romania if it has received a marketing authorisation either at European level, based on the centralised procedure, or by the NAMMD, as per the local procedure and also, mainly in case of prescription drugs, only if it has an approved maximum producer price in the National Catalogue of Prices (CANAMED).

Legislative changes in the pharmaceutical sector are quite frequent in Romania, with the overall number of such legislative changes exceeding 1,200 modifications in the past 10 years.

Regulatory authorities

2 | Which authorities are entrusted with enforcing these rules?

The authorities in charge are the MOH, the NAMMD and the National Health Insurance House.

The NAMMD is a central regulatory authority with legal personality, which functions under the subordination of the MOH and is in charge of regulating and supervising a wide range of areas such as marketing authorisation and related activities, clinical trials, marketing, promotion and advertising activities regarding medicinal products, pharmacovigilance, medicinal product quality control, pharmaceutical inspection activity, issuing of wholesale licences and regulation of wholesale activity.

The National Health Insurance House is an institution with legal personality, which is in charge of ensuring the coordinated and unitary functioning of the social healthcare insurance system in Romania.

Pricing

3 | Are drug prices subject to regulatory control?

Prescription drugs have regulated maximum prices that are subject to the approval of the MOH while prices of drugs released without medical prescription (OTCs) are not subject to any regulatory control (aside from exceptional cases when OTCs are prescription-based and included in the list of reimbursed drugs). Prices of prescription drugs do not stop being regulated at some point, for example, after patent expiry.

In Romania, there are two catalogues: CANAMED and the Public National Prices Catalogue.

The first includes maximum prices as approved and revised (in theory) annually by the MOH based on a pricing methodology and published in CANAMED. The pricing methodology also comprises specific rules for the referencing of generic and biosimilar drugs (65–80 per cent of the innovative price).

The maximum prices in question are, in essence, established based on the lowest out of 12 given countries (Austria, Belgium, Bulgaria, the Czech Republic, Germany, Greece, Hungary, Italy, Lithuania, Poland, Slovakia and Spain), except for certain products, such as vaccines and blood products and a number of generics on the WHO list of essential drugs. The maximum distribution price and maximum retail price are calculated using an algorithm based on the producer price.

The Public Catalogue is based on the average of the three lowest prices in the basket, and the prices in question are indicated to be used in certain specific situations, as well as for the referencing in other countries.

Prices in Romania are set in lei. When assessing the baskets, the MOH uses some exchange rates that are usually behind the times, with the associated consequences.

Distribution

4 | Is the distribution of pharmaceutical products subject to a specific framework or legislation? Do the rules differ depending on the distribution channel?

The distribution of pharmaceutical products is indeed subject to a (heavy) regulatory framework, specific to each relevant distribution channel, such as wholesale or retail (pharmacies). The regulatory framework defines the conditions for obtaining the relevant distribution licences, as well as the set of legal obligations and procedures required for performing the relevant activity.

For example, the regulation and supervision of wholesale activity falls under the competence and supervision of NAMMD (eg, NAMMD issues or withdraws the wholesale licence and performs inspections at the authorised distribution warehouses).

Under Romanian law, it is prohibited to sell Rx products via the internet, while the online sale of OTC products was legalised in 2019, subject to specific authorisation and implementation conditions.

Intersection with competition law

5 Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

We would mainly note the following:

- the obligation on marketing authorisation holders (MAHs) to ensure that the distribution of pharmaceutical products (under the reimbursement list) is carried out via at least three wholesalers, which annihilates the possibility of granting exclusivity to one wholesaler (allowed under competition law, under block exemptions);
- significant delays in HTA approval by NAMMD (in some cases, exceeding the legal deadline by more than one year) are susceptible to creating a discriminatory regime for companies with products delayed under HTA assessment compared to competing drugs that are already under reimbursement;
- centralised, national tenders organised by the MOH with a period of approximately two years are susceptible to foreclosing the market for new products (generics, biosimilars) that enter the market after the finalisation of the tender in question; and
- the clawback tax also potentially distorts competition, as the percentage of the tax is calculated based on the growth of the market, as opposed to that of each relevant company (the actual contribution being calculated by applying that percentage to the revenues from reimbursed drugs of each MAH).

COMPETITION LEGISLATION AND REGULATION

Legislation and enforcement authorities

6 What are the main competition law provisions and which authorities are responsible for enforcing them?

The main pieces of legislation are the Competition Law No. 21/1996 (the Competition Law) and Unfair Competition Law No. 11/1991. The institution in charge of enforcing competition law in Romania is the Competition Council, which has issued a set of regulatory instructions and orders issued by the Competition Council on the implementation of the Competition Law, and to ensure the transposition of EU regulations into Romanian law.

Romanian antitrust legislation is largely harmonised with that at EU level.

Public enforcement and remedies

7 What actions can competition authorities take to tackle anticompetitive conduct or agreements in the pharmaceutical sector and what remedies can they impose?

The Competition Council may do the following:

- open infringement investigations (ex officio or based on a complaint) whenever it suspects a conduct in breach of competition law;
- if there is a risk of immediate and irreversible damage being caused by a behaviour suspected of being anticompetitive, based on a careful assessment of the facts, order interim measures (behaviour remedies) aimed at an immediate cessation of the suspected anticompetitive conduct in question;
- impose behaviour and structural remedies in its decision on the merits of the case; and
- impose fines ranging from 0.5 per cent to 10 per cent of the turnover accomplished by the incumbent in the preceding financial exercise.

Anticompetitive conduct as such was sanctioned with fines.

Remedies have mainly been considered in merger control analysis. After Romania joined the EU, this was primarily the case in Romania in the medical services area, as opposed to the pharmaceutical sector as such.

For instance, in 2011, the Competition Council approved through Decisions Nos. 19 and 20 the purchase of local dialysis centres Renamed and Nefromed by Fresenius, imposing on the latter behavioural and structural remedies. Therefore, Fresenius had one year to sell two dialysis centres, and undertook not to make it conditional that the medical centres who purchase Fresenius medical equipment buy other such products during the warranty and even post-warranty period, and were to continue until the whole transaction was approved.

Also, in 2017, the Council approved a major transaction (approximately €50 million) that consisted of the acquisition of Hiperdia's network of clinical imagistic centres by the Affidea Group, only after structural remedies had been offered by the buyer (Decision No. 24/2017). In this case, the purchaser had to sell a certain number of centres and undertake not to try to acquire them again for a period of 10 years.

Private enforcement and remedies

8 Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Yes, remedies can be sought through private enforcement by a third party, as per specific legislation, although the jurisprudence has been poor in dealing with such cases so far.

Sector inquiries

9 Can 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 Competition Council has the legal prerogative to conduct sector inquiries and has been quite active in the pharmaceutical sector.

Thus, in 2011, the authority finalised a sector inquiry into the wholesale distribution market and, two years later, in 2013, started a new, extensive investigation into the pharmaceutical producers' market, which was finalised in September 2017 (the most comprehensive one so far). While the initial scope of the investigation was to look into direct-to-pharmacy/direct-to-hospital (DTP/DTH) practices and also reduced distribution models, the investigation veered into other topics such as the marketing and promotion of prescription drugs and their possible correlation with the degree of generic penetration in Romania.

Currently, the Competition Council is carrying out a sector inquiry into the production and trading of OTC products and food supplements, being particularly interested in the evolution and increases in the prices of OTC products in Romania.

Health authority involvement

10 To what extent do health authorities or regulatory bodies play a role in the application of competition law to the pharmaceutical sector? How do these authorities interact with the relevant competition authority?

The Competition Council is the only institution authorised to enforce competition law in Romania, in all business sectors. The role of health authorities is therefore rather limited in this respect (the same as the role of any other entity in relation to the Council). In theory, this mainly manifests in the form of requesting endorsements or opinions from the Competition Council, before passing legislation that may have an anti-trust impact on the market.

Authorities may also bring to the attention of the Council conduct or market deficiencies that may be deemed to infringe competition law, but it remains the prerogative of the Council to open an investigation or not (in practice, the opposite is more frequent – the Council receives complaints about the allegedly anticompetitive conduct of various authorities).

Also, the Competition Council's sector inquiry reports usually make policy adjustment recommendations to health authorities and regulatory bodies where appropriate or necessary.

In theory, the Competition Council can impose a change of conduct on other authorities if the original conduct is considered to breach competition rules; however, there is no relevant precedent.

NGO involvement

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

Trade associations such as the Romanian Association of International Drug Producers (ARPIM) or the Romanian Association of Generic Drugs' Producers (APMGR) may be deemed rather active in signalling to the Competition Council any market deficiencies or conduct that may be deemed an infringement of competition law, and also in initiating or providing feedback on legislative proposals published to provide transparency. However, it is, of course, the Competition Council that decides whether to open an investigation in all cases.

While trade associations could theoretically file a formal complaint about an alleged infringement of competition law, we have not seen such actions in practice so far.

However, various correspondence and meetings regarding competition law concerns take place rather regularly.

REVIEW OF MERGERS

Thresholds and triggers

12 What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

There are the same thresholds as for any other merger: worldwide turnover of over €10 million of all parties involved and at least two parties involved each with over €4 million Romanian turnover (both turnovers having been obtained in the financial year prior to the transaction).

13 Is the acquisition of one or more patents or licences subject to merger notification? If so, when would that be the case?

Similar to EU legislation, only a transfer of business is deemed an economic concentration and thus subject to merger control.

Thus, for the acquisition of a patent to be subject to merger control, such patent or licence needs to generate revenues for the seller and be attributed a market share.

In other words, the acquirer would be taking over an existing market position of the seller. In contrast, the grant of a licence would not be deemed a notifiable operation if there was no current revenue generating activity associated with it (eg, a licence for the global distribution of a future pipeline pharmaceutical would not normally amount to a notifiable merger).

Market definition

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

A specific feature of the pharmaceutical market consists of the existence of a classification system in which drugs are grouped as per functional substitutability; in other words, as per therapeutic indications, the anatomic therapeutic chemical (ATC) system is hierarchically organised and comprises 16 categories (A, B, C and D) each having up to four levels. The first level (ATC1) is the most general one and the fourth one (ATC4) is the most detailed one.

The third level (ATC3) allows the grouping of drugs based on their therapeutic indications and may be used as an operational market definition. These groups of drugs normally have the same therapeutic indication and may not be substituted with products under a different ATC3. This level is normally used as a starting point in the definition of relevant product markets.

In line with the case law of the European Commission, the Competition Council considers it appropriate to carry out analyses at ATC3 level, ATC4 level or a mixture of ATC3 and ATC4, if the circumstances of the case show that the undertakings involved face sufficiently strong competitive constraints at another level and there are indications that the ATC3 class in itself does not lead to a correct market definition.

Also, the Council shall analyse the particularities of the relevant market, including elements related to the special characteristics of the drug and prescription modality; reimbursement or non-reimbursement; and inclusion in a national health programme. Basically, the substitutability of demand represents the most direct and efficient force that operates on the undertakings supplying a product, especially as regards decisions taken with respect to the price.

The approach in dominant cases is less predictable and tends to narrow down market definitions.

National tenders may be deemed a market in themselves.

The geographical relevant market is usually national in scope, except for medical services where it is likely to have a rather narrow geographical market, based on patient proximity criteria.

Examples of Competition Council decisions in the pharmaceutical sector include as follows:

- Decision No. 19/2019 (regarding the *Roche* investigation in a potential abuse of dominance case);
- Decision No. 84/2016 (regarding the acceptance of commitments offered by GSK in the context of an abuse of dominance investigation);
- Decision No. 40/2015 (regarding the economic concentration involving *Alvogen*/*CVC Fund*); and
- Decision No. 66/2009 (regarding an economic concentration involving *Ozone*/*Advent*).

Sector-specific considerations

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

The Competition Council normally takes into account sector-specific features when assessing a merger, not only in the pharmaceutical sector but as a working methodology.

Addressing competition concerns

16 Can merging parties put forward arguments based on the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

In their notification of a merger, parties can include efficiency-based arguments and such arguments do matter. However, in a pragmatic approach, if the merger results in a cumulated market share over 40 per cent (under Romanian law, a market share over 40 per cent is an express presumption of dominance), there is a clear risk of having to consider structural remedies, in the form of divestures.

Horizontal mergers

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

A horizontal merger would be assessed by the Competition Council just like in any other sector (there are no special rules for the pharmaceutical sector), by looking in principle at the resulting combined market share of the involved companies and its impact on the market, in terms of whether a dominant market share would thus be formed.

To date, since Romania joined the EU, there have been very few problematic local mergers in the pharmaceutical sector (the complex cases having an EU dimension and being handled at EU level, and Romania mainly seeing the implementation of aspects arising from EU decisions). Even prior to Romania's accession to the EU, complex cases were duplicated in Romania, as was the case with the merger between Sanofi Synthélabo and Aventis that had to be notified in Romania as well as the EU (with associated commitments), as Romania was not yet part of the EU (the Romanian market did not have a relevantly different structure at the time on the relevant markets).

Local complex mergers in the healthcare sector mainly concerned the medical services area. In the acquisition of Hiperdia diagnostic clinics by the Affidea Group (2017), the Council defined relevant geographic markets at the level of each city, and if the combined market share in such territory was considered to exceed 40 per cent, the purchaser was expected to offer structural remedies in the form of divestures.

Also, in 2011, the Competition Council approved, through Decisions Nos. 19 and 20, the purchase of local dialysis centres Renamed and Nefromed by Fresenius, imposing on the latter behavioural and structural remedies. Therefore, Fresenius had one year to sell two dialysis centres, and undertook not to make it conditional that the medical centres that purchase Fresenius medical equipment buy other such products during the warranty and even post-warranty period, and were to continue until the whole transaction was approved.

Product overlap

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

The Competition Council would analyse such overlap in terms of potential competition, similar to the manner in which the European Commission looks at potential competition (eg, a company is treated as a potential competitor of another company if it is likely that the former, within a short period, would undertake the necessary additional investments or other necessary switching costs to enter the relevant market on which the latter is active). This assessment must be based on realistic grounds; the mere theoretical possibility of entering a market is not sufficient.

Remedies

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

In mergers that are likely to give rise to a dominant market position of the acquirer on the relevant market or markets concerned, the remedies that typically need to be considered by the acquirer are the structural ones (the Competition Council has recently stated its reluctance to accept behavioural remedies in mergers that are problematic).

ANTICOMPETITIVE AGREEMENTS

Assessment framework

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

The general framework for the assessment would be the transposition into Romanian law of article 101(1) of the Treaty on the Functioning of the European Union (TFEU) – more specifically, article 5(1) of the Competition Law.

In essence, an agreement, express or tacit, may be considered anticompetitive to the extent that its object or effect is to restrict, prevent or distort competition on the Romanian market (or a part of it), in particular those aimed at:

- fixing, directly or indirectly, the selling or purchase prices, as well as any other terms of trading;
- limiting or controlling production, trading, technological development or investments;
- allocating distribution markets or input sources;
- imposing unequal terms for equivalent services to trading partners, thus causing a competitive disadvantage to some of them;
- conditioning the conclusion of contracts by imposing upon partners the acceptance of certain clauses stipulating additional services that, either by their nature or by commercial usage, do not relate to the scope of such contracts;
- participating, in a concerted manner, with rigged bids in auctions or any other forms of competitive tendering; and
- eliminating competitors from the market, limiting or preventing access to the market and the free exercise of competition by other undertakings, as well as agreements not to purchase from or sell to certain parties without reasonable justification.

Technology licensing agreements

21 To what extent are technology licensing agreements considered anticompetitive?

While the case law of the Competition Council is rather poor in dealing with cases of technology licensing agreements, in accordance with general principles, the authority would primarily examine the terms and conditions of the technology licence agreement so as to determine whether they may be considered anticompetitive, either by object or effect; for example, if they would enable the parties to reduce or exclude competition from the market and thus create artificial market entry barriers.

If the agreement comprises certain anticompetitive restrictions but the parties believe they could make an efficiency claim deriving, for example, from the benefits to final consumers, the Council will perform an assessment of the efficiencies versus the restrictions, as per article 5(2) of the Competition Law (the transposition of article 101(3) TFEU).

Article 5(2) creates a framework for individual exemption, to the extent the licence agreement is found to meet the following four cumulative conditions:

- it must contribute to improving the production or distribution of goods or contribute to promoting technical or economic progress;
- consumers must receive a fair share of the resulting benefits;
- the restrictions must be indispensable to the attainment of these objectives; and
- the agreement must not afford the parties the possibility of eliminating competition in respect of a substantial part of the products in question.

Co-promotion and co-marketing agreements

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

Co-promotion and co-marketing agreements, if they are not concluded between competitors, would not normally raise any competition law concerns.

However, if such agreements are concluded between competitors, they may be considered anticompetitive to the extent they comprise restrictions of competition (eg, a territory allocation of customers) or are likely to generate an anticompetitive effect on the market, by preventing or limiting competition or creating market entry barriers.

Other agreements

23 | What other forms of agreement with a competitor are likely to be an issue? How can these issues be resolved?

Any type of agreement between competitors is susceptible to raising antitrust concerns and should be carefully reviewed from a competition law perspective so as to identify any restrictions of competition that may amount to antitrust infringements, including joint venture agreements, research and development agreements, and joint commercialisation agreements.

In the pharmaceutical sector, the Competition Council dealt with a couple of bid-rigging cases, the most relevant one being the insulin investigation closed in 2008, when the authority fined a producer and three of its wholesalers on account of participation in a market-sharing arrangement, including bid-rigging practices.

Once an agreement with a competitor has been concluded and the agreement comprises antitrust restrictions likely to amount to an infringement of competition law, the remedies would be relevant only for the future and thus not fully efficient (eg, the immediate termination of the agreement or exclusion of anticompetitive restrictions). However, this would not exclude the antitrust risk for the period when the agreement was in force.

Confidentiality provisions would not be of any use, as they would not prevent the parties from making use of whistle-blower leniency provisions. Also, in the event of a dawn raid, the Competition Council would be allowed to review and seize the agreements, despite any confidentiality clauses, those not being enforceable against the Council in the event of an investigation.

Issues with vertical agreements

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

Normally, the vertical restrictions most likely to give rise to antitrust concerns in the pharmaceutical sector would be as follows:

- resale price maintenance, agreed between the supplier and the wholesaler, which would be prohibited irrespective of the market share of the parties involved and thus could not be block exempted; and
- export bans.

An example of the latter is the Council's sanction against Bayer and Baxter, and their distributors on account of the export ban clauses in their agreements with distributors. The companies in question tried to defend (unsuccessfully) by arguing that the clauses in question were agreed long before Romania's accession to the EU, and the parties argued that they were never enforced in practice and did not produce any anticompetitive effects on the market.

Patent dispute settlements

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

Since most pharmaceutical companies that are active on the Romanian market belong to multinational groups of companies and have obtained their patents at EU level, it would be less likely for a patent dispute settlement to take place in Romania.

However, if the Competition Council was to analyse such cases, it would likely look at it mainly from a potential abuse of dominance perspective. This is likely to arise if the generic company enters into a settlement with the innovative company, having as object or effect the delaying of generic entry past the date of patent expiry, in exchange for the payment of a consideration to the generic company.

In the case law of the Competition Council there is one precedent, in 2010, when the authority examined a complaint filed by a generic company (Actavis) in connection with the allegedly abusive conduct of an innovative company (Novartis), but the complaint was dismissed as lacking grounds for the finding of dominance.

In essence, the alleged abuse of the innovative company consisted of filing an action to request the annulment of marketing authorisations of the generic company, on account of patent infringement and later on proposing to enter into a settlement agreement. The settlement proposed by the innovative company implied that the generic company, among other conditions, would agree not to submit for price approval until 90 days prior to the expiry of the patent. The generic company refused the settlement and filed a complaint with the Competition Council, claiming an abuse of dominance.

In its decision on this matter (Decision No. 3/2010), the Competition Council considered that an agreement between the innovative company and the generic one, whereby the generic company undertakes not to file for price approval until 90 days prior to the patents' expiry date, would not be capable of delaying generic entry and thus there would be no sufficient grounds for an abuse of dominance to be found.

The main considerations retained by the authority in support of its decision were the following:

- 90 days is the maximum legal term for the MOH to issue a price approval;
- the approval of producer prices for generic products does not confer the right to commercialise the generic product as long as the corresponding innovative product is still under patent protection; and
- even if the generic company is not allowed to commercialise the product, the price decision obtained by the generic company before the patent expiry date may trigger the decrease of the innovative product's reimbursement price.

Joint communications and lobbying

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

In a highly regulated sector such as the pharmaceutical one, it is often required for the pharmaceutical companies to engage in joint communications, especially regarding the very frequent legislative changes that impact their activity in Romania in a very significant manner. This is

usually done though trade associations, such as ARPIM and APMGR, which should have a clear set of rules in place regarding the meetings and interactions between competing companies.

The principles to be followed by such trade associations are the usual ones and include, for example, ensuring that adequate measures are in place to prevent the disclosure of competitively sensitive information between members, disseminating information only in aggregate form and only if historic, with no coordination of commercial behaviour, etc.

In 2013, the Competition Council issued a guide describing best practice recommendations on petitioning activities, which sets out the general principles.

Public communications

27 To what extent may public communications constitute an infringement?

Public communications may constitute an infringement to the extent that it could amount to an exchange of sensitive information that would be likely to enable the coordination of competitive behaviour between the competitors on the market (exchange of information on discount policies).

Exchange of information

28 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?

Exchanges of sensitive information should not necessarily be more likely, despite the transparency obligations deriving from the regulatory framework (in any case, the information required under transparency obligations is normally in aggregate form and historic).

For clarity, payments under clinical trials are not made public in Romania, as per the current approach of the competent authority to the legal framework.

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

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

Abuse of dominance is dealt with under the Competition Law, similar to the corresponding provisions of article 102(1) TFEU.

In the pharmaceutical sector, the practices most likely to give rise to an abusive conduct would mainly be as follows:

- refusal to supply;
- abusive pricing policy, especially in the form of a margin squeeze;
- discrimination among customers, despite similar transactions; and
- dual pricing practices, between various distribution channels (hospital versus retail), consisting of applying different prices (lower in hospital and higher in retail), aimed at gaining new patients in hospitals that would remain 'locked' on the product and boosting sales in retail, as a direct consequence of initiating patients in hospitals. The rationale is that a dominant company is presumed to be powerful enough to grant very significant discounts to one channel, namely a hospital, to gain and secure very significant sales on the retail channel (cross-subsidisation between the channels), to the detriment of its competitors who would run the risk of being excluded from the market or seeing their market share drastically diminish.

De minimis thresholds

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

There are no such de minimis thresholds in cases that deal with an abuse of dominance.

Market definition

31 Do antitrust authorities approach market definition in the context of unilateral conduct in the same way as in mergers? If not, what are the main differences and what justifies them?

Market definition would, as a matter of principle, be approached by the Competition Council in line with the Commission Notice on the Definition of Relevant Market for the Purposes of Community Competition Law, transposed as such into Romanian law.

If unilateral conduct is assessed in the context of dominance, or where a merger is likely to give rise to a dominant market power, the Council would most likely consider a rather narrow market definition, at ATC4 level, and would perform a comprehensive in-depth analysis of the relevant market and its configuration, focusing in particular on:

- the market configuration and its evolution, the main competitors of the parties and their market shares;
- the barriers to market entry; and
- the trends of offer and demand and influencing factors.

In mergers that are not considered problematic (eg, combined market shares are below 30 per cent), the Council will likely leave the market definition open, similar to the practice of the European Commission.

Overall, market definition in cases of potential abuse of dominant position tend to be narrower in practice than in merger control cases.

Establishing dominance

32 When is a party likely to be considered dominant or jointly dominant? Can a patent owner be dominant simply on account of the patent that it owns?

Under Romanian law (unlike EU law), there is an express presumption of dominance once the market share exceeds 40 per cent on the relevant product and geographical market. In theory, this is rebuttable; however, in the case law of the Competition Council, there have not yet been situations when the parties concerned were able to successfully overturn the presumption of dominance, although, at least theoretically, this remains possible, as there are several other elements that need to be analysed in addition to market share before reaching the ultimate conclusion that a company is dominant (market shares of competitors, barriers to entry, excess capacity, etc).

A patent holder would not normally be deemed dominant simply on account of the patent itself. However, the patent would most likely enable its holder to acquire a dominant market share, as a result of the revenues accomplished on the relevant market throughout the entire exclusivity period conferred by the patent.

IP rights

33 To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) expose the patent owner to liability for an antitrust violation?

An antitrust risk may exist to the extent that an application would exceed the mere exercise of legitimate rights concerning patents. This might include a more comprehensive abusive strategy by a dominant company to harm competitors, by preventing their entry on the

market. However, there would need to be more elements pointing to such abusive conduct than the simple application for a patent or other IP rights.

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

Life-cycle strategies could expose a patent owner to antitrust liability to the extent that they could be deemed to fall under the ambit of an abuse of dominance, being designed by a dominant company to exclude competitors and to create, maintain or enhance its dominant market power.

The Competition Council has not yet dealt with cases concerning specifically life-cycle management strategies, although at the beginning of 2020 the authority fined the Romanian subsidiary of Roche in connection with conduct allegedly aimed at preventing the entry of generic products on the market for certain oncological medicines. The total fine amounted to €12.8 million and the sanctioning decision was issued following two separate investigations initiated in 2017.

In the first investigation, the authority found that Roche's actions included margin squeeze practices within the context of public tenders. According to the authority, Roche's conduct was motivated by a strategy to delay access to the market of biosimilar alternatives (as per the Competition Council, if the wholesalers were given a chance to win the tenders, they would have been able to replace Roche products with similar, cheaper products of other manufacturers).

In the second investigation, the authority fined Roche for designing a commercial strategy aimed at preventing the sale of competing, cheaper drugs containing the same active substance as one of its innovative medicines; in practice, the incriminating conduct consisted of directing patients to one of its expensive products, through the Roche Patient Card and the Roche Call Centre programmes, and covering the price difference that patients should have had to pay when purchasing its product, in order for them not to buy another similar drug. The authority's conclusions were that this conduct led to the creation of barriers to market entry, with foreclosing effects, delaying the entry of biosimilar products.

Communications

35 | Can communications or recommendations aimed at the public, HCPs or health authorities trigger antitrust liability?

Such communications would need to comply with relevant legal requirements concerning the promotion and advertising of prescription and non-prescription drugs. In the case of breaches, it would primarily be a regulatory issue rather than a competition law one.

Under Romanian law, the promotion of prescription drugs to the general public is strictly prohibited, while promotion of prescription drugs to HCPs is permitted under certain forms and subject to certain conditions. Also, the ARPIM Code provides for additional rules and constraints regarding the various forms of promotion towards HCPs (hospitality, sponsorships, promotional materials) that are binding on ARPIM members.

Such communications may nevertheless have an antitrust impact and may amount to abusive conduct to the extent that the entity disseminating them is dominant and they are targeted at preventing or limiting generic penetration on the market and encouraging the prescription of the innovative product. They could also be analysed as unfair competition practices if they are aimed at denigrating competing products or engaging in an unpermitted comparison with competing products.

Authorised generics

36 | Can a patent owner 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?

There is no express prohibition to market or license a drug as an authorised generic before the expiry of the patent protection.

However, if this is done as part of a more comprehensive strategy aimed at delaying or preventing the entry of the generic products into the market, this could be analysed by the Competition Council as a possible abuse of dominance.

Restrictions on off-label use

37 | Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

For clarity, under Romanian law, the promotion of off-label usage is prohibited, unless done as a response to an express written request from an HCP.

In principle, if the patent covers the off-label use, its holder could indeed enforce it in accordance with the relevant patent legislation, without such triggering antitrust liability, as it would be the exercise of a legitimate right.

Pricing

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

Pricing conduct by a dominant undertaking could indeed trigger antitrust liability, if it can be considered an abuse of dominance. Given the fact that maximum prices are set by the law, an abuse could not take the form of excessive pricing in this sector; however, the interplay and replacement of various forms of the same drugs may raise issues.

However, practices like roll-back fidelity discounts would be a typical example of a pricing practice likely to give rise to an abuse, since the customers would be heavily incentivised to purchase most or all of their requirements from the dominant company, to benefit from the low net prices resulting from the application of the roll-back discounts.

Margin-squeeze would be another example of an abusive pricing practice, relevant especially in the case of public tenders when the dominant company, present both on the upstream market (where it sells to its wholesalers) and on the downstream market (where it competes with its wholesalers), offers, for example, a bidding price that is equal to or lower than the price at which its distributors are purchasing the products from it, leaving them no reasonable margin to compete in the respective tender.

By way of example, at the beginning of 2020, the Competition Council fined the Romanian subsidiary of Roche in connection with, inter alia, margin-squeeze practices within the context of public tenders (Roche competed in tenders with its own wholesalers, but the price at which Roche offered the drugs to the wholesalers was higher than the price Roche offered to the hospitals in the tenders, so the competition authority found that these actions led to the elimination of competition in tenders since the wholesalers were not able to compete effectively or profitably).

Sector-specific issues

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

While the pharmaceutical sector does have particular features mainly related to the necessity of ensuring adequate and sufficient quantities of drugs for the patients, a company could not objectively justify anticompetitive behaviour by such special features, to obtain a free pass from antitrust liability.

For example, if a drug would objectively need to be banned from export to serve the interests of Romanian patients (eg, there is an urgent national need for chronic disease drugs and the drugs in questions are scarce), such measure would typically need to be taken by the MOH (as per specific legal provisions dealing with export bans and within the limits of the *acquis communautaire*) and not as a private initiative, by the pharmaceutical company that supplies the drugs in question via an export ban in relation to its wholesalers.

One cannot exclude specific situations with more flexibility (eg, a dominant company abruptly interrupting supply to a wholesaler for which there is evidence of lack of safety); however, this would be handled on a case-by-case basis.

UPDATES AND TRENDS

Recent developments

40 Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?

Overall, the Competition Council appears to be following the trends set by the European Commission, especially as regards its concerns and proposal of remedies aimed at ensuring a higher penetration of generic products on the Romanian market.

The Competition Council seems determined to pursue its in-depth analysis of the pharmaceutical market by opening its third sector enquiry in this area: on the OTC and food supplements market, where it seems to be particularly concerned with increases in the prices of OTC products in the past couple of years.

The Council also seems more inclined to open investigations in cases that concern a potential abuse of dominance rather than vertical restrictions. In this respect, the Council finalised, in 2018, the investigation against GSK in connection with DTP/DTH and refusal to supply allegations via the acceptance of commitment offered by GSK, and has an ongoing investigation against Novartis (also in connection with DTP/DTH aspects). Also, at the beginning of 2020, the authority closed an investigation against Roche in connection with an allegedly abusive pricing strategy in public tenders (the margin-squeeze), as well as conduct aimed at preventing generic entry on the oncology market.

In August 2020, the competition authority fined GSK for non-compliance of some of the commitments it made in the investigation finalised in 2017 concerning a potential abuse of a dominant position, when GSK undertook to supply two medicines on the Romanian market for two years to remove the concerns raised by the authority. After monitoring the implementation of the commitments, the Competition Council found the partial non-compliance, by ceasing the marketing of three forms of one of the relevant products before the two-year deadline.

In the context of the pandemic, the Competition Council is conducting a sector investigation into the sale of products and equipment set up as emergency medical stocks, flu vaccines and PCR tests.

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Coronavirus

41 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

According to Presidential Decree No. 195/2020 indicating the rules to apply in the state of emergency (in force as of 16 March 2020, applicable for two months), the following rules applied in healthcare area during the state of emergency:

- prices for acquisitions of drugs for the treatment of patients affected by covid-19 can exceed the Canamed prices;
- as a measure of gradual applicability, the Decree mentions that the drugs prices could be capped in the future (at the level of the average of the last three months), depending on the evolutions;
- dapping the claw-back percentage at the level of Q4 2019;
- off-label prescriptions are allowed if endorsed by the medical policy committee at the level of the relevant hospital;
- family doctors can prescribe drugs for chronic patients also from the restricted lists;
- no financial limit for covering the assistance in hospitals (with beds);
- threshold of reimbursement in primary assistance and ambulatory increased to eight patients per hour;
- possibility of exceeding the budget for Q1 2020;
- simplified reimbursement measures (no need of the health card for the patient, no need to report within three days); and
- the Ministry of Health may introduce new health programmes and new medical services in connection with the fight against covid-19.

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