PHARMACEUTICAL ANTITRUST

Brazil

LEXOLOGY
Getting The Deal Through

Consulting editor
Clifford Chance

Pharmaceutical Antitrust

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Quick reference guide enabling side-by-side comparison of local insights into pharmaceutical regulatory law (framework, authorities, pricing, distribution and intersection with competition law); competition legislation and regulation (legislation and enforcement authorities, public and private enforcement and remedies, sector inquiries, health authority and NGO involvement); review of mergers; anticompetitive agreements; anticompetitive unilateral conduct; and recent trends.

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PHARMACEUTICAL REGULATORY LAW

Regulatory framework

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

The main pieces of legislation that set out the regulatory framework for the pharmaceutical sector in Brazil are:

- Law No. 5,991/1973, which provides for the sanitary control of drugs, medicines, pharmaceutical and related inputs marketing;
- Law No. 6,360/1976, which provides for the sanitary control to which medicines, drugs, pharmaceutical and related inputs are subject;
- Law No. 9,782/1999, which defines the national system of sanitary control and creates the National Health Surveillance Agency (ANVISA);
- Law No. 9,787/1999, which amends Law No. 6,360/1976 by providing for generic drugs;
- Law No. 9,965/2000, which limits the sales of steroids or anabolic peptides to the presentation of a prescription issued by a doctor or dentist;
- Law No. 10,742/2003, which defines rules for the pharmaceutical sector and creates the Chamber of Drug Market Regulation (CMED);
- Decree No. 4,766/2003, which regulates CMED's powers and operation;
- Decree No. 4,937/2003, which regulates article 4 of Law No. 10,742/2003 to establish the criteria for the adjustment of drug prices;
- Decree No. 8,077/2013, which regulates the conditions for the functioning of companies subject to sanitary licensing, and the registration, control and monitoring of products subject to sanitary control, according to Law No. 6,360/1976; and
- Law No. 13,021/2014, which provides for the exercise and supervision of pharmaceutical activities.

ANVISA also has several rules regarding matters such as drug registration, licences for pharmaceutical laboratories and other agents of the pharmaceutical production chain.

CMED is the inter-ministerial body in charge of price regulation.

Law stated - 26 September 2022

Regulatory authorities

Which authorities are entrusted with enforcing these rules?

ANVISA regulates matters regarding drug registration, licences for pharmaceutical laboratories and other agents of the pharmaceutical production chain.

CMED regulates prices for original, branded generic and generic drugs, and regularly publishes price lists. Prices of new drugs are defined based on overall reference values and a basket of other countries' market prices.

Law stated - 26 September 2022

Pricing

Are drug prices subject to regulatory control?

Drug prices are subject to the control of CMED, which defines the criteria for the calculation of the maximum distribution and retail prices of drugs, under the provisions of Law No. 10,742/2003. Retail price limits are calculated based on the manufacturer price, which is adjusted by four factors:

- the official inflation index rate published yearly;
- a productivity coefficient determined by CMED, considering pharmaceutical companies' earnings projections;
- an intra-sector price adjustment coefficient, calculated by companies' market power; and

an inter-sector price adjustment coefficient, originated by price fluctuation of inputs.

After manufacturer price lists are sent by pharmaceutical companies to CMED, the chamber establishes the applicable coefficients for the factors listed above and then issues an annual resolution, which serves as a guide to calculate the maximum retail price for each drug.

Relevant legislation regarding drug prices control in Brazil is as follows:

- Law No. 10,742/2003;
- Decree No. 4,766/2003;
- Decree No. 4,937/2003;
- Resolution No. 5/2015, which defines the criteria for drug prices adjustment calculation; and
- Resolution No. 1/2017, which has defined the rules for the calculation of maximum distribution and retail prices since 31 March 2017.

The prices of allopathic drugs (including over-the-counter drugs) are under constant regulation. The maximum distribution and retail prices of drugs can be found on ANVISA's website .

CMED can only increase the price cap of drugs. The Administrative Council for Economic Defence (CADE), the Brazilian antitrust authority, has criticised CMED's price-cap system for benefitting dominant companies and harming competition.

CADE has, therefore, in recent years opposed three bills proposing to extend the drug price-cap system to markets such as orthotics, prosthetics and medical devices (ie, Bills Nos. 380/2015 , 657/2015 and 2,454/2015) but has supported Bill No. 1050/2022 , which would allow CMED to not only increase but also decrease the price caps of drugs. Congress is currently reviewing all those bills.

Law stated - 26 September 2022

Distribution

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

ANVISA is responsible for regulating activities related to the distribution of pharmaceutical products in Brazil. Some of the rules issued by ANVISA on distribution activities are as follows:

- Resolution No. 304/2019, which determines the duties of companies that distribute pharmaceutical products;
- Resolution No. 204/2006, which establishes that all undertakings that perform distribution activities, among other things, must comply with the guidelines provided in the Technical Rules of Good Practice for the Distribution and Fractioning of Pharmaceutical Inputs; and
- Resolution No. 39/2013, which provides for the administrative proceedings for granting of the Certificate on Good Distribution Practices.

In general, these rules do not distinguish between the different distribution channels.

Law stated - 26 September 2022

Intersection with competition law

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

The most relevant aspects of the Brazilian regulatory framework to the application of competition law to the pharmaceutical sector aim to promote competition between originator and generic drugs. These are as follows:

doctors within the public health system shall prescribe the active ingredient rather than the brand in the prescription;

the government shall organise bids listing the active ingredient rather than any given brand;

the entry price of generics must be at least 35 per cent under the price of the originator product (prices are regulated by CMED); and

originator companies shall supply samples to generic competitors to allow them to produce generic drugs.

Law stated - 26 September 2022

COMPETITION LEGISLATION AND REGULATION

Legislation and enforcement authorities

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

Competition law and practice in Brazil is primarily governed by Law No. 12,529/2011 (the Competition Law), which entered into force on 29 May 2012. The Competition Law consolidated the investigative, prosecutorial and adjudicative competition functions into one independent agency, the Administrative Council for Economic Defence (CADE).

CADE's structure includes a tribunal composed of six commissioners and a president, a General Superintendence (GS), a general-attorney's office and an economics department.

Regarding merger enforcement, the GS is responsible for clearing simple transactions and challenging complex cases before the tribunal, while CADE's tribunal is responsible for adjudicating complex cases challenged by the GS, the tribunal itself or third parties. The GS is also the chief investigative body in matters relating to anticompetitive practices.

CADE's tribunal is responsible for adjudicating the cases investigated by the GS.

All of CADE's decisions are subject to judicial review.

Certain anticompetitive conduct (primary cartel conduct) constitutes a crime in Brazil. Federal and state public prosecutors are responsible for enforcing the criminal statute. Further, the police (local or federal) may initiate

investigations of anticompetitive conduct and report the results of their investigations to CADE and prosecutors, who may indict the individuals.

The administrative and criminal authorities have independent roles and powers and may cooperate on a case-by-case basis.

Law stated - 26 September 2022

Public enforcement and remedies

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

Brazil's competition law applies to corporations, associations of corporations and individuals. For corporations, fines range between 0.1 and 20 per cent of the company's or group of companies' pre-tax turnover in the economic sector affected by the conduct in the year prior to the beginning of the investigation.

In 2016, CADE imposed a 5.3 million reais fine, equivalent to 17 per cent of the relevant turnover, on two pharmaceutical companies, AB Farmo Química and Brasvit Indústria e Comércio, for cartel conduct that affected the price of antiretroviral drugs purchased in government bids as a part of a 'cocktail' to treat AIDS (Administrative Proceeding No. 08012.008821/2008-22).

Apart from fines, CADE may also:

- order the publication of the decision in a major newspaper at the wrongdoer's expense;
- prohibit the wrongdoer from participating in public procurement procedures and obtaining funds from public financial institutions for up to five years;
- include the wrongdoer's name in the Consumer Protection List;
- recommend that the tax authorities block the wrongdoer from obtaining tax benefits;
- recommend that the IP authorities grant compulsory licences of patents held by the wrongdoer;
- order a corporate spin-off, transfer of control or sale of assets; and
- prohibit an individual from exercising market activities on its behalf or representing companies for five years.

The law also includes a broad provision allowing CADE to impose any 'sanctions necessary to terminate harmful anticompetitive effects'. CADE's wide-ranging enforcement of this provision may prompt judicial appeals.

Law stated - 26 September 2022

Private enforcement and remedies

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?

At the administrative level, private parties can petition CADE to be admitted to the administrative proceedings aimed at investigating the anticompetitive conduct or agreement as an 'interested third party'. Such parties have the ability to file arguments or documents before CADE, but the antitrust authority is responsible for imposing the remedies deemed necessary.

Private parties that were victims of anticompetitive conduct or agreement may also seek recovery of actual damages

and lost earnings, and moral damages by filing a judicial lawsuit.

Courts may order other types of relief, such as court injunctions, to cease the illegal conduct. The scope of those orders is broad. Possible examples include ordering a defendant to stop selling a product or to change pricing conditions or any other contractual provisions.

There are already damages claims filed by generic drugs companies against originator companies pending before judicial courts. This could represent an additional area of concern when dealing with non-ordinary life-cycle management strategies in Brazil.

Law stated - 26 September 2022

Sector inquiries

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?

Brazil's antitrust authorities may conduct sector-wide enquiries. According to the Competition Law, CADE's tribunal and GS can retain professionals to conduct analyses, studies and inspections as well as request information from any individual, authority, agency and public or private entities deemed necessary. CADE's economic department can also, by its own initiative or at the request of CADE's tribunal or GS, conduct studies and economic opinions.

The Competition Law also provides that the Economic Monitoring Office at the Ministry of Finance is the agency responsible for competition advocacy and may, among other measures, develop studies examining competition in specific sectors of the national economy.

There has not been a sector inquiry into the pharmaceutical sector since 2009 and 2010, when the then secretariat of economic law sent out questionnaires to approximately 40 originator companies questioning practices related to patent extensions. Under article 40 of Law No. 9,279/1996 , the maximum period for patent protection is 20 years.

Law stated - 26 September 2022

Health authority involvement

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 intersection between the pharmaceutical sector and competition law is widely recognised by the Brazilian authorities.

In 2013, the National Health Surveillance Agency (ANVISA) and CADE executed a technical cooperation agreement, with the goal of enhancing the relationship between the two agencies through, for example, workshops, technical visits, and joint studies and research. The agreement also provides for the exchange of information, reports, databases and other relevant documents.

In 2019, CADE and ANVISA signed an addendum extending the term of the technical cooperation agreement to January 2023. The addendum points out ANVISA's support in merger cases on topics such as relevant market definition, and analysis of anticompetitive conduct (involving primarily drug patents and information on products that have had their ownership transferred). The agreement also raises the need for analysis of abusive practices in the hospital sector, including abusive pricing.

Law stated - 26 September 2022

NGO involvement

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

Any individual or entity, including non-government groups, can file a complaint before CADE's GS in relation to alleged anticompetitive practices.

Non-government groups can be requested to provide information in proceedings related to merger review or anticompetitive conduct. They can also petition CADE to be admitted to different proceedings as an interested third party.

Federal, state and municipal governments, public prosecutors, any government consumer protection agency, publicly held entities and private non-profit organisations that have in their by-laws the protection of consumer or antitrust rights and were incorporated at least one year before the filing can stand in class actions related to anticompetitive conduct.

Historically, PróGenéricos, the Brazilian association of generic companies, has played a very active role before CADE, bringing most of the complaints challenging life-cycle management strategies on the part of originator companies.

The Brazilian Institute for Consumer Protection asked CADE to be admitted as an interested third party and to include pharmaceutical producers in the price-gouging investigation opened in 2020 (Preparatory Proceeding No. 08700.001354/2020-48) given the critical situation of the country's inventory of several medicines, including atracurium, rocuronium, sedatives and omeprazole, that could help in the treatment of covid-19 symptoms.

Law stated - 26 September 2022

REVIEW OF MERGERS

Thresholds and triggers

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

Law No. 12,529/2011 requires that a transaction be filed in Brazil if the following criteria are met:

- each of at least two parties to the transaction meet the turnover threshold;
- the transaction amounts to 'a concentration act'; and
- the transaction produces effects in Brazil, as defined by article 2 of Law No. 12,529/2011 (the Competition Law) (the effects test).

Brazil's competition law provides for a minimum-size threshold, expressed in total revenues derived in Brazil by each of at least two parties to the transaction. One party must have Brazilian revenues in the last fiscal year of at least 750 million reais, and the other party 75 million reais. Both the acquirers and sellers, including their whole economic group, should be taken into account.

The Competition Law provides that any 'concentration act' must be submitted to Administrative Council for Economic Defence (CADE) for review, provided that the turnover threshold is met. Whereas the Law specifically refers to 'concentration acts', it defines those very broadly as when:

- two or more companies merge;
- one company acquires, directly or indirectly, sole or joint control of another, or even a minority shareholding;

- an absorption of other companies takes place; or
- a joint venture, an associative agreement or a consortium is formed.

The General Superintendence (GS) has been considering the following to assess whether a given transaction fulfils the effects test:

- whether the target has or is expected to have (following the transaction) activities in Brazil or generate revenue in the country (there is no de minimis exception);
- whether the parties have horizontal or vertical relationships that could affect Brazil; or
- whether the geographic scope of the relevant market includes a region encompassing Brazil.

Law stated - 26 September 2022

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

The acquisition of licences or patents would be subject to mandatory filing if the relevant thresholds for the review of 'concentration acts' are met.

Law stated - 26 September 2022

Market definition

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

The product market is generally defined by CADE as including all the products and services considered substitutable by consumers because of their features, prices and usage. A relevant product market could encompass a certain number of products and services that present physical, technical or business characteristics that recommend the grouping.

CADE has consistently taken as a starting point for market definition purposes the anatomical therapeutic chemical (ATC) classification system devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and IMS Health.

In most cases, CADE has adopted the fourth ATC level (ATC4) as the criterion to define the relevant product market; however, it has also stated that it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level of ATC classification and based on the effective substitutability of the products in order to define the relevant market. In most of those exercises, CADE has considered ATC3 and the drug's therapeutic use.

In a recent CADE decision (January 2021) referring to the acquisition by Hypera SA of Takeda Pharmaceuticals International AG in which overlaps in six ATC codes were identified, a segmentation between over-the-counter (OTC) medicines and medicines that required medical prescription for sale was adopted by CADE to assess the overlaps (Merger Case No. 08700.003553/2020-91).

In the past, CADE has considered originator drugs and their generic copies as belonging to the same relevant product market, as generics can effectively substitute originator drugs after the patent expiry, especially if the regulatory system encourages switching, as is the case in Brazil.

Furthermore, in its decisional practice, CADE has defined separate product markets for out-licensing, supply of active pharmaceutical ingredients and contract manufacturing.

From a geographic perspective, CADE has traditionally defined the market to be national in scope, given the limited

weight of imports, the high level of regulation, the obligation for laboratories and medicines to be registered before the National Health Surveillance Agency and the fact that pharmaceutical companies generally offer their medicines throughout the country with uniform price policies.

Law stated - 26 September 2022

Sector-specific considerations

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

Not applicable. As in any other sector, CADE's review of mergers in the pharmaceutical industry are based on the knowledge built from its precedents. There are no specific guidelines applied by CADE to the pharmaceutical industry.

Law stated - 26 September 2022

Addressing competition concerns

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?

CADE traditionally follows a five-step review process provided for in the Horizontal Merger Guidelines , consisting of:

1. definition of the relevant market;
2. determination of the parties' market share;
3. assessment of the probability of the parties exercising significant market dominance following the transaction;
4. examination of the efficiencies; and
5. evaluation of the net effect on welfare.

Based on this review process, the authorities consider whether perceptible efficiencies resulting from the merger are likely to reduce or reverse adverse effects arising from the transaction. It is incumbent upon the merging firms to substantiate efficiency claims so that CADE can verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved, how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.

CADE's case law shows that efficiencies arguments have limited weight in the agency's decision-making process. Historically, whenever CADE has reached point (4), the transaction has either been blocked or cleared subject to substantial remedies.

Non-competition issues, such as industrial policy or public interest, are not traditionally factored into the review process.

Law stated - 26 September 2022

Horizontal mergers

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

The Competition Law presumes market power to exist if the parties jointly hold a share of at least 20 per cent of the market. CADE's Guidelines on Horizontal Mergers describe threshold levels of market concentration that raise concerns about the possible exercise of market power in a few ways:

- by a single firm unilaterally when that firm has a market share of at least 20 per cent; or
- through coordination of firms (collective dominance) in a market in which the four-firm concentration ratio is at least 75 per cent and the resulting firm has a market share of at least 10 per cent.

If the market concentration exceeds either of those levels, CADE proceeds to the third step: assessment of market power.

Following the US or the European Commission standards, CADE's guidelines also consider the Herfindahl-Hirschman Index (HHI) as a measure of concentration.

For example, when reviewing Merger Case No. 08700.009834/2014-09 (Anovis/União Química), CADE considered that no competition concerns would arise if the combined market share was under 20 per cent. For the two ACT4 category classes for which the resulting concentration was over 20 per cent, CADE resorted to the HHI index, which indicated the high market share was prior to the transaction, with little increment following the transaction. As the concentrations were over 50 per cent, CADE took a conservative approach and proceeded with the analysis of the possibility of exercise of market power, which would not be significantly affected by the merger, and thus cleared the case.

In Merger Case No. 08700.005093/2016-59 (Sanofi/Boehringer Ingelheim), despite finding a concentration above 20 per cent in the market segments involved in the transaction and an HHI variation above 200 points, CADE unconditionally cleared the case owing to the fact that (1) the parties' products included in the same market segment were not close substitutes; and (2) there is a great number of companies with high market share in the segments affected.

A similar approach was taken by CADE while reviewing Merger Case No. 08700.006159/2016-28 (Pfizer/ AstraZeneca). Even though the transaction resulted in a high market share in some of the affected markets – and in some cases the HHI variation was also relevant – CADE cleared the transaction without restrictions because, among other things:

Pfizer's high market share was only identified considering the scenario in terms of value (as opposed to volume), which could be related to drugs over which the company previously had patents;

- the market share of the parties in terms of units was very low;
- new drugs entered the market and there is projection of new products; and
- the presence of important competitors in the affected markets.

More recently, in the acquisition of Extrafarma by Pague Menos, both drugstore chains, CADE used a different threshold to presume market power: 40 per cent instead of 20 per cent. According to the Reporting Commissioner, 40 per cent follows CADE's case law in cases involving retail chains (Merger Case No. 08700.005053/2021-74 – Pague Menos/ Extrafarma).

Law stated - 26 September 2022

Product overlap

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

An overlap concerning products that are being developed may be problematic in some scenarios, such as if the patent rights related to the active principles of the developing product may increase current and potential costs of third parties, strengthening the merging parties' dominant position and increasing barriers to entry; or if there is a risk that the merged entity will terminate or reduce the development of the product to avoid competition with products currently being marketed by the other party to the transaction.

In more recent years, CADE has reviewed a number of joint ventures between pharmaceutical companies aimed at developing new products in Brazil. In those cases, competition concerns arose when the partnership resulted in potential elimination of future competition between the parties, preventing them from entering the market alone.

When Pfizer and Orygen filed the formation of a joint venture aimed at producing and selling up to five biosimilar products in Brazil (Merger Case No. 08700.005601/2014-37 – Pfizer/Orygen), CADE assessed the estimated market shares and potential horizontal overlaps with regard to each relevant ATC4 class. Since there were no relevant horizontal overlaps, CADE identified no risk of potential competition elimination, leading to the approval of the transaction with no conditions.

Law stated - 26 September 2022

Remedies

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

The Competition Law allows CADE to take whatever measures deemed necessary to ensure the merger will not impact competition. There is a preference for adopting structural rather than behavioural remedies.

If CADE finds a transaction to be harmful to competition, it may block it or accept remedies, particularly divestitures of production facilities, stores, distribution networks or brands.

Under the Competition Law, parties can negotiate undertakings with CADE to remedy perceived competition issues. Parties can offer undertakings from the day of filing up to 30 days following the challenge of the transaction before the tribunal by the GS.

In March 2019, CADE cleared the acquisition of All Chemistry do Brasil by SM Empreendimentos Farmacêuticos (Merger Case No. 08700.005972/2018-42) on the condition that SM does not make any acquisitions of rivals in the next two years and that it will notify CADE of all transactions in the next two years. The transaction was not originally submitted to CADE for review because it did not meet the thresholds, but the authority determined the notification of the deal after receiving a complaint.

In June 2022, CADE cleared the acquisition of Extrafarma by Pague Menos (Merger Case No 08700.005053/2021-74), subject to structural remedies negotiated with the companies that should be implemented before the parties are able to close the deal, in accordance with the fix-it-first model. The remedies package included the sale of eight drugstores in cities where the parties' combined market share exceeded at least 40 per cent, and two confidential behavioural remedies.

Law stated - 26 September 2022

ANTICOMPETITIVE AGREEMENTS

Assessment framework

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

The basic framework for the assessment of anticompetitive agreements or conduct in Brazil is set by article 36 of Law No. 12,529/2011 (the Competition Law). Article 36 deals with all types of anticompetitive conduct other than mergers.

The Competition Law prohibits acts 'that have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Article 36(3) contains a lengthy but not exhaustive list of acts that may be considered antitrust violations provided they have the object or effect of distorting competition. Potentially anticompetitive practices include resale price maintenance, price discrimination, tying sales, exclusive dealing and refusal to deal.

Resolution No. 20/1999 of the Administrative Council for Economic Defence (CADE)specifically provides that exclusivity agreements, refusal to deal, price discrimination and other vertical restraints are not per se infringements in Brazil and shall be assessed under the rule-of-reason test. Annex II of CADE Resolution No. 20/99 outlines 'basic criteria for the analysis of restrictive trade practices', including:

- definition of relevant market;
- determination of the defendants' market share;
- assessment of the market structure, including barriers to entry and other factors that may affect rivalry; and
- assessment of possible efficiencies generated by the practice and balance them against potential or actual anticompetitive effects.

In practice, no case has yet been decided on the basis that harmful conduct was justified by pro-competitive efficiencies.

Law stated - 26 September 2022

Technology licensing agreements

To what extent are technology licensing agreements considered anticompetitive?

Article 36 of the Competition Law includes as examples of anticompetitive practices conduct performed through the abuse of IP rights, and CADE has consistently stated that the grant of IP rights may lead to anticompetitive effects (when, for example, a party licenses IP rights to one party and refuses to do the same to its rivals).

Restraints involving IP rights are assessed under the rule of reason; therefore, it is likely that the assessment would take into account the specific characteristics of each case and balance potentially competitive against anticompetitive effects.

In 2013, for example, CADE cleared with conditions four transactions involving licensing agreements between Monsanto and four other companies (Don Mario Sementes, Nidera Sementes, Syngenta and Coodetec – Cooperativa Central de Pesquisa Agrícola) in relation to the development, production and marketing of soybean seeds with Mosanto's Intacta RR2 PRO technology. The conditions refer to changes in clauses of the agreement that granted Monsanto the possibility of influencing strategic decisions of the licensee companies (eg, the agreement established a compensation mechanism for licensee companies that was based on the sales of the Intacta product and on the sales of certified seeds of Monsanto's competitors).

Law stated - 26 September 2022

Co-promotion and co-marketing agreements

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

The Competition Law provides no clear-cut guidance on the subject; however, since these agreements are reviewed under the rule of reason, it is likely that the assessment would take into account the specific characteristics of each case, and balance potentially pro-competitive and anticompetitive effects.

Law stated - 26 September 2022

Other agreements

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

Under article 36 of the Competition Law , agreements with competitors would be an issue if they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

There is, therefore, no specific form of agreement that is forbidden a priori by the legislation. Besides their object and effect, CADE will take into consideration the market power held by the involved parties to assess the likeliness of antitrust risks.

For agreements that may concern the exchange of commercially sensitive information among competitors, confidentiality provisions will be useful tools to help reduce this exchange and thus avoid further antitrust liability.

Cartel cases are an exception to the assessment under the rule of reason, as CADE historically defined it as a per se conduct. CADE also includes in the definition of cartel the exchange of commercially sensitive information that may lead to a change of market conditions, even if an agreement is not reached by the parties.

Law stated - 26 September 2022

Issues with vertical agreements

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

Vertical agreements raise antitrust concerns when they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Article 36(3) of the Competition Law contains a lengthy but not exhaustive list of acts that may be considered antitrust violations, provided they have the object or effect of distorting competition. Potentially anticompetitive practices include resale price maintenance, price discrimination, tying sales, exclusive dealing and refusal to deal.

Law stated - 26 September 2022

Patent dispute settlements

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

CADE has recently considered pay-for-delay conduct to be a potential violation of the Competition Law and liability may apply if a pharmaceutical company settles a patent dispute with the sole purpose of delaying the entry of a competitor into the market. We are not aware of a case targeting this conduct being reviewed by CADE.

Law stated - 26 September 2022

Joint communications and lobbying

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

Joint communications or lobbying actions, by themselves, are not presumed to be harmful to competition; however, when communications result in the exchange of commercially sensitive information such as prices, discount policies, costs, clients and suppliers, among other things, the practice may amount to antitrust infringement, and companies and individuals may be subject to sanctions imposed by CADE.

Regarding lobbying actions, the regular exercise of the right to complain before the public sector with the purpose of defending the sector's best interests and ensure the defence of rights do not arouse competition concerns. This only happens when the exercise of such right is considered abusive, which can also amount to a sham litigation.

Although there have been no recent relevant cases involving pharma companies, in an investigation concerning petrol stations located in Natal that allegedly acted to prevent the enactment of a law that would increase rivalry in their market, CADE considered three cumulative conditions to assert the abusive exercise of the right to complain:

- the complaints' success probability;
- the argument's plausibility; and
- the adequacy of the forms and instruments used (Administrative Proceeding No. 08700.000625/2014-08).

CADE's tribunal concluded that the companies aimed only to maintain the legislation already in force, which was more beneficial to them, and that they did this through adequate means, not abusing its rights.

Law stated - 26 September 2022

Public communications

To what extent may public communications constitute an infringement?

Public communications are potentially anticompetitive when they involve the exchange of commercially sensitive information that can be used to facilitate or induce collusive practices. Such statements can also constitute a competition violation if they result in one of the effects established in article 36 of the Competition Law.

In 2009, ABICAB (the Trade Association of Chocolate and Candy Producers), its president and vice president disclosed in a press conference its expectations for price increases and volume of production adjustments before Easter. CADE found that such signalling had the potential to promote uniform commercial conditions among competitors. The case was settled in 2013, after the payment of a fine of 96,000 reais and the commitment to stop signalling future commercial policies.

Similarly, in 2020, CADE opened a preparatory procedure to investigate statements made by the executives of two Brazilian companies active in the food market (JBS and BRF). During a conference held by a global investment bank, the executives stated that their products' prices would increase since the price of corn had increased. Ultimately, the case was dismissed by CADE's General Superintendence, owing to the lack of evidence of antitrust violations.

Law stated - 26 September 2022

Exchange of information

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?

The Brazilian Research-Based Pharmaceutical Manufacturers Association Code of Conduct sets forth transparency clauses regarding relationships (section 1.1.5), contracts (section 3) and donations (section 12) in the pharmaceutical sector. Clinical trials are also experiencing growth in Brazil and are contributing to the development of scientific research in Latin America.

The increased transparency granted by these measures does make it more likely for anticompetitive exchanges of information to occur. We are not aware of a case targeting a similar conduct being reviewed by CADE.

Law stated - 26 September 2022

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

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

Conduct carried out by a firm with monopoly or market power will be considered anticompetitive if it has 'as [its] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

The Administrative Council for Economic Defence (CADE) will consider whether the company has a legitimate business reason for its conduct, whether the conduct is solely intended to harm competitors and whether the company's rivals are able to compete despite the effects of the conduct in the market.

Law stated - 26 September 2022

De minimis thresholds

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

No, there is no de minimis threshold for conduct to be found abusive.

Law stated - 26 September 2022

Market definition

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?

In theory, yes, but in practice the agency tends to be less restrictive when defining a relevant market in behavioural cases.

Law stated - 26 September 2022

Establishing dominance

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?

Article 36 (2) of Law No. 12,529/2011 (the Competition Law) provides that a dominant position is presumed when 'a company or group of companies' controls 20 per cent of a relevant market.

Article 36 further provides that Administrative Council for Economic Defence (CADE) may change the 20 per cent threshold 'for specific sectors of the economy'. Such an assumption provides some guidance to private parties as it would be unlikely for CADE to find a violation in the absence of market power.

Law stated - 26 September 2022

IP rights

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?

The application for the grant or enforcement of a patent will not, by itself, expose the patent owner to antitrust liability; however, a patent owner may be found liable if it uses its patent right in an abusive manner, resulting in at least one of

the effects listed in article 36 of the Competition Law.

In 2007, PróGenéricos filed a complaint against Eli Lilly do Brasil and Eli Lilly and Company for allegedly abusing their rights regarding Gemzar, a drug to treat cancer, to prevent generics entry. Among other alleged practices, Eli Lilly filed six different claims before the judicial courts to enforce its rights and required one additional five-year period of exclusive marketing rights given the discovery of a new use for the drug. An injunction ensured an additional protection for eight months, and for three months the pharmaceutical company Sandoz was not allowed to offer the competing drug Gemcit in the market.

In June 2015, CADE's tribunal found that Eli Lilly abused its rights by presenting misleading information to courts, with 'serious harm to public health and economy'. According to CADE, the drug maker did not clearly explain before the courts that the request for a patent was never granted, an omission that was considered to be strategic and malicious, enabling the company to exclude competitors from the market. According to the Reporting Commissioner, 'the company behaved in an anticompetitive manner by presenting multiple claims before several courts, omitting information to obtain artificially the monopoly in the sale of the medicine, besides unduly obtaining an exclusive right to sell the drug'.

CADE imposed a fine of 36.6 million reais. When calculating the fine, CADE doubled the expected fine in view of recidivism considering Eli Lilly's sanction in the alleged cartel against generic drugs (Administrative Process No. 08012.011508/2007-91).

Law stated - 26 September 2022

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

Life-cycle management will not, by itself, expose the patent owner to antitrust liability; however, a patent owner may be found liable if this management comprises the use of the patent right in an abusive manner, resulting in at least one of the effects established in article 36 of the Competition Law.

In 2008, PróGenéricos, a local generic manufacturers' association, filed a complaint against Abbott for allegedly abusing its power through patent violation claims against Cristália Produtos Químicos e Farmacêuticos regarding anaesthetics and the launch of a new antiviral drug that was not considered to be an improvement over the original drug (Administrative Inquiry No. 08012.011615/2008-08). In January 2019, the investigation was dismissed owing to lack of evidence.

Furthermore, in 2011, PróGenéricos filed a complaint against AstraZeneca for allegedly abusing its rights as a consequence of patent violation claims against the National Health Surveillance Agency (ANVISA) regarding a number of blockbuster drugs, namely Crestor (cholesterol drug), Nexium (acid reflux relief drug) and Seroquel (drug for schizophrenia, bipolar disorder and major depressive disorder). AstraZeneca was accused of engaging in ring-fencing practices regarding its IP holdings to deter generic entry, as well as sham litigation practices before courts (Administrative Inquiry No. 08012.001693/2011-91).

The investigation was closed by the General Superintendence in December 2020, as it understood that the lawsuits filed by AstraZeneca were justified and did not qualify as sham litigation. In January 2021, Commissioner Lenisa Prado asked to review the case to investigate whether AstraZeneca's strategy was abusive, but the majority of CADE's tribunal voted against reopening the investigation.

Law stated - 26 September 2022

Communications

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

Statements with the intent to influence costumers or healthcare professionals are not per se antitrust infringements. Those actions will only be found anticompetitive if they result in one of the effects listed under article 36 of the Competition Law.

We are not aware of any cases regarding this conduct being adjudicated by CADE; however, we understand, for example, that recommendations made by pharmaceutical companies that harm the credibility of an entrant competitor and its products, without having grounds on solid arguments, may constitute the creation of a barrier to entry and amount to an antitrust infringement.

Law stated - 26 September 2022

Authorised generics

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?

No. Generic drugs may only be registered with the National Health Surveillance Agency (ANVISA) when the patent expires or is totally withdrawn by the patent holders. Individual licensing agreements or a decision by the owner of the patent to manufacture a generic drug are not sufficient to obtain the regulatory approval.

Law stated - 26 September 2022

Restrictions on off-label use

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

Yes. CADE has already adjudicated actions of patent holder companies to prevent off-label drugs entry, through strategic use of intellectual property in several judicial and administrative claims.

In 2015, CADE's tribunal found that Eli Lilly do Brasil and Eli Lilly and Company abused its rights to prevent generics entry by presenting misleading information to courts in six different claims, with 'serious harm to public health and economy'.

According to the reporting commissioner of the case at CADE, 'the company behaved in an anti-competitive manner by presenting multiple claims before several courts, omitting information to artificially obtain the monopoly in the sale of the medicine, besides unduly obtaining an exclusive right to sell the drug'. CADE imposed a fine of 36.6 million reais.

Law stated - 26 September 2022

Pricing

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

Conduct such as coordination of prices between competitors, abusive increase of prices compared with the increase of costs, price of sale intentionally below the cost price and resale price-fixing may be considered anticompetitive if they result in one of the effects established in article 36 of the Competition Law.

There is no record of a fine imposed by CADE to a pharmaceutical company owing to high prices practices.

Although CADE can theoretically rule on this matter, our understanding is that this control is exercised by the Chamber of Drug Market Regulation (CMED), since Law No. 10,742/2003 establishes the sanctions for companies that disrespect the price regulation of CMED.

In July 2019, CADE opened a preliminary inquiry to investigate Gilead in the alleged conduct of exercising or abusing IP rights by charging excessive prices on the sales of the medicine Sovaldi (sofosbuvir) after the company was granted the patent. The proceedings were opened following a complaint by nine parties, including charitable entities and the Federal Public Defender's Office. The investigation is ongoing (Preparatory Proceeding No. 08700.005149/2019-18).

In March 2020, CADE opened a preparatory administrative inquiry into the healthcare sector, in view of price increases during the covid-19 pandemic (Preparatory Proceeding No. 08700.001354/2020-48). The purpose of the investigation is to verify whether the price increases were abusive. CADE issued several requests for information to collect information.

In May 2022, CADE closed the investigation owing to lack of evidence of an antitrust violation. According to CADE, the results of the market test demonstrated that the abrupt price increases were generally caused by shortages of some products and as the market was gradually returning to a 'normal' situation, CADE should not replace market players to arbitrate prices of goods and services related to the impacts of the pandemic.

Law stated - 26 September 2022

Sector-specific issues

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

CADE has historically not been open to extra-economic reasons as an acceptable justification for anticompetitive practices.

Law stated - 26 September 2022

UPDATES AND TRENDS

Recent developments

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

In recent years, the government has increased its investment in state-owned laboratories, and the Administrative Council for Economic Defence has paid increasing attention to conduct that has the potential to create entry barriers to off-label drugs.

In March 2019, the General Superintendence (GS) issued a decision in Merger Case No. 08700.000831/2019-14 (GlaxoSmithKline/Ares Trading) that could prove important for other pharmaceutical companies. The two companies entered into an agreement by which they would develop and commercialise a product to treat biliary tract cancer and non-small cell lung cancer, which is still at the early development stage.

The General Superintendence (GS) decided that the agreement did not require antitrust clearance because the product that will result from the agreement is not marketable yet and, since the drug does not have an anatomical therapeutic chemical classification, the authority would not have the means to conduct the antitrust assessment. This view could potentially reduce the number of merger filings involving pharmaceutical companies in Brazil.

There are ongoing investigations related to alleged cartels in the pharmaceutical sector. For example, in November 2021, CADE opened administrative proceedings to investigate an alleged international cartel in the market for scopolamine-n-butylbromide (SnBB). The proceedings comprise seven pharmaceutical companies, such as Alchem and Boehringer Ingelheim, and started from a leniency agreement (Administrative Proceeding No. 08700.004235/2021-28).

In December 2021, the GS fined Comercial Cirúrgica Rioclarense, Dimaci Material Cirúrgico, Drogafonte Medicamentos e Material Hospitalar and five other pharmaceutical firms for participating in a cartel to allocate the market for supplying drugs in several Brazilian states. The case was referred to CADE's tribunal and a final ruling is pending (Administrative Proceeding No. 08012.002222/2011-09).

Law stated - 26 September 2022

Jurisdictions

Brazil	Levy & Salomão Advogados
China	Lifang & Partners
Czech Republic	dubanska & co
European Union	Herbert Smith Freehills LLP
Finland	Castrén & Snellman
France	Intuity
Germany	Allen & Overy LLP
India	AZB & Partners
Japan	Anderson Mōri & Tomotsune
Norway	Advokatfirmaet Thommessen AS
Romania	Bondoc & Asociatii
South Africa	Herbert Smith Freehills LLP
Turkey	Zesa Attorney Partnership
USA	Clifford Chance