

# Pharmaceutical Antitrust

The application of competition regulation  
in 28 jurisdictions worldwide

# 2010

Contributing editor: Marleen Van Kerckhove



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# Colombia

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## Pharmaceutical regulatory law

- 1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs?

Price regulation can be found in the following legislation:

- Law 81 of 1988;
- Article 245 of Law 100 of 1993;
- Decree 126 of 2010; and
- Circulars issued by the National Commission on Prices of Medicament and Medical Devices.

Marketing authorisation legislation is comprised of:

- Law 9 of 1979 (Title VI);
- Decree 2092 of 1986;
- Decree 2742 of 1991;
- Decree 677 of 1995;
- Decree 2085 of 2002;
- Decree 4725 of 2005;
- Resolution 1478 of 2006 issued by the Ministry of Social Protection;
- Resolution 2564 of 2008 issued by the Ministry of Social Protection; and
- Resolutions, circular letters and agreements issued by the National Institute for Surveillance of Food and Medicaments (INVIMA)

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

The National Commission on Prices of Medicaments and Medical Devices requires from pharmaceuticals, whether producers or importers, information about prices. The National Health Superintendence has some regulatory, surveillance and review powers over the entire health-care system.

INVIMA is charged with controlling the quality of medicaments marketed in Colombia as well as compliance with all the marketing authorisations and requirements.

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

The aforementioned regulations have two distinctive impacts on competition as they curtail price competition and act as barriers to entry into the market.

Price competition is subject to a special price control regime overseen by the National Commission on Prices of Medicaments and Medical Devices. There are three price regimes:

- Direct control, in which the Commission establishes the maximum price that distributors and producers can charge;
- Regulated liberty, in which the Commission establishes the criteria and parameters by which distributors and producers can determine and alter prices; and

- Liberty under surveillance, in which producers and distributors are free to establish prices only being required to strictly inform the Commission about all price determinations and alterations.

Most medicaments fall in the two less rigorous standards of price control. The Commission, through circular letters, determines the medicaments included in the direct control and regulated liberty regimes and the methodology and criteria to be used to determine prices in both regimes.

Production, importation, exportation, distribution and marketing of medicaments requires approval (Sanitary Registry) issued by INVIMA. New medicaments, whose active principle is a chemical entity not included in the Colombian pharmacological rules, can apply for a Sanitary Registry using information that has not been made public. Subsequent applicants cannot rely on the non-divulged information submitted to INVIMA by the first applicant to support their own Sanitary Registry application.

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## Competition legislation and regulation

- 4 Which legislation sets out competition law?

The basic framework of Colombia's competition regime is found in the following laws, decrees and regulations:

- Law 155 of 1959;
- Law 256 of 1996;
- Law 1340 of 2009;
- Decree 1302 of 1964;
- Decree 2153 of 1992;
- Decree 3523 of 2009; and
- the Unified Circular of the Superintendence of Industry and Trade.

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

There are no specific guidelines of competition law that are applicable to the pharmaceutical sector.

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

Law 1340 of 2009 appointed the Superintendence of Industry and Trade (SIC) as Colombia's sole antitrust authority with only a few regimes falling outside its review powers or jurisdiction. Accordingly, the SIC is the administrative agency charged with investigating and deciding on all investigations dealing with mergers and transactions that may have an anti-competitive effect in the pharmaceutical sector.

It should be noted that, before the enactment of Law 1340 of 2009, the SIC had already received by virtue of Decree 2221 of 2008,

the power to investigate and decide cases of disloyal competition and restrictive trade practices, including abuse of dominant position, arising in the national health system. Before 2008, the Superintendence of Health was charged with investigating and deciding antitrust violations occurring in the general health system of social security.

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

The general sanctions regime established for antitrust violations is applicable to all types of anti-competitive conducts or agreements.

Law 1340 of 2009 reaffirmed fines as the remedy for antitrust violations and updated the amounts of the fines. Under article 25, corporations can be fined up to 100,000 times the minimum monthly wage (equal to about US\$25,750,000 depending on the exchange rate valid at time of penalty) or 150 per cent the amount of the profit achieved through the anti-competitive conduct.

According to article 16, individuals are subject to fines of up to 2,000 times the minimum monthly wage (equal to about US\$515,000 depending on the exchange rate valid at time of penalty) for violations of the antitrust laws.

In cases where the parties fail to inform about business integrations, the SIC has the authority to order the reversal of the operation.

In the context of patents, article 66 of the Andean IP Regime (Decision 486 of the Andean Community Commission) establishes that IP authorities of each member country (in Colombia this is also the SIC) can grant mandatory licenses if the patent holder is found to be violating antitrust laws, especially when abusing its dominant position.

The granting of the mandatory patent license has to be preceded by the declaration, by the antitrust authority, of a violation of an antitrust law. Thus, in order to apply for a mandatory license on grounds of an antitrust violation from the exercise of the patent rights, the SIC will have to find the patent holder guilty of an antitrust violation in connection with the misuse of the patent rights.

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

Interested third parties (ie, competitors or consumers) can become parties in the investigations carried out by the SIC. They may offer evidence and file arguments in favour or against the imposition of sanctions against the investigated party and in abuse of dominant position cases it is possible to request injunctions from the SIC. However, under the Colombian antitrust regime there are no other provisions allowing for remedies for affected third parties.

The fines described in question 7 are all to be paid to the SIC. Affected competitors can seek redress and economic reparation through the courts via reparation actions, provided they can prove all the elements required by law.

**9** May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

The SIC has authority to launch sector wide inquiries and it has not done so in the pharmaceutical sector.

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

The Ministry of Social Protection, the National Health Superintendence and INVIMA, to some extent, have regulatory attributions that

can include the ability to implement pharmaceutical specific competition rules.

Law 1340 of 2009 established that all regulatory authorities and agencies have to inform the SIC of any proposed regulation to be enacted that may affect competition. The SIC can then issue a non-binding opinion. When the regulatory agency decides to issue a regulation objected by the SIC it has to explicitly state why is not following the SIC's recommendation.

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

In general terms, Colombian law prohibits agreements that limit free competition. Nonetheless, article 1 of Law 155 of 1959 allows the government to authorise agreements that, although they may limit competition, seek to secure the stability of production of goods or services in a basic sector of the economy.

Article 1 of Decree 1302 of 1964 further defined the goods and services considered as basic sectors of the economy. It explicitly listed production and distribution of goods satisfying the basic health needs of the Colombian population as a basic sector covered by the exception to the prohibition of anti-competitive agreements.

The SIC's unified circular regulates the process whereby a party seeks to obtain authorisation for an anti-competitive agreement. Such authorisation has to be requested before the agreement enters into effect. The parties seeking approval from the SIC, for an otherwise forbidden agreement have to provide, among other information, the following:

- the number of employees in the sector and its impact on the national or regional labour market;
- the interrelation with other economic sectors; and
- a detail justification of the agreement proving the expected stabilisation effects in the sector.

In cases of business integrations like mergers, the parties can ask the SIC not to object a projected operation on the basis of the efficiency exception. In those cases, the interested parties have to prove that the benefits to the consumers outweigh the anti-competitive effects and the results cannot be reached through alternative means.

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

As stated above, all antitrust investigations are open to the intervention of interested third parties. Article 19 of Law 1340 of 2009 authorises competitors, consumers and anyone who proves a direct and individual interest in the investigation to present evidence and briefs before the SIC. Consumer associations and leagues are, by law, recognised as interested parties.

Antitrust violations are subject to public prosecution by the SIC. Private prosecution for damages, although possible via civil claims or class actions, is extremely rare in Colombia.

### Review of mergers

**13** To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

Pharmaceutical mergers are reviewed following the general guidelines established under the unified circular if the operation meets the review thresholds established by law. The parties have to file and the SIC will review, among other things, the following information:

- information about the merging companies;
- information about the affected products and their market;
- information about importers or exporters;

- information about entry barriers;
- information about raw materials and inputs required for production;
- information about competitors; and
- information about clients for the affected products.

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

Both product markets and geographical markets are subject to the standard definition for review set forth by the unified circular.

Product markets are defined by the product's available presentations, brands, principle uses and applications, the product's target population and the main habits of the users. Furthermore, availability of substitute products is taken into account when defining the markets as is the existence of share production lines with different products.

For horizontal integrations the product market involves the concurrent products offered by the companies involved in the transaction and for vertical integrations products part of the same value chain.

Geographical markets are defined for each affected product taking into account the Colombian place of business of the merging companies, their area of influence and annual production capacity. In defining the geographical markets, the SIC takes into account past production numbers, the areas in the country where production is destined and the minimum optimum size required by a production facility to supply the product.

When defining geographical markets, the incidence of transport costs is taken into consideration.

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

Article 9 of Law 1340 of 2009 states that any operation or merger in which the parties have a combined participation in the relevant market of less than 20 per cent is deemed authorised and the SIC only needs to be notified. Hence, the law only considers a combined market participation of more than 20 per cent worth reviewing.

The true challenge for the interested parties lies in making sure their internal assessment of market participation is accurate. Because if they are mistaken and the SIC considers that they should have asked for complete authorisation but did not, fines may be imposed on the companies, penalties may be imposed on the individuals leading the operation and the operation itself may be reversed. Accurate definition of the market and participation therein are left to the parties, but the ex-post control and penalising powers of the SIC make so that erring on the side of caution is the best possible route until specific guidelines are implemented.

Mergers above the 20 per cent market participation threshold are subject to authorisation by the SIC. It is not clear what circumstances are considered as problematic when the review takes place and neither the law nor current regulations clearly define what precise circumstances will be considered as threats for competition.

Nonetheless, when reviewing mergers the SIC studies the parties' market power and relevant market share, applying tests and indexes. It also reviews the availability of substitute products, the barriers to entry and the possibility of competition from national and foreign producers. When a number of the analysed categories raise concerns, it is likely that the proposed merger will be perceived as problematic.

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

The unified circular indicates that the SIC expects from the parties information about all the overlapping products for horizontal integrations or those that are part of the same product chain for vertical integrations. In describing the information requirements, the SIC's

unified circular uses the wording 'products offered' by the parties.

Hence, it seems there is no obligation to provide the SIC with information about products being developed (those not being offered to the consumers or suppliers). Furthermore, the information requirements inquire about consumer habits, production facilities and production numbers for past years, which confirms our belief that no reporting obligations exist for products under development.

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

The SIC can accept, deny or condition a proposed operation. When it conditions the operation the law states that the SIC can impose conditions or obligations to be met by the merging parties. There is no list of acceptable remedies as the law gives the SIC discretion when deciding on the measures to be taken in each case.

Divestiture, licensing or obligations to maintain a brand available to consumers are all possible remedies. For example, in a recent decision the SIC conditioned a proposed operation to a guarantee by the parties to continue offering their two competing brands to the consumers and to allocate equitably between the two products the advertising budget for a predetermined period of time.

Although the SIC has the final word on which remedies are to be imposed, Colombian law allows the parties to offer guarantees to the antitrust authority during the review process. A guarantee is understood as a suggestion on a remedy to be implemented so that any anti-competitive concerns raised by the operation are adequately addressed.

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

Colombian law establishes a reporting requirement, subject to the threshold described in question 15, for all business integrations by companies part of the same economic activity or production (value) chain, regardless of the legal structure of the operation.

Acquisitions of business lines and assets have been considered as operations covered by the reporting requirement. The acquisition of a group of assets including one or more patents can be subject to the reporting requirements, provided that the reporting thresholds are met.

Since licensing does not transfer ownership over the patent, it is difficult to see such transaction as the business integration subject under Colombian law to reporting requirements.

### Anti-competitive agreements

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

Article 47 of Decree 2153 of 1992 defines anti-competitive agreements as those with the following objectives or effects:

- price fixing;
- establishing discriminatory sales or commercialisation conditions;
- dividing markets between producers or suppliers;
- assigning production or supply quotas;
- assigning, limiting or dividing the access to raw materials and inputs required for production;
- limiting technical developments;
- tying the supply of products to other obligations;
- abstaining from producing in order to affect the product's production levels;
- colluding in tender offers or agreeing to distribute the allocation of contracts, tender offers or to offer the same terms; or
- obstructing or blocking the access to the market or the distribution channels.

### Update and trends

The Colombian healthcare system has experienced a nationwide crisis that led to the recent declaration of a state of emergency. The government has issued several decrees (Decree 126 of 2009 listed in question 1 is one of them) introducing changes to healthcare regulations, including pharmaceuticals regulations.

Among the discussions on the healthcare crisis, many experts and social sectors have criticised the high prices of medicaments in Colombia and have called for reforms to bring them closer to the prices offered by pharmaceuticals in other Latin-American nations.

The decrees issued under the state of emergency powers

have been heavily criticised to the point that the government has announced that it will ask Congress to overturn some of the changes implemented. Also, the decrees are yet to be reviewed by the Constitutional Court. Should the Court decide that the declaration of the state of emergency was unconstitutional, all the decrees issued by the government under the special powers will be voided.

Regarding antitrust regulation, almost all of those who deal with this challenging area of law are waiting for SIC to issue or update its guidelines relating to the application of the principles recently set forth in Law 1340 of 2009.

The unloyal competition regime (ie, anti-competitive behaviour) also considers as an antitrust offence entering into exclusivity agreements with the objective or effect of blocking a competitor's accesses to the market or monopolising the distribution of goods or services.

Article 48 of Decree 2153 of 1992 also describes the following acts as anti-competitive:

- violating the advertising rules established under the Consumer Protection Statute;
- exerting influence over a company so that it raises its prices or to desist from reducing them;
- refusing to deal with a company as retaliation for its price policy.

**20** Have there been cartel investigations in the pharmaceutical sector?

SIC has open investigations of healthcare providers for anti-competitive conducts but not of pharmaceutical companies.

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

Agreements can be considered anti-competitive by their objective or by their effects. Technology licensing agreements whose effects meet any of the legal classification listed in question 19 are at risk of being characterised as anti-competitive.

Nonetheless, if the licensing has the objective of enabling cooperation to carry out investigation or to allow the development of new technologies, then the agreement will not be considered as anti-competitive as it will be covered by one of the legal defences set forth by Decree 2153 of 1992. Exclusive licensing may fall under the scope of the disloyal competition provision explained in question 19.

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

Co-promotion and co-marketing agreements can be considered anti-competitive if their objective or effects in the market match one of those listed in Article 47 of Decree 2153 of 1992 listed in question 19 and are not covered by any exception.

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

Any type of agreement entered into to achieve one of the objectives considered by the law as anti-competitive exposes the parties to antitrust liabilities. The same is true if the effects of the agreement are deemed anti-competitive under the law.

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

Vertical agreements raise anti-competitive concerns when they are exclusive, due to the disloyal competition provisions (ie, competitors

are blocked from accessing raw materials or distribution channels).

Non-exclusive vertical agreements that have the effect of dividing the market between competitors in the secondary market or that block the access to raw materials, eliminate competition or discriminate between competitors raise antitrust concerns.

Other non-exclusive vertical agreements raise less issues. However, if there is dominant position, discriminatory dealing (ie, offering different conditions to competitors or raising entry barriers in the secondary market) can be characterised as abuse of dominant position.

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

If the settlement agreement has any of the anti-competitive effects prohibited by law, then the parties may be liable for an antitrust violation.

### Anti-competitive unilateral conduct

**26** In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

Article 50 of Decree 2153 of 1992 defines the conducts considered as abuse of dominant position as follows:

- predatory pricing;
- discriminatory dealings that will leave a supplier or consumer in a disadvantaged position with another supplier or consumer;
- conducts tying the product to additional obligations;
- sales to a buyer offering different conditions than those offered to other buyers with the intent of reducing or eliminating competition;
- selling or offering services at different prices in particular areas of the Colombian territory with the intent or the effect of reducing or eliminating competition in that particular area and the offered price does not reflect an associated transactional cost; and
- obstructing or blocking the access to the market or the distribution channels.

Any such agreement or practice is considered abuse of dominant position. Nevertheless, under Colombian law only firms with dominant position are liable for abuse, in other words, for the conduct to be characterised as abuse the infringer or infringers have to hold a dominant position in the market.

Un-loyal competition is also an antitrust violation. Following the Paris Agreement, to which Colombia is party, Law 256 of 1995 defines un-loyal competition as all acts with concurrent goals, affecting the market and considered against commercial custom, mercantile good faith, the usual industrial or commercial practices and those acts aimed at affecting the choices of consumers or the markets.

The following are specific acts considered by law as offences constituting un-loyal competition:

- dishonest diversion of clients;
- tampering with the internal organisation of a company;

- creating confusion about another company's activities or commercial offerings;
- deceiving the public about another company's activities or commercial offerings;
- discrediting competitors based on untruthful or incorrect asseverations;
- identically copying a competitor's commercial features and undertakings when doing so will confuse consumers or taking advantage of the competitor's goodwill;
- appropriating a competitor's commercial, industrial or professional goodwill;
- violating a competitor's trade secrets, whether by breaching a confidentiality agreement or espionage;
- inducing workers, suppliers and clients to breach contracts they entered into with a competitor; and
- realising in the market a competitive advantage achieved through the infraction of a legal rule.

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

Dominant position is defined by Decree 2153 of 1992 as the possibility to either directly or indirectly determine market conditions.

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

Due to the broad definition of dominant position a patent holder will likely be found to be dominant due to the legal monopoly granted by the patent rights if the market has to be narrowly defined.

In the context of market definition, the possibility of substituting the patented product will play an important role on determining if the patent itself allows the patent holder to, directly or indirectly, determine market conditions. In any event, there will only be an antitrust violation if abuse of dominant position is proven.

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

Application for the grant of a patent itself will hardly expose the applicant to antitrust liability. Only if the application can be characterised

as unloyal competition (ie, misappropriation of trade secrets) would there be an antitrust liability.

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

In general terms, enforcement of a patent will not attach any antitrust liability. Only if the enforcement can be characterised as abusive of a dominant position or un-loyal competition, probably knowingly enforcing an invalid or illegal patent (realising in the market a competitive advantage achieved through the infraction of a legal rule), then it will expose the owner to antitrust liability.

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

If the strategies fall into one of the categories of anti-competitive acts, un-loyal competition or abuse of dominant position, the owner of the patent could be exposed to antitrust liabilities.

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

Yes. Law 256 of 1994 explicitly incorporated exclusivity agreements, with the objective or effect of blocking a competitor's accesses to the market or monopolising the distribution of goods or services, as violating the Colombian un-loyal competition regime.

Under the general abuse of dominant position regime, such agreements may fall under the obstructing or blocking the access to the market or the distribution channels category which attaches antitrust liabilities.

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

There are no industry-specific defences recognised by law.

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