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Alexander Ehlers

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GETTING THE DEAL THROUGH

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Contributing editor

Alexander Ehlers

Ehlers, Ehlers & Partner

Publisher
Gideon Roberton
gideon.roberton@lbresearch.com

Subscriptions
Sophie Pallier
subscriptions@gettingthedealthrough.com

Business development managers
George Ingledew
george.ingledew@lbresearch.com

Alan Lee
alan.lee@lbresearch.com

Dan White
dan.white@lbresearch.com

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Colombia

Carlos R Olarte, Andrés Rincón and Gina Arias
OlarteMoure

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

Health care in Colombia is part of the social security system. The Colombian Constitution does not establish health care as a fundamental right for all citizens. However, article 49 states that all citizens shall benefit from public health care, and therefore the social security system should regulate public health services and establish conditions to grant the whole population access.

The national government manages the health-care system through the Ministry of Health and Social Protection and the National Superintendency of Health. Recently, the government eliminated the Health Regulatory Committee through Decree 2560 of 2012, giving its functions to the Ministry of Health and Social Protection. Also active in the health-care system are health promotion entities (EPS), professional risk managers and health institutions.

The social security system is mostly regulated by Law 100 of 1993, which establishes the duty of equity in access to health services and a mandatory health insurance for every citizen. Originally, the system had two regimes to achieve this – one contributive and one subsidised. The contributive regime stated that every employer had to affiliate their employees to the health-care system, whereas through the subsidised regime, the national government would ensure that those without an employer or otherwise unable to contribute were affiliated. In 2008, however, the Constitutional Court declared this distinction illegal (see decision T-760, 2008) and stated that the national government should accomplish its duty through a single regime with equal conditions for the whole population. This decision, together with other endemic problems in Colombia's health-care system, triggered a structural change to the health system. On 19 January 2011, the Colombian Congress issued Law 1438, which, inter alia, unifies access to health services as of 1 July 2012.

Finally, there are two plans to grant patients in Colombia access to health care: the National Public Health Plan, which provides free programmes for the entire population to prevent diseases and promote health care through information systems; and the Mandatory Health Plan (POS), which covers essential medication and treatment for diseases. The latter was originally different for the contributive and subsidised regimes: affiliates of the contributive regime had full coverage, whereas affiliates of the subsidised regime had access to only half the coverage provided. As mentioned, since 1 July 2012 both regimes have the same benefits regarding the POS. To complement the POS, users may choose to voluntarily pay for an additional health plan.

Medical care for those who are not affiliated to any regime is supposed to be provided by public health institutions or by private entities that have contracts with the government to provide such services.

2 How is the health-care system financed in the outpatient and in-patient sectors?

The health-care system is financed by the national government for the attention of general diseases and non-occupational risks. The National Fund for Solidarity (FOSYGA) manages the resources designed for health care. The Ministry of Health and Social Protection mandates this fund to fulfil its obligation to distribute the portion of the budget assigned to the social security system. The resources are distributed to the following accounts:

- ECAT; this account covers the costs of caring for victims of traffic accidents and victims of catastrophic events or terrorism;
- the compensation account, which finances the contributive regime;
- the solidarity account, which raises the resources provided by all parties in the subsidised system; and
- the promotion account, which finances educational activities for health promotion and prevention of diseases.

Recently, the Health-care Reform Bill was approved on second hearing. The Bill introduces a new public entity, Salud Mia, which will act as a distribution centre for over US$30 billion of the government budget for annual health-care costs. Salud Mia will have administrative and budgetary autonomy, and its main purpose will be to collect and manage public resources into the health-care system (see the 'Update and trends' section).

Once the health-care reform enters into force, the future of the FOSYGA is uncertain given that Salud Mia will be created as a new public entity in charge of health-care system funds.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

Advertisement of medical products to the general public and health-care professionals is regulated by article 79 of Decree 677 (1995), providing a general rule according to which pharmaceutical products may only be advertised in scientific or technical publications addressed to professionals in the field, with the exception of over-the-counter medicaments that may be advertised through press, television or any other media following the parameters stated in Resolution 4320 (2004).

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The rules and principles for advertising aimed at health-care professionals relate to the nature of the information such advertising may include. Information must be complete, and include all of the actions, indications, therapeutic uses, contraindications, side effects and management risks of, and precautions and warnings about, the drug. In addition, the bibliography upon which the information is based must always be cited, and the active pharmaceutical ingredient (API) must always be identified by its generic name, which in the case of essential medicines must use the exact same letter size as the trade name.

5 What are the main rules and principles applying to advertising aimed at the general public?

Only over-the-counter medicaments can be advertised to the general public following the parameters stated in Resolution 4320 (2004). As to medical pharmaceutical products, over-the-counter medicaments require a marketing authorisation (MA), and the information provided must include appropriate guidelines for the final user, as well as impartial information about the product's benefits, indications and contradictions.

In addition, advertising material cannot use elements that attract the attention of children, and must always include the product's MA number, together with statements that the product is a drug, and that the user should read indications and contraindications, should not exceed the stated dosage and should consult a doctor in the event that symptoms persist.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

In practice, the most common violations of advertising rules relate to the circulation of international magazines that include prescription drug advertisements aimed at the general public. These sorts of advertisements are mostly found in pharmacies and health facilities.

There have been few cases of local manufacturers launching prescription medicaments with aggressive advertisements aimed at end-users containing indirect or hidden references to the product. Most of those campaigns are normally stopped either by the regulatory or unfair competition authorities.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Although there is no specific regulation regarding off-label use of medicaments, it is possible to infer from Decree 677 (1995) that providing information regarding off-label use to health-care professionals is forbidden, since drug advertisements cannot contain information or even suggestions about indications different from those approved in the MA.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the outpatient and in-patient sectors?

There is no specific statute governing collaboration between the pharmaceutical industry and health-care professionals. However, article 106 of Law 1438 (2011) specifically states that pharmaceutical companies are not allowed to provide any sort of privilege or gifts to any player in the health-care system, including health-care professionals and physicians.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

Apart from the general rules already mentioned in question 8, there are no specific rules or regulations developing the general prohibition outlined in article 106 of Law 1438 (2011).

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

Manufacturers are usually tempted to provide information about off-label use to health-care professionals. It is also common to find products with information about prescription medicaments that does not comply with the regulations in article 79 of Decree 677 (1995).

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There is no specific regulation regarding this matter. However, in practice the collaboration between pharmaceutical companies and patient organisations is based on research activities and general support of patient care. In addition, as a general principle, pharmaceutical companies should not encourage patient organisations to prescribe their medicaments.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Unlike the regulatory authorities, the competition authorities cannot pursue ex officio investigations of unfair competition acts related to pharmaceutical products. However, the pharmaceutical industry is very active in this regard, and it is relatively common for competition authorities to be asked to take action regarding conduct that may affect the market or the final consumer of a given product.

13 Is follow-on private antitrust litigation against manufacturers possible?

There is no legal norm specifically providing for follow-on private antitrust litigation. Affected third parties may bring an ordinary declaratory civil suit seeking damages caused by the proven anti-competitive behaviour. However, to our knowledge, there has been no follow-on litigation against manufacturers. Nevertheless, recent pricing pressures and enforcement of price control mechanisms (see the 'Update and trends' section) may make follow-on litigation more attractive in the future.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Collaboration between manufacturers of medical devices and health-care professionals and patient organisations, although not specifically provided for, should be governed by the general principle of article 106 of Law 1438.

In connection with the advertisement of medical devices, the National Institute for Food and Drug Regulation (INVIMA) verifies that any disclosure is made in accordance with the MA and with technical and legal standards. Class I medical devices can be advertised in mass media, but medical devices in classes IIa, IIb and III should be advertised only in scientific and technical magazines (notwithstanding that INVIMA may authorise advertising in other media). No prior authorisation from INVIMA is required for the advertisement of medical devices, unless permission to advertise moderate to high-risk medical devices (class I, IIa, IIb, and III) in mass media is requested. Usually INVIMA monitors medical devices advertising after it is launched. The advertisement is valid for the time the MA is in force.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The regulatory framework for granting MAs for medicaments is set out in Decree 677 (1995). This regulation, however, has undergone several amendments and modifications, including those in Decree 2227 (1996), Decree 2091 (1997), Decree 1792 (1998), Decree 822 (2003), Decree 2510 (2003), Decree 2888 (2005), Decree 426 (2009), Decree 2086 (2010) and Decree 1313 (2010).

Decree 4725 of 2005 regulates the procedure for obtaining MAs for medical devices in Colombia, and Decree 1782 (2014) for Biological/Biotechnological products. Resolution 1606 (2014) provides the technical guidelines for the submission of information in vaccine control.

This list of statutes includes regulations that might be summarised by the following principles:

- medicaments, pharmaceutical preparations based on natural resources, biological and biotechnological products, vaccines and medical devices require an MA from INVIMA, for their manufacture, trading, import, packing, processing and selling in Colombia;
- the above products must fulfil the technical and quality requirements established by INVIMA;
- marketing approvals are valid for a five-year term counted from the issuing of the registration, and may be renewed for the same period upon request of the interested party. The renewal application shall be filed at least three months before the expiration of the marketing approval, and will follow the same procedure as the first application;
- there are two types of pharmaceutical product according to Decree 677:
  - new medicaments: namely, those whose API has not been included in the Colombian Pharmacological Code, or whose API is already included, but is related to new associations, fixed dosages, new indications or new pharmaceutical forms; and
  - medicaments already included in the Colombian Pharmacological Code; and
- pharmaceutical and biological manufacturing facilities require an operating licence issued by INVIMA, after verification of GMP compliance.

16 Which authorities may grant marketing authorisation in your jurisdiction?

According to article 245 of Law 100 (1993), the competent authority for granting MAs for pharmaceuticals is INVIMA.

17 What are the relevant procedures?

An authorisation from INVIMA is required to obtain operating licences, MAs for new medicaments and MAs for medicaments included in the Colombian Pharmacological Code.

To obtain MAs for new medicaments, the applicant must first submit a pharmacological evaluation application.

The pharmacological evaluation estimates the safety and efficacy of the drug and is performed by the Medicaments Reviewing Committee, which takes into account the following features: efficacy, safety, dosage, indications, contraindications, warnings, toxicity, trading conditions and restrictions. In addition, article 27, paragraph 1 of Decree 677 provides an abbreviated procedure by which INVIMA can forgo conducting a pharmacological evaluation (safety and efficacy) of a product whenever such product is already approved in at least two reference countries and has not been rejected in any of the other reference countries.

Regarding biological and biotechnological products, a pharmacological evaluation must be performed even if the active ingredient (drug substance) is already included in the Colombian Pharmacological Code. This evaluation assesses the efficacy (indications, contraindications, interactions, precautions, warnings, pharmacokinetics, pharmacodynamics, dose, risk-to-benefit ratio) and safety (adverse effects, immunogenicity, trading conditions, special restrictions and risk-to-benefit ratio). Specific requisites for the submission of information for pharmacological evaluation are detailed in Decree 1782.

Once the pharmacological evaluation is approved, the new medicament is included in the Colombian Pharmacological Code (when not previously included, in the case of biologicals) and, subsequently, an MA application can be filed, which involves a pharmaceutical and a legal evaluation.

The pharmaceutical evaluation shall estimate the capabilities of the manufacturing process and the product's quality. The legal evaluation focuses on the legal documentation filed by the applicant, in compliance with the legal regulations governing this matter.

Finally, to obtain MAs for medicaments already included in the Pharmaceutical Code (this is not the case for biological products), only the MA application, involving the pharmaceutical and legal evaluation of the product, must be filed.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

According to article 93 of Decree 677, in order to protect the health of the community, an MA will elapse and cease to be valid if the pharmaceutical product has not been effectively marketed on the Colombian market for a continuous 24-month period.

An exception to this rule applies when the title-holder provides fully justified reasons for not complying with this obligation at least one month before the established deadline. In such case, INVIMA may set (one time only) a new term for the marketing of the product.

19 Which medicines may be marketed without authorisation?

As a general rule, all pharmaceutical products require market authorisation from INVIMA to be marketed in the Colombian territory. However, article 96 of Decree 677, amended by article 1 of Decree 822 of 2003, states that INVIMA may allow the import of pharmaceutical products without an MA in the following exceptional cases:

- when the Ministry of Health and Social Protection or INVIMA authorises a clinical trial of the product;
- when a health emergency is declared by the Ministry of Health and Social Protection; or
- when the Ministry of Health and Social Protection is obliged to provide a pharmaceutical product required by the Immunisation Programme to control diseases affecting the public health, and such product is unavailable on the domestic market.

Furthermore, Decree 481/2004 states that 'vital-unavailable' medicaments (those with low frequency of use and low returns) can be imported without an MA.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Named patient programmes – understood as the granting of access to a drug prior to its approval, under the specifications of an authorised healthcare professional, to a patient who has exhausted all alternative treatment options – are not provided for under the Colombian internal legislation. However, there has been at least one case where a patient was able to obtain access to a drug (that had marketing approval for a different use than the one requested) through a constitutional action for the protection of fundamental rights, by the fundamental right to life and health. The decision was opposed by the manufacturer of the product and by the Ministry of Health, but the court sustained the ruling.

On the other hand, Decree 481-2004 allows the importation of 'vital-unavailable' medicaments for an individual patient or a specific group of patients without requesting an MA, but restricts said benefit only for medicaments containing active ingredients (drug substances) already included in pharmacological codes and that are not under clinical research.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

According to Circular 04 of 2006, Colombia has two regimes related to the market price of a medicinal product. The first regime, regulated freedom, states that the pharmaceutical companies may establish a product's price if any of the following apply:

- there are public health considerations, such as in relation to cases of HIV and AIDS, tuberculosis, malaria and other epidemics, as well as circumstances of extreme urgency or national emergency;
- the drug has a concentration index Herfindahl-Hirshman(>0.45); and
- it is a new product with no substitutes.

The second regime is direct price control, which states that the unit price must not exceed the reference price (average of the three lowest prices in the reference countries). In practice, however, the Ministry of Health has regulated the direct price control regime through Decree 4474 (2012), Resolution 5529 (2010), Resolution 5 (2011), Resolution 1020 (2011), Resolution 1697 (2011), Resolution 3470 (2011) and Resolution 4316 (2011), which establish that most of the authorised medicaments in Colombia are ruled by the direct price control regime.

Circular 03 of 2013 (issued on 21 May 2013) establishes the methodology for the application of direct price control for medicaments marketed in the national territory. This methodology involves:

- defining the relevant market;
- determining the degree of market concentration;
- establishing the reference prices; and
- fixing the maximum retail price.

A product will be ruled by the direct price control regime if the relevant markets are highly concentrated and if the national referenced price is above the international referenced price. Holders of MAs for this type of medicaments must periodically report their sales, which are then published in the Medicaments Price Information System (SISMED).

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

Negotiation of drug prices between pharmaceutical manufacturers and public health-care providers is neither regulated nor prohibited in Colombia.

In practice, however, companies that tried in the past to negotiate with public health-care providers or the government were disadvantaged because their competitors (mostly national companies) demanded access to the information exchanged during the negotiation. Some officials of public health-care providers are now being investigated on suspicion of having acted illegally to favour research and development companies and avoid potential adverse effects of a price control.

23 In which circumstances will the national health insurance system reimburse the cost of medicines?

The EPS are obliged to organise and ensure the medicaments and treatments included in the POS to their users. The EPS transfer the payment of each user to the FOSYGA, and the FOSYGA returns to the EPS a capitation payment unit (UPC) for each affiliated person. The UPC should be equivalent to the actual value of the POS.

If any user requests the provision of a drug or medical service that is not provided by the POS, the EPS is entitled to charge the FOSYGA the value of that particular drug or treatment.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

According to article 245 of Law 100 of 1993, the National Committee for Pharmaceutical Prices is the competent authority to make decisions

Update and trends

Decree 1782/2014 (Decree), which was issued on 18 September 2014, establishes the procedures for the pharmacological and pharmaceutical evaluation of biological medicaments within the process for obtaining marketing authorisation to manufacture, import and commercialise said medicaments.

The Decree was particularly developed to promote free competition and a reduction in the price of these kinds of medicaments, whose high costs have been blamed for the financial breakdown of the health system.

The Decree fixes the regulations for the pharmacological evaluation of these medicaments, and for observing biological efficacy and safety, and establishes three routes for the submission of information for the pharmacological evaluation: the complete file route, comparability route and shortened comparability route. Although the Decree requires the submission of common information for all three routes (including immunological asessment) and indicates that the 'overall evidence and complexity of the molecule' will be considered, the shortened route has been widely criticised since it allows the easy registration of bio-similar products without clinical trials supporting their safety and efficacy in studies performed for a reference product (which is not identical) or on 'a group of medicaments containing a highly similar active ingredient'. The aforementioned extrapolations are not accepted by the regulatory agencies of high sanitary surveillance countries due to the uncertain health risks that might arise from the structural differences of biotechnological products and from their manufacturing process. Furthermore, the applicant is the one who chooses the route for information submission, with the inevitable result that most applicants forgo generating relevant clinical information about their products.

The Decree also establishes requisites of compliance with, inter alia, good manufacturing practices and pharmacovigilance and health surveillance.

Guidelines for immunogenicity assessment, risk management and stability will be issued within the next 12 months.

The Statutory Health Law (health-care reform bill), which has been awaiting presidential sanction since May 2014:

- etablishes health as an autonomous fundamental right, and establishes that the health system must be integral (that is, not only treating the disease, but also maintaining well being);
- eliminates authorisations for emergency room procedures;
- guarantees access to all persons to the medicines, services and technologies that they require to ensure their welfare: distance or low income cannot be an excuse for neglecting people in remote areas;
- maintains custody actions to safeguard access to health services;
- etablishes that the state must provide sufficient resources to ensure the financial sustainability of the health system over time;
- etablishes that the state shall regulate medicament prices throughout the commercialisation chain;
- etablishes that the health system should provide users with service networks that contain institutions and resources able to provide services in terms of opportunity, quality and efficiency; and
- revives the free doctor–patient relationship (medicaments and treatments prescribed by physicians and dentists cannot be changed, restricted or delayed by the EPS).

regarding the pricing and reimbursability of medical products. However, the government has historically issued the legal framework for price control; this is considered illegal by some sectors, which have promoted the annulment of Decree 4474 and its further resolutions implementing the system.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

There is no specific regulation that obligates either the manufacturers or the distributors of medicinal products to give a discount.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Colombia provides administrative and legal actions to prevent the counterfeiting and illegal distribution of medicines. With regard to administrative actions, any interested third party may file a complaint before INVIMA requesting the investigation of an illegal action, and INVIMA is authorised to impose the corresponding sanction.

In addition, Colombian law provides for criminal actions against those who counterfeit or illegally distribute medicines.

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Colombia has health-care information systems in both the public and the private sector, which unfortunately are not integrated. Government strategy to facilitate the public's access to information has been focused on implementing telemedicine and the Integrated System of Information for Social Protection (SISPRO). The Ministry of Health and Social Protection promotes SISPRO, whose purpose is to incorporate information related to the entire social security system.

SISPRO has different information systems, including SISMED, which incorporates the pricing information of prescription-only medicines for the general public. This information is provided by health promotion entities, health facilities and pharmacies.

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OLARTE MOURE & ASOCIADOS LTDA.

Carlos R Olarte **carlos.olarte@olartemoure.com**
Andrés Rincón **andres.rincon@olartemoure.com**
Gina Arias **gina.arias@olartemoure.com**

Carrera 5 No. 34-03
Bogota 110311
Colombia
Tel: +57 1 601 7700
Fax: +57 1 601 7799

Carrera 43A No. 1 Sur-31, Of 403
Medellín 050021
Colombia
Tel: + 57 4 266 0392
Fax: +57 4 266 0392

Carrera 51B No. 80-58, Of 1103
Barranquilla 080020
Colombia
Tel: +57 5 345 0193
Fax: +57 1 601 7799

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28 Outline major developments to the regime relating to safety monitoring of medicines.

INVIMA, through the National Pharmacovigilance Programme, promotes the safe use of medicaments by monitoring them after they are marketed. The Programme has two groups of parties: people (patients and health-care professionals, among others); and institutions (hospitals, health facilities, pharmaceutical companies, etc). The Programme allows INVIMA to gain knowledge of any adverse effects and other problems related to medicament use, helping to improve the health-care information system and to promote the safe and proper use of pharmaceutical products in Colombia. Resolution 2004009455 of 2004 establishes that the MA holders, manufacturers and health-care providers have an obligation to report periodically to INVIMA any adverse effect of the use of any drug or any alert issued by any other sanitary authority in the world. This information is consolidated in INVIMA's pharmacovigilance database and, when necessary, INVIMA can issue alerts about the safe use of medicaments commercialised in Colombia.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

The Broadening Immunisation Programme (PAI) contains the minimum vaccines and doses that the government considers a child must be immunised with before the age of five, and are provided free. The PAI covers tuberculosis (BCG), hepatitis B, diphtheria-pertussis-tetanus, haemophilus influenzae type b, oral rotavirus, oral polio, measles-rubella-mumps, pneumococcus, yellow fever, hepatitis A, adult diphtheria-tetanus toxoid and human papilloma virus (for girls aged 11 to 17 years).

Other vaccines, such as for chicken pox and a-cellular vaccines, that are not included in the PAI but are recommended by global vaccination schemes, are available in Colombia at different costs.

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