GETTING THE DEAL THROUGH

Life Sciences

in 25 jurisdictions worldwide

Contributing editor: Alexander Ehlers

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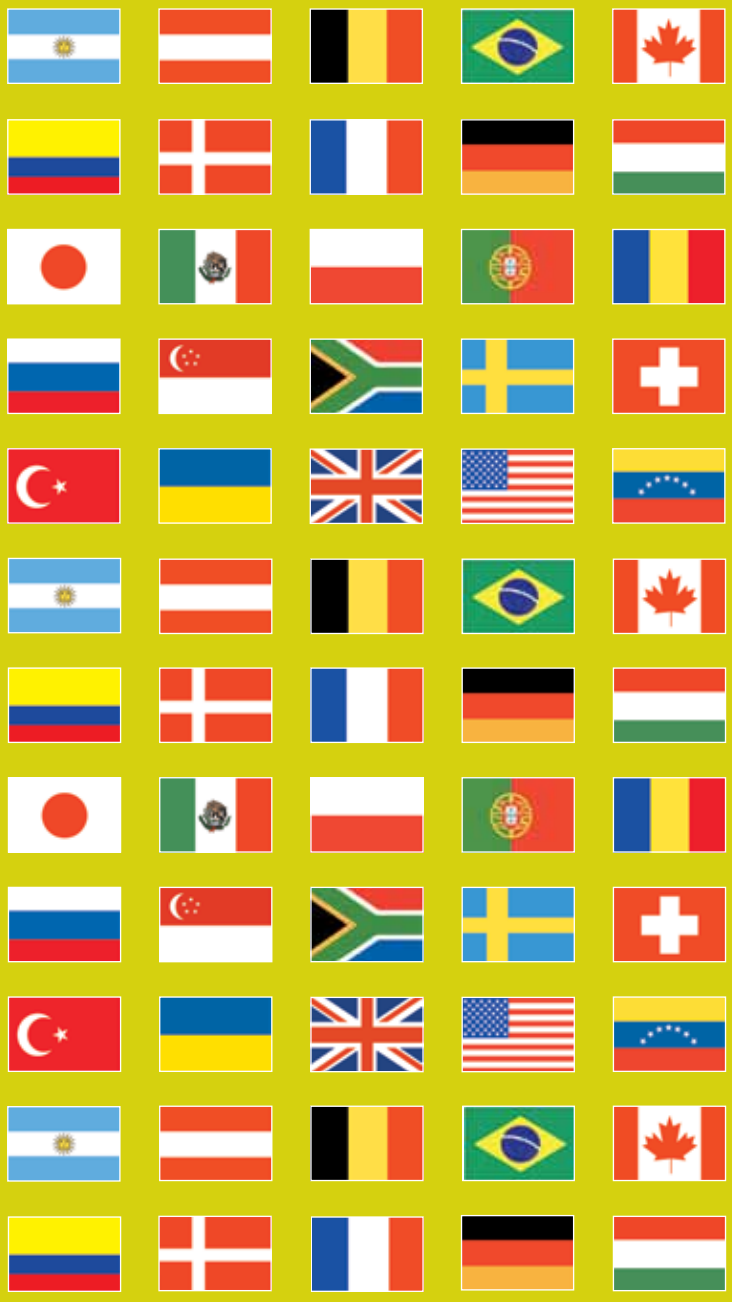

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Colombia

Carlos R Olarte, Andres Rincon and Liliana Galindo

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 the 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, the Health Regulatory Committee (CRES) and the National Superintendency of Health. Also active in the health-care system are the health promotion entities (EPS), the professional risk managers and the 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 workers with 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 among others 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 plan 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 half the coverage provided. As mentioned, since 1 July 2012 both regimes have the same benefits regarding the Mandatory Health Plan. To complement the Mandatory Health Plan, 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.

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 drugs 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, management risks, precautions and warnings of the drug. In addition, the bibliography upon which the information is based must always be cited, and the active principle 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 drugs can be advertised to the general public following the parameters stated in Resolution 4320 (2004). As for all medical pharmaceutical products, over-the-counter drugs require

market approval 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.

Also, publicity material cannot use elements that attract the attention of children, and must always include the product's market approval number, together with statements that the product is a drug, that the user should read indications and contraindications, not exceed the stated dosage, and consult a doctor in case 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 drugs 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 the 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 drugs, 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 different information from the information in the market approval.

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

There is no specific statute governing collaboration between the pharmaceutical industry and health-care professionals. However, article 136 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.

Other regulations such as Decree 2200 (2005) regulate the pharmaceutical service, and state that pharmaceutical companies may provide information about the proper use of the pharmaceutical products to non-medical staff. In addition, article 79 of Decree 677 (1995) states that pharmaceutical companies should not provide information on the trade name of the product to non-medical staff.

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 136 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 drugs 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 drugs.

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

Unlike the regulatory authorities, the competition authorities cannot pursue ex officio the investigation 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 '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?

Advertising of medical devices is not regulated in Colombia. However, 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 136 of Law 1438.

Pharmaceuticals regulation

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

The regulatory framework for product market approval is set out in Decree 677 (1995). This regulation, however, has undergone several amendments and modifications, including those in Decree 2227 (1996), Decree 341 (1997), 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). This list of statutes includes regulations that might be summarised by the following principles:

- drugs, including pharmaceutical preparations based on natural resources, require marketing approval from the National Institute for Food and Drug Regulation (INVIMA), for their production, trading, import, export, packing, processing and selling;
- pharmaceutical products must fulfil the technical and quality requirements established by the 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

Update and trends

Biosimilars

Colombia is not yet considering a specific legal regulation for market approval of biosimilars, understood as any non-innovator biotech pharmaceutical product.

The issue, however, has been on the government's radar since 2008, when the Colombian Health Authority (INVIMA) decided to grant market approval for a biosimilar for Etanercept. The approval was issued in less than 40 days and without performing a pharmacological evaluation of the product, which met with protest from the R&D industry and patient associations in general. Although INVIMA confirmed its decision to grant market approval for the product, its Medicament Review Committee (MRC) clarified that the grant did not imply interchangeability with the innovator product, stating that this is something that has to be decided by doctors when prescribing the drug according to the information provided by the manufacturers of each product. The MRC also recommended that INVIMA issue a directive creating internal procedures allowing for differentiation between innovator and biosimilar products.

While INVIMA has not yet issued this directive suggested by the MRC, it has informally adopted the practice of undertaking pharmacological evaluations for all biological products requesting market approval since 2008.

According to this practice, the MRC will request pre-clinical and clinical studies to certify the safety and efficacy of a given biological product. This practice has generated official actions from the MRC requesting a biosimilar applicant to provide relevant information on safety and efficacy of the products.

In most cases, the information has not been provided and the applications for market approval have been systematically rejected. INVIMA's current practice has been strongly opposed by the generic industry interested in marketing biosimilar products in Colombia.

Conscious of the importance and necessity of a specific pathway for biotech products in Colombia, and in the framework of a structural modification of the health system, on 19 January 2011 the Colombian congress issued Law 1438 in which article 89 ordered the Ministry of Health to issue a regulation for obtaining market authorisations for biotech products. Authorities were provided with a one-year term to implement this regulation. Although this regulation should have been in place since 19 January 2012, only drafts and projects of what this regulation should look like have circulated. By the time this chapter is published, a third draft of the regulation on biologics will have been published for comments, and most probably a final regulation will be issued for the beginning of 2013.

Price control

Annulment actions against the legality of Decree 4474 and its further regulation through resolutions have been filed before the Council of State, the highest administrative court in the country. On 8 October 2012, the Council of State decided to admit one of those nullity claims and issued a preliminary injunction against the Ministry of Health according to which Decree 4474 is to be suspended on the assumption it openly contradicts article 245 of Law 100 (1993), which assigns the responsibility for regulating prices of medicines to the National Committee for Pharmaceutical Prices (NCPP), making it the competent authority to make decisions regarding the pricing and reimbursabitity of medical products (see case 201100130).

The government is taking measures in order to avoid the collapse of the price control system, and it is expected to have new regulations issued by the NCPP in the near future, most probably before the end of 2012.

the marketing approval, and will follow the same procedure of the first application;

- there are two types of pharmaceutical product according to Decree 677: (i) new drugs, namely, those whose active ingredient has not been included in the Colombian Pharmacological Code, or whose active ingredient is already included, but is related to new associations, fixed dosages, new indications or new pharmaceutical forms; and (ii) drugs already included in the Colombian Pharmacological Code; and
- drug-manufacturing facilities require an operating licence issued by the INVIMA.

16 Which authorities may grant marketing authorisation in your jurisdiction?

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

17 What are the relevant procedures?

Authorisation from INVIMA is required to obtain an operating licence, market approval for new drugs; and market approval for drugs included within the Colombian Pharmacological Code.

To obtain market approval for new drugs, the applicant must submit a pharmacological, pharmaceutical and a legal evaluation of the product. The legal evaluation contains all the legal documentation filed by the applicant, in compliance with the legal regulations governing this matter.

A request for pharmaceutical evaluation shall be made to INVIMA, which shall estimate the capabilities of the manufacturing process and the product's quality. The pharmacological evaluation estimates the safety and efficacy of the drug. The pharmacological evaluation shall be issued by INVIMA through the pharmaceutical review committee, and will take into account the following features: efficacy, safety, dosage, indications, contraindications, warnings, toxicity, and commercialisation terms and restrictions. Also, 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.

Finally, to obtain market authorisation for drugs included in the pharmaceutical code, the applicant must only submit a pharmaceutical evaluation and a legal evaluation of the product.

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, a marketing authorisation 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 a case, INVIMA may set 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 in order 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 a market authorisation in the following exception cases:

- when the Ministry of Health and Social Protection or INVIMA authorised 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 in the domestic market.

20 Are any kinds of named patient (or similar expanded access) 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 health-care professional, to a patient who has exhausted all alternative treatment options – is not provided by the Colombian internal legislation. However, there is 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, citing their fundamental right to life and to health. The decision was opposed by the manufacturer of the product and by the Ministry of Health, but the court sustained the ruling.

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. First, regulated freedom, which 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/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 exceed the reference price (average of the three lowest prices in the reference countries). Yet in practice, 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 drugs in Colombia are ruled by the direct price control regime.

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. However, in practice 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 multinational 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 health promotion entities (EPS) have the obligation to organise and ensure the provision of the mandatory health plan (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 person affiliated. 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 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 (NCPP) is the competent authority to make decisions 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.

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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?

In order to prevent the counterfeiting and illegal distribution of medicines, the Colombian jurisdiction provides administrative and legal actions. 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 divisions. One of them is the Information System of Drug Prices, which incorporates the price information of prescription-only medicines for the general public. This information is provided by the health promotion entities, health facilities and pharmacies.

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

INVIMA, through the National Pharmacovigilance Programme, promotes the safe use of drugs 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).

This programme allows INVIMA to know the adverse effects and other problems related to drug use, helping to improve the health-care information system and to promote the safe and proper use of pharmaceutical products in Colombia.

Article 3 of Resolution 2004009455 of 2004 establishes that the pharmaceutical companies and the health-care providers have the obligation to report any adverse effect of the use of any drug.

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