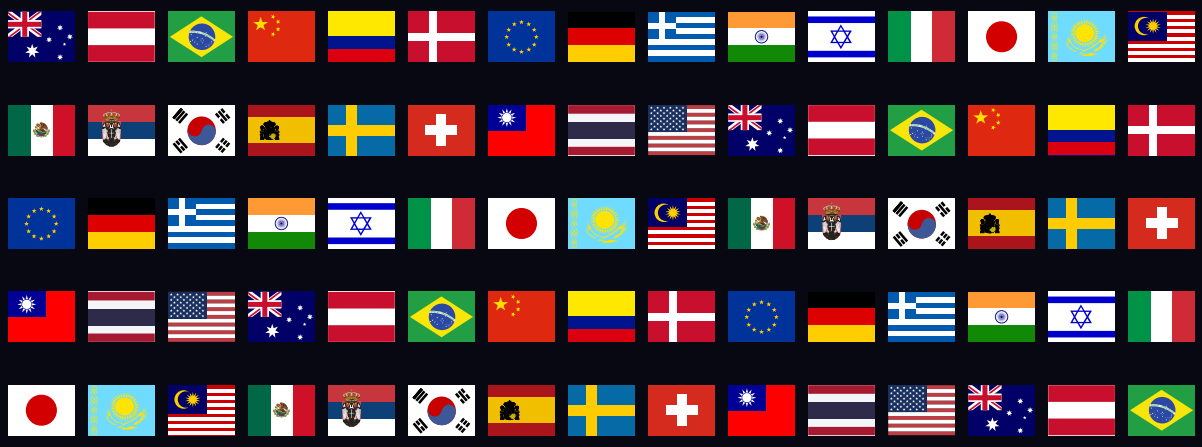
PHARMA & MEDICAL DEVICE REGULATION

Colombia



LEXOLOGY
Getting The Deal Through

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Pharma & Medical Device Regulation

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DLA Piper

Quick reference guide enabling side-by-side comparison of local insights, including into the regulatory framework; clinical practice; marketing authorisation; amending authorisations; recall; promotion; enforcement of advertising rules; pricing and reimbursement; off-label use and unlicensed products; sale and supply; and recent trends.

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REGULATORY FRAMEWORK

Competent authorities for authorisation

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The National Food and Drug Surveillance Institute (INVIMA) is the competent authority for granting marketing authorisation for medical devices, medicinal products, cosmetics and dietary products, and for the surveillance of manufacturing facilities by issuing good laboratory practices and good manufacturing practice certification. INVIMA also has the administrative authority to investigate and punish violations of sanitary rules, examine over-the-counter drug advertising, and control prescription drug advertising.

Products monitored by INVIMA are classified according to the definitions provided by regulatory law. For example, 'medical devices' are defined as any instrument, apparatus, machine, software, biomedical equipment or other similar or related articles, whether used alone or in combination, including components, parts, accessories and software necessary for proper application, proposed by the manufacturer for use on human beings for:

- the diagnosis, prevention, monitoring, treatment or alleviation of disease;
- the diagnosis, prevention, monitoring, treatment, alleviation or compensation for an injury or disability;
- the investigation, replacement, modification or support of the anatomical structure or physiological process;
- the diagnosis of pregnancy and conception control;
- care during pregnancy, birth or thereafter (including care of newborns); and
- the disinfection or sterilisation of medical devices.

Medical devices must comply with the provisions of Decree 4725 of 2005. This decree defines the criteria and procedures for the classification, registration and marketing of medical devices in the country. It also sets out the quality, safety and efficacy requirements that products must meet in order to obtain the necessary approval for sale and post-marketing liabilities.

Medicines are defined in Colombian legislation as pharmaceutical preparations containing active pharmaceutical ingredients, with or without excipients, in a determined pharmaceutical dosage form, employed for the relief, diagnosis, treatment, cure or rehabilitation of an illness. Packaging, labels and containers are integral components of medicines since they warrant their quality, stability and appropriate use. The classification and approval process for medicinal products is governed by Decree 677 of 1995, whose latest amendments are contained in Decrees 843 of 2016 and 334 of 2022. These regulations establish the guidelines for marketing approvals, renewals and amendments.

Cosmetic products are defined in Colombian legislation as any substance or formulation of local application to be used in various surface parts of the human body (eg, epidermis, hair, capillary system, nails, lips, external genital organs, the teeth or oral mucous membranes) in order to clean, perfume, modify appearances, protect or keep them in good condition, and prevent or correct body odours. Andean Decision 833 of 26 November 2018 is the regulation that applies to cosmetic products. Decision 833 attempts to harmonise domestic legislation on cosmetic products of Andean Community member countries (ie, Colombia, Ecuador, Peru and Bolivia).

'Dietary supplements' are defined as products, the purpose of which is to supplement a normal diet and are a concentrated source of nutrients and other substances with physiological or nutritional effects that may contain vitamins, minerals, proteins, amino acids, other nutrients and nutrient derivatives, plants, plant concentrates and plant extracts, alone or in combination. Dietary supplements are regulated by Decrees No. 3249 of 2006 and 3863 of 2008, which define the requirements and procedures for the classification, manufacture, registration and marketing of dietary

supplements in the country.

Law stated - 26 September 2023

Approval framework

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

Law stated - 26 September 2023

CLINICAL PRACTICE

Applicable rules

What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Resolution No. 13437 of 1991 regulates hospital ethics committees and adopts the Decalogue of Patients' Rights. This rule defines the confirmation process for committee members, their functions and some operating mechanisms, including the obligation of sending the minutes of their meetings to the Ministry of Health and Social Protection.

Resolution 3823 of 1997 defines the rules for regulating scientific development activities in the health sector.

Resolution No. 2378 of 2008 adopts good clinical practices for institutes that undertake medical research with pharmaceutical candidate compounds in humans.

Institutions conducting clinical trials must also comply with the following rules.

Resolution No. 3100 of 2019, and its amendments Resolutions 2215 of 2020, 1317 of 2021, 1138 of 2022 and 544 of 2023 , which define the procedures and conditions for the registration of health service providers and the authorisation of health services.

Decree No. 2200 of 2005 , incorporated within Decree 780 of 2016, the Sole Regulatory Decree of the Health Sector, which regulates the activities and processes of the pharmaceutical service, including the technical sanitary regulation for the supply of medicines and medical devices, as well as activities related to the supply chain of health technologies.

Resolution No. 1403 of 2007, which determines the management model of the pharmaceutical service, and adopts the Manual of Essential Conditions and Procedures as well as other provisions.

Resolution No. 444 of 2008 , which adopts the Instrument for Verification of Compliance with Good Elaboration Practices for Compounding Pharmacies and Subsequent Guidelines for Compounding Pharmacies Manufacturing Cannabis Formulas (2019).

Decree No. 351 of 2014 , incorporated within Decree 780 of 2016, regulates the comprehensive management of waste generated in healthcare.

Resolution No. 839 of 2017 establishes the standards for the management of clinical histories.

Law No. 2015 of 2020 creates the interoperable electronic medical record and directs other provisions.

Resolution No. 2011020764 of 2011 establishes the regulation on the content and periodicity of adverse event reports in the phase of clinical research of drugs in humans, which deals with article 146 of Decree No. 677 of 1995.

Resolution No. 8430 of 1993 establishes the scientific, technical and administrative standards for clinical trials of medical devices. The essential aspects are that an ethics committee must comply with include elements that ensure

the fulfilment of its responsibility to society as well as the fundamental rights of the participating subjects. The rules for ethics committee approval are provided in the Technical Annex, which is an integral part of Resolution No. 2378 of 2008.

The National Food and Drug Surveillance Institute (INVIMA) is responsible for evaluating the clinical research protocols that are carried out in Colombia, monitoring the investigation and issuing good manufacturing practices certificates to healthcare provider institutions (IPS) that carry out clinical investigations.

For clinical trials of medications in humans, the party must request approval from INVIMA. This evaluation is performed by a specific department, named the Clinical Research Group. The requirements for requesting evaluation are contained in the Guide for the Presentation of Research Protocols and include the following:

- an approval letter issued by an INVIMA-registered research ethics committee;
- approval from a local health authority confirming that the investigation centre is suited to providing health services;
- a good manufacturing practice certificate issued by INVIMA (valid for five years);
- an insurance policy to cover third-party damages (to cover possible adverse events associated with or attributable to the clinical trial);
- a robust research protocol (including the operation methodology, theoretic framework, justification, results from analysis plan and patient data management); and
- consent and insurance.

Clinical trials of medical devices must be approved first by the ethical committee of the research site (ie, the IPS) where the trial will be conducted and subsequently by the INVIMA Medical Devices Reviewing Commission. The requirements for requesting evaluation are contained in the Presentation Format and Evaluation Protocols for Medical Clinic Research and Other Technologies guidelines and include:

- approval from a local health authority confirming that the investigation centre is suited to providing health services;
- a letter of application for approval of the research protocol;
- problem formulation;
- research summary;
- theoretical framework;
- medical device information and safety tests;
- details of hypothesis, objectives and methodology;
- ethical considerations;
- project management details; and
- bibliographic references (Vancouver standards).

During the health emergency generated by the covid-19 pandemic, the Ministry of Health issued Resolution No. 730 of 2020 and External Circular No. 1000–174–20 of 2020 , which contain flexible requirements, measures and actions applicable to the development of clinical trials for covid-19 therapies. In addition, new technologies such as telemedicine, electronic consent, home visits, electronic medical records, electronic signatures and online procedures were implemented for the first time in Colombia.

On 30 June 2022, the health emergency generated by the covid-19 pandemic came to an end. As a result, these measures were repealed.

Law stated - 26 September 2023

Reporting requirements

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

Law stated - 26 September 2023

Consent and insurance

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

Resolution No. 8430 of 1993 establishes that informed consent obligations include providing clinical trial subjects with information on:

- investigation objectives;
- procedures that will be used;
- inconveniences and expected risks;
- benefits that may be obtained; and
- alternative procedures that could be advantageous for the research subject.

Also, clinical trial subjects must:

- receive answers to any questions and doubts;
- be free to withdraw consent and to stop participating in the study;
- have patient confidentiality;
- be provided with updated information obtained during the study;
- be given medical treatment if any injuries arise as a result of the investigation; and
- be reimbursed for any additional expenses.

According to Resolution No. 2378 of 2008, to safeguard the fundamental rights of research subjects, civil liability insurance must be put in place. The insured value should be determined according to international standards. If the insurance does not completely cover the damages, the promoter, clinical trial investigator or the head of the institution or centre in which the trial was carried out are jointly and severally liable.

Statutory Law No. 1581 of 2012 related to personal data protection may also apply.

Law stated - 26 September 2023

MARKETING AUTHORISATION

Time frame

How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

Medicinal products

New medicinal products must go through the complete registration process. The process involves three parallel assessments:

- a pharmacological evaluation, which involves a safety and efficacy assessment carried out by the Medicines Reviewing Commission (MRC) and, if successful, allows the product to be included in the Colombian Pharmacological Code;
- a pharmaceutical evaluation, including chemistry, manufacturing and controls assessments; and
- a legal evaluation.

Pharmacological and pharmaceutical evaluations are performed by the Medicines Directorate.

Once all three assessments have been performed, a session of the specialised chamber of the MRC will take place where a consolidated decision is to be taken and then a resolution granting or denying the marketing authorisation is issued.

The National Food and Drug Surveillance Institute (INVIMA) takes approximately six to 10 months to grant a marketing authorisation through a fast-track proceeding, which involves a visit to the local manufacturing facility.

Conventional and unified proceedings to obtain a marketing authorisation (ie, 2020 marketing authorisation applications) may take from 12 to 24 months.

Generic versions of products included in the Pharmacological Code will only need the pharmaceutical and legal assessment to obtain a marketing authorisation. Marketing authorisations are valid for five years.

The official fee for a new marketing authorisation for chemical synthesis medicines is between 11,607,991 to 18,683,673 Colombian pesos and between 12,518,853 to 79,575,025 pesos for biological products.

Medical devices

Marketing authorisations for low-risk (Classes I and IIa) medical devices are issued automatically (within a maximum of one week). Marketing authorisations for high-risk medical devices (Classes IIb and III) were extended to 300 days in 2019. Products that have not obtained a marketing authorisation in other countries or whose risk classification is not clear may have to request a prior evaluation from the Medical Devices Reviewing Commission.

Marketing authorisation is valid for 10 years. The corresponding fee is approximately 4 million Colombian pesos.

To mitigate the effects of the health emergency caused by the covid-19 pandemic, in 2020, the government defined a group of medical devices considered vital and unavailable that could be temporarily imported or marketed without the need for marketing authorisation under the supervision of INVIMA. As the health emergency ended on 30 June 2022, this flexibility is not currently maintained.

Law stated - 26 September 2023

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

There is a term of protection for pharmaceutical patents for 20 years counted from the date of filing the patent application. To maintain this validity, annuities must be paid for years in advance, the expiration of which is taken into account from the last day of the month in which the application was submitted. The patent validity does not necessarily coincide with the marketing authorisation stage as the patent is usually requested in the early stages of the

development process and takes years to be granted. Therefore, in practice, the pending patent term when a drug is approved for marketing in Colombia lasts for approximately three to seven years.

On the other hand, Decree No. 2085 of 2002 regulates aspects of medicines related to the protection of the regulatory information provided to obtain health registration regarding new chemical entities.

Subject to this provision, nothing shall prevent summary approval procedures from being carried out on the basis of bioequivalence or bioavailability studies.

Law stated - 26 September 2023

Protecting research data

What protections or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

Decree No. 2085 of 2002 provides for regulatory test data protection for a five-year exclusivity term from the grant of the marketing authorisation. In practice, this prevents generic applicants from receiving such an authorisation during this term. Subsequent modifications, label extensions, paediatric indications or new pharmaceutical forms are not subject to additional protection.

According to Decree No. 2085 of 2002 and INVIMA Circular No. DG 005-03 of 2003 , which regulate regulatory data protection in Colombia, the requirements for obtaining data exclusivity are:

- protection must be expressly requested;
- the active principle has not been included in the Colombian Pharmacological Code;
- undisclosed data supporting the safety and efficacy of the new drug contained within the dossier must be declared; and
- the considerable effort made by the originator to obtain the undisclosed information must be declared and demonstrated.

Since 2002, test data protection has been automatic and relatively straightforward to obtain, and INVIMA's practice was to automatically and summarily reject generic marketing authorisation applications for products still covered by the test data protection term. However, since 2018, INVIMA's practice has reflected cracks in the system, signalling that, in certain situations, effective test data protection is at risk.

Law stated - 26 September 2023

Freedom of information

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

The information provided within a marketing authorisation application, specifically the pharmacological dossier, is not public. Although a third party is allowed to file a freedom of information application, the authority may and will only provide general information regarding the filing date and the applicant. No research data will be provided by INVIMA.

Law stated - 26 September 2023

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

Chemically synthesised medicines

For marketing authorisation approval, Decree No. 677 of 1995 requires, among other items:

- a certificate of pharmaceutical product from the healthcare authority of the country of origin;
- a good manufacturing practice certificate from a reference country or issued by INVIMA;
- stability studies performed at Zone IVB (see Resolution No. 3157 of 2018); and
- technical information in common technical document format.

The marketing authorisation is valid for five years.

Phytotherapeutic medicines

For the manufacture, production, import, export, processing, packaging and sale of phytotherapeutic medicines, a health registration must be issued by INVIMA. Decree No. 1156 of 2018 contains the dispositions approval of phytotherapeutic medicines (including traditional medicines).

Plant or plant combination must be included within the list of approved medicinal plants otherwise a prior evaluation to assess the safety and efficacy of the phytotherapeutic medicine will be needed.

- a certificate from the healthcare authority of the country of origin demonstrating that the product is freely commercialised;
- a good manufacturing practice certificate from INVIMA or from the country of origin; and
- technical information in a common technical document format.

The marketing authorisation is valid for 10 years and may be renewed.

Homoeopathic medicines

For marketing authorisation approval, Decree No. 3554 of 2004 and Decree No. 1861 of 2006 require, among other items:

- homeopathic good manufacturing practice certificates or similar;
- marketing authorisation from the country of origin;
- a free sales certificate; and
- details of product composition according to a valid homoeopathic pharmacopoeia.

The validity of a homoeopathic registration is 10 years and is renewable for periods of the same length.

Biological medicines

Decree 1782 of 2014 contains requirements for obtaining marketing authorisation approval, which include requirements for:

- the active pharmaceutical ingredient and the finished product;
- stabilities;
- chemistry, manufacturing and controls information;
- cold chain validations; and
- legal documents, such as good manufacturing practice certificates issued by a reference country or INVIMA and certificates of pharmaceutical product.

Safety, efficacy and immunological data are also required. Resolution No. 2950 of 2019 contains the Guide for the Evaluation of the Comparability of Biological Medicines, which states that a complete characterisation and a quality comparison build the basis for a possible data reduction or exemption in non-clinical and clinical development.

The marketing authorisation is valid for five years and is renewable for periods of the same length.

Dietary supplements

For marketing authorisation approval, Decrees No. 3249 of 2006 and 3863 of 2008 require, among others:

- components approved for their use in dietary supplements for Colombia;
- good manufacturing practice certificates;
- free sales certificates; and
- stability studies for those with a shelf life longer than two years.

The validity of this registration lasts for 10 years and is renewable for periods of the same length.

Law stated - 26 September 2023

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

There are currently no incentives or rewards that are applicable for application, approval and distribution in the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars.

Law stated - 26 September 2023

Post-marketing surveillance of safety

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

To ensure the ongoing safety and efficacy of medicinal products after marketing authorisation has been granted, Colombian legislation provides a reporting procedure concerning adverse events and any other quality issues relating

to the use of drugs. In this regard, INVIMA requires marketing authorisation holders or pharmaceutical product manufacturers to report adverse events and quality issues. This is to acknowledge the medication profile in such a way that the pre-existing factors are identified in time.

Resolution No. 2004009455 , issued by INVIMA on 28 May 2004, specifies the requirements and frequency with which pharmacological reports must be created under Decree No. 677 of 1995, article 146. Under this regulation, the marketing authorisation holder or the pharmaceutical product manufacturer must adopt a pharmacovigilance programme to ensure the creation of periodic reports on the safety and efficacy of the medicinal product. The reports must be submitted according to the following considerations:

- any serious and unexpected adverse event must be reported within 72 hours of its knowledge under the pharmacovigilance programme; and
- any non-serious or unexpected adverse event must be reported within the last five working days of each two-month period.

An 'adverse event' is defined in the resolution as an undesired medical event that occurs during treatment with a medicinal product. The occurrence of such an event does not need to have a causal relationship with the medical treatment or product.

Resolution No. 4816 of 2008 regulates the national techno-surveillance programme for medical devices. The reports of adverse events or incidents occurring during the use of a medical device must be submitted according to the following considerations:

- any serious and unexpected adverse event must be reported within 72 hours of its knowledge under the techno-surveillance programme; and
- any non-serious or unexpected adverse event must be reported within eight working days after each three-month period.

Medical devices imported or commercialised as vital and unavailable, although being temporarily exempt from marketing authorisation, must comply with techno-surveillance requirements.

Law stated - 26 September 2023

Other authorisations

What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

Medicinal products

Manufacturers must comply with good manufacturing practices and provide a certificate issued by the competent authority from the country of origin or otherwise request INVIMA to issue one. Such certificates from the following countries are accepted by INVIMA:

- the United States;
- Canada;

- Switzerland;
- the United Kingdom;
- Germany;
- France;
- Denmark;
- Japan;
- the Netherlands;
- Norway;
- Sweden;
- South Korea; and
- Australia.

Good manufacturing practice certificates from countries that have signed mutual recognition agreements with the above countries are also accepted under Decree No. 335 of 2022.

Manufacturers located in different countries must request a visit from INVIMA to certify good manufacturing practices. Local manufacturers must also be certified by INVIMA. Importers, distributors and wholesalers must comply with dispositions on the storage and handling of medicines contained in Decree No. 2200 of 2005 (contained in Decree 780 of 2016) and Resolution No. 1403 of 2007.

The applicable fee to obtain such a certificate from INVIMA depends on the location of the manufacturing facility, whether the product to be manufactured is a biologic and whether the facility also manufactures the active pharmaceutical ingredient. The fees range from between 29,468,476 to 181,794,107 Colombian pesos.

Medical devices

Foreign manufacturers are not obliged to provide a good manufacturing practice certificate, but it is expected they comply with all conditions guaranteeing the quality of medical devices (ie, International Organization for Standardization's ISO 13485).

There are no regulations on such certificates for local manufacturers of medical devices. These local manufacturers must comply with the technical sanitary conditions for medical devices that are applicable to their specific products. These conditions can be taken from Decree No. 1030 of 2007, and Resolutions No. 4396 of 2008, 2968 of 2015 and 4002 of 2007 (ISO 13485 is also taken as a reference). Importers of medical devices must obtain a certificate of storage and conditioning capacity (CCAA) issued by INVIMA.

In addition, wholesalers and distributors must comply with provisions on the storage and handling of medicines and medical devices contained in Decree No. 2200 of 2005 (contained in Decree No. 780 of 2016) and Resolution No. 1403 of 2007.

Importers of medical devices declared as vital and unavailable (for example, during the covid-19 healthcare emergency) do not have to obtain a CCAA for medical devices and biomedical equipment.

Law stated - 26 September 2023

Sanctions

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

The Ministry of Health and Social Protection, INVIMA, and the sectional and district health departments have sanctioning authority over marketing authorisation holders of medicines or medical devices for failing to comply with the requirements established in law for the commercialisation of these products. These entities will sanction marketing authorisation holders through mechanisms such as sanitary safety measures that consist of preventing the commercialisation of a product while its safety is re-evaluated. Manufacturers that fail to comply with the technical regulations can also be sanctioned.

Sanctions provided by the law include reprimands, the imposition of fines, confiscation of products, cancellation of the marketing authorisation and the applicable licence, and temporary or permanent closure of the establishment. Regarding criminal sanctions, if a potential crime is identified in the sanctioning process, the authority must inform the Attorney General's Office.

Law stated - 26 September 2023

Exemptions

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

In general, there is no medicinal product exempt from the requirement to obtain marketing authorisation. It is a mandatory requirement for all medicinal products regardless of their components or manufacturing method to comply with the requirements of Decree No. 677 of 1995. However, compounding formulas (phytotherapeutic, homeopathic or medicinal products for an individual patient) do not require marketing authorisation. They must be manufactured in pharmacies and certified for good manufacturing practices by INVIMA (by pharmacists).

Decree No. 481 of 2004 states that vital unavailable medicines (VUMs) (eg, named-patient supply) do not require marketing authorisation. However, their safety and efficacy must be proved through other special requirements.

Certain medical devices do not require marketing authorisations. The Ministry of Health and INVIMA have included tailor-made orthopaedic, dental and traumatological products in this exemption.

In response to the emergency caused by covid-19, INVIMA declared the most widely used drugs and medical devices for covid-19 treatment to be VUMs to strengthen supply and ensure adequate care for patients suffering complications associated with the disease. This provision implies that these products can be marketed in Colombia without the need to obtain marketing authorisation (Resolutions No. 520 and 522 of 2020, and others substituting or updating them). These measures ceased to apply on 30 June 2022 when the state of national emergency came to an end.

Law stated - 26 September 2023

Parallel trade

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

From a strictly intellectual property perspective, parallel imports are permitted in Colombia. Andean Decision No. 486 of 2000 , article 54, establishes international exhaustion of rights once the product has been introduced into the flow of commerce of 'any country' by the owner, or another person authorised by the right holder or with economic ties to that patent owner. Two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent or when a third party is able to exert that influence over both persons.

However, in practice, parallel imports for pharmaceutical products are practically non-existent because of regulatory requirements that prevent a potential parallel importer from obtaining marketing authorisation for the patent holder's product (see Decree No. 677 of 1995). Although this regulatory barrier was modified by Decree No. 1313 of 2010 , which authorises parallel imports for pharmaceutical products without authorisation from the manufacturer (normally the patent holder), it is not usually applied owing to the absence of supporting regulation aimed at reducing counterfeit, contraband and quality risks that may derive from its application. Nevertheless, Decree No. 1313 of 2010 was clearly aimed at promoting price reductions.

Law stated - 26 September 2023

AMENDING AUTHORISATIONS

Variation

What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Regulations on post-grant amendments to marketing authorisation are contained in Decrees No. 677 of 1995, 3454 of 2004 , 1782 of 2014, 843 of 2016, and 334.

Decree No. 334 of 2022 (amended by Decrees 1036 of 2022 and 322 of 2023) was issued to adapt local provisions to match international standards. This decree will be entirely in force after the issuance of specific guidelines on quality, safety and efficacy-related modifications, which is expected to be published by the end of 2023, and after an update on the regulations on advertisement is released, which is expected to happen in January 2024.

Law stated - 26 September 2023

Renewal

What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

Decree 843 of 2016 and Decree No. 334 of 2022 contain provisions for the renewal of marketing authorisations for chemical synthesis medicines, biologicals and homoeopathic gases, which will be filed automatically by the National Food and Drug Surveillance Institute (INVIMA). Decree 843 will continue to be applicable until Decree No. 334 enters into force. Renewals of marketing authorisations of biological medicines granted under Decree No. 1782 of 2014 may also be automatic.

The application for automatic renewal must be submitted to INVIMA no less than one month in advance of the expiration date of the health registration. If the application is filed outside of this term, the marketing authorisation holder must proceed to a new request for health registration.

Law stated - 26 September 2023

Transfer

How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

Transfers of marketing authorisations for medicinal products or medical devices may be requested only by the marketing authorisation holder and require:

- an assignment contract signed by the assignor (former marketing authorisation holder) and the assignee (new marketing authorisation holder);
- a certificate of incorporation of the former and new marketing authorisation holders;
- an authorisation issued by the manufacturer to the assignor to perform the assignment; and
- the payment of a fee of approximately 800,000 Colombian pesos by the marketing authorisation holder.

This procedure approximately takes between 20 and 30 business days.

Law stated - 26 September 2023

RECALL

Defective and unsafe products

What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

Any medicinal consumer can submit a complaint directly to the manufacturer, importer or marketing authorisation holder, depending on the individual circumstance. Local good manufacturing practices require that the company responsible for the product in Colombia has a quality management system in place to handle product complaints properly and to manage a recall, if necessary.

In addition, consumers can submit product complaints to the National Food and Drug Surveillance Institute (INVIMA), which will then decide whether to conduct a surveillance inspection and take any corresponding actions.

Also, upon receiving any indication (from the marketing authorisation holder or from another source) that the product has been altered, is fraudulent, or presents a failure of quality, performance or safety, INVIMA may decide to perform a joint analysis (with the marketing authorisation holder and other involved authorities) and advise whether a recall is necessary. Alternatively, if there is an imminent risk to health, INVIMA may immediately publish a health alert on its website informing the health maintenance organisations and consumers of the prohibition against marketing the products, and, when appropriate, that a recall is ongoing. The manufacturer or marketing authorisation holder may also directly advise their clients of the situation.

Law stated - 26 September 2023

ADVERTISING AND PROMOTION

Regulation

Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

The advertising and promotion of medical products are regulated by Decree No. 677 of 1995, article 79, which sets out the general rule that prescription medicinal products may be advertised only at scientific or technical events, or in publications addressed to healthcare professionals, and must be consistent with the regulatory information approved by the marketing authorisation holder, particularly regarding indications. The direct promotion of prescription-only medicinal products to patients is prohibited under Colombian legislation, which includes online advertising. When non-advertising information about a prescription medicine is to be provided on the marketing authorisation holder's website, measures are to be taken to avoid information being accessed by patients (Decree No. 334 of 2022, article 13, which will be entirely in force as of January 2024).

In connection with the advertising of over-the-counter medicines, there are mandatory parameters contained in Resolution No. 4320 of 2004 that must be observed (eg, details of the nature of the medicine, indications, mechanism of action, therapeutic uses, contraindications, side effect risk management, precautions and warnings of drug dependence). Promotional information must be balanced and the benefits of the product must not be overstated. Resolution 4320 is currently being reviewed and new dispositions are expected to be issued by the end of 2023 or in early 2024.

Marketing authorisation holders are directly responsible for complying with the obligations and prohibitions stated under Decree No. 677 of 1995, article 79, and under Resolution No. 4320 of 2004. Failure to comply with these obligations can lead to the suspension or cancellation of the marketing authorisation.

In addition, in 2016 and 2019, the Association of Pharmaceutical Research and Development Laboratories and the Pharmaceutical Chamber of the National Business Association of Colombia published their codes of ethics containing guidelines concerning business conduct, promotional and educational activities, and the relationship between the pharmaceutical industry and all relevant actors of the Colombian health system. Self-regulation and the codes bind the pharmaceutical companies that have subscribed to the association agreements.

The advertising and promotion of medical devices are regulated under Decree No. 4725 of 2005, article 58, which states that promotional scientific information of medical devices must be consistent with the approved information contained within the marketing authorisation, as well as aligned with the scientific evidence available for the product. The benefits cannot be overstated.

This regulation distinguishes between three different types of medical devices depending on their profile risk to human health, in terms of efficacy and security as well as their uses. Categories are determined in Classes I, II and III, with Class I having the lowest level of risk and Class III having the highest level of risk. Class I medical devices may be advertised on mass media (eg, online advertising), taking into account the terms and conditions approved by means of the marketing authorisation. Medical devices and biomedical equipment in Classes IIa, IIb and III, intended for exclusive use by health professionals or prescribed by them, may only be advertised in scientific or technical publications. Notwithstanding the foregoing, the health authority may authorise other means of advertising.

Finally, the National Business Association of Colombia (ANDI) and its Chamber for Medical Devices, which clusters domestic and international manufacturers, importers and suppliers of medical devices, issued its Code of Ethics and Transparency (CET) in 2015, aimed at governing the interactions between medical device companies and healthcare professions as well as organisations that operate, distribute and use medical devices. The CET also sets principles and guidelines on advertising said devices before healthcare professionals and the public, when available. The last update of the CET made by the ANDI Chamber for Medical Devices includes:

- a prohibition against directly sponsoring healthcare professionals to attend academic events;
- measures to improve transparency by means of the creation of an external ethics tribunal to investigate violations of self-regulation; and
- the requirement to publish said cases.

The promotion of the products of the industry must be ethical, precise and duly supported. In this sense, clinical trials, scientific research and sponsored clinical studies must be transparent and pursue scientific, not promotional, purposes. In this regard, in the case of market research that is carried out by pharmaceutical companies, it is prohibited to use the information collected as advertising data or promotional material. Additionally, such data cannot be used in such a way as to be misleading because they appear to have origins in scientific studies.

Among other regulations related to promotion and advertising, the CET establishes that all information material for drug promotion must indicate who sponsors or finances it and when it refers to published studies, it must be faithfully reproduced or offer a clear reference that facilitates its access. Pharmaceutical companies must have clear and written

policies for the approval processes of promotional materials and activities. In this sense, each pharmaceutical company will be responsible for:

- scientific endorsement of the content, materials and promotional activities related to their products;
- procedures for obtaining, printing, disseminating and appropriate use of scientific references; and
- the surveillance, control and harmony of the information to prescribe, current and approved by the competent authority in Colombia.

Decree No. 334 of 2022, which will be entirely in force in January 2024 states that any advertising and promotion are to be consistent with the conditions approved in the health registration. Article 10 specifies that the information and advertising of chemically synthesized medicines, medicinal gases, biological, homoeopathic and phytotherapeutic products sold under prescription may only be made in publications whose distribution is restricted and directed exclusively to professionals in medicine and dentistry. Additionally, it is prohibited to provide information, advertising and promotion of prescription medication in mass media and mass dissemination through digital platforms, instant messaging applications and social media.

However, with respect to information and advertising on chemically synthesised, biological, homeopathic and phytotherapeutic over-the-counter drugs, Decree No. 334 of 2022, article 12, specifies that this must be done in compliance with the regulations issued by the Ministry of Health and Social Protection (eg, Decree No. 4320 of 2004, which is currently under review). The holders, importers and manufacturers of these products shall inform the National Food and Drug Surveillance Institute (INVIMA) in advance about the advertising pieces and communication media to be used. This publicity will not require prior approval by the Ministry of Health.

Law stated - 26 September 2023

Inducement

What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

Law No. 1438 of 2011 , article 106, and Law No. 1474 of 2011 , article 133, specifically state that pharmaceutical and medical device companies are not allowed to provide any sort of privilege or gift, in money or in kind, to any player in the healthcare system, including healthcare professionals. Those who infringe on this norm may be sanctioned with fines of up to 1.16 billion Colombian pesos.

Law stated - 26 September 2023

Reporting transfers of value

What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

According to Resolution No. 2881 of 2018 , the companies that market medicines or medical devices (ie, transfers of value that are delivered to actors in the health sector) that can be placed into the following categories must be registered:

- Natural persons who:
  - prescribe services, pharmaceutical products or health technologies;
  - work or provide services in a public or private institution in the health sector;

- are in charge of purchasing pharmaceutical products and health technologies;
- lead and teach courses, programmes or professional careers related to health issues, in universities or other types of teaching or research entities; or
- work or provide services covering health issues in any medium.

- Legal persons, constituted as:
  - organisations of professionals in the health sector;
  - scientific, medical or union societies or associations;
  - professional associations in the health area;
  - educational institutions;
  - patient or caregiver organisations;
  - non-governmental organisations, foundations, associations and corporations that participate, directly or indirectly, in the supply or reception of health services;
  - entities administering benefit plans and health service providers; and
  - forms of media that cover topics related to health.

Transfers of value in Colombia are defined as the delivery of goods or services to the aforementioned health sector actors, in forms such as:

- the delivery or payment of food or drinks;
- the payment of trips, transportation or per diem;
- the financing of clinical studies and health research;
- the financing of education programmes or scholarships;
- the financing of holding events, workshops, seminars or conferences;
- the financing of publications or subscriptions to educational material;
- the financing of patient programmes;
- the delivery of articles of medical utility;
- the delivery of promotional material;
- the delivery of medical samples; and
- the payment of fees for service provision contracts.

In addition, it is mandatory to make a report to the Ministry of Health when the sum of the deliveries, in any modality or quantity, to a single recipient exceeds the amount of 1 million Colombian pesos during a six-month period. In that case, the report must include all goods or services delivered.

Law stated - 26 September 2023

Enforcers

Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

In the first instance, INVIMA is in charge of any surveillance and control of a scientific and technical nature. INVIMA works for the protection of the individual and collective health of Colombians through the application of health regulations associated with the consumption and use of food, medicines, medical devices and other products subject to health surveillance. This institute was created by Law No. 100 of 1993 .

Additionally, INVIMA is the entity in charge of initiating a sanctioning process in cases that prove an alleged infraction or violation of the health regime according to article 577 of Law No. 9 of 1979 (modified by Decree No. 2106 of 2019 , article 98) Finally, although health regulations contain the preferably applicable norms, the Consumer Protection Regulation contained in Law No. 1480 of 2011 , article 61, could also apply and the Superintendence of Industry and Commerce will be in charge of investigating breaches to the Consumer Law.

In terms of self-regulation, pharmaceutical companies operating in Colombia are mainly affiliated with two entities: the ANDI's Pharmaceutical Chamber and the Association of Pharmaceutical Research Laboratories. These companies have issued codes of ethics that seek to collect good practices of conduct regarding the interactions of companies with actors in the health sector and, particularly, set forth what they consider should be allowed in the field of drug promotion.

Thus, promotional information must be clear, legible, exact, balanced, honest and complete so as to allow the recipient to form his or her own opinion about the therapeutic value of the drug in question. It must be based on an updated evaluation of all relevant and clearly reflected evidence. It should not be confused by distortion, exaggeration, undue emphasis or omission, or in any other way. Any ambiguity should be avoided by all means. Absolute statements such as 'unique' or 'none' should only be used when they are adequately supported by science.

Law stated - 26 September 2023

Sanctions

What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

In the event of a breach of the provisions of any applicable laws, an administrative proceeding will be followed to determine the circumstances of the breach.

Initially, through a health and safety measure, INVIMA may order the suspension of the advertisement violating the norm. If damage had already been caused, according to the administrative proceedings, manufacturers, importers and distributors may be subject to sanctions such as reprimands, fines of up to 386,666,666 Colombian pesos, confiscation of products, suspension or cancellation of marketing authorisation or licences, and temporary or permanent closure of the premises, constructions or services concerned (Law No. 9 of 1979).

Law stated - 26 September 2023

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

According to Decree No. 677 of 1995, article 79, which sets out that any promotion of medicines must be consistent with the regulatory information approved by the marketing authorisation (particularly regarding indications), off-label promotion is not permitted.

Additionally, in accordance with Decree No. 334 of 2022, article 11, information regarding indications, therapeutic uses, contraindications, collateral effects, administration risks, drug dependence risks, and other precautions and warnings must be provided to the prescriber. Off-label prescription cannot be induced by the supplying laboratory, to the extent that it must be the medical staff who autonomously make the decision to prescribe the medication or not outside of the approved indication.

Additionally, the self-regulatory codes issued by the National Business Association of Colombia's Pharmaceutical Chamber and the Association of Pharmaceutical Research Laboratories prohibit the promotion of off-label drugs directed at health professionals, taking into account that they require prior approval by the National Food and Drug Surveillance Institute (INVIMA), which means that the drug must have a health registration. Therefore, health professionals may prescribe such a medication only in exceptional cases.

Law stated - 26 September 2023

Unlicensed products

What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

Vital unavailable medicines (VUMs) can be imported or manufactured without a licence (ie, a marketing authorisation issued by the healthcare authority). These are mostly prescribed to patients suffering from orphan diseases recognised in Colombia that are listed within Resolution No. 023 of 2023 or correspond to medicines not commercialised in Colombia.

Decree No. 481 of 2004 allows the importation and manufacture of VUMs for an individual patient, a specific group of patients or in a clinical emergency without the need for prior marketing authorisation, thus allowing for faster market entry, provided that the following conditions are met:

- the active pharmaceutical ingredient has already proven its safety and efficacy in other countries, and is not under clinical research;
- the drug is not being marketed or is in insufficient supply in the country; and
- there is no therapeutic substitute for the drug.

For an individual patient, INVIMA requests:

- a medical prescription, fulfilling requirements found in Decree No. 2200 of 2005, article 17, which was entirely included in Decree No. 780 of 2016, article 2.5.3.10.16, duly signed by the treating physician and including his or her professional registration number;
- an application containing the name of the patient and identification, justifying the need for the treatment;
- a summary of the clinical record; and
- payment of the official fee (tariff code 4002–24).

The authorisation to import a VUM for an individual patient may take from eight to 15 working days.

For a clinical emergency, INVIMA requests an application explaining the urgency, preferably providing the clinical information (as complete as possible) and payment of the official fee. The VUM import authorisation for emergency cases is issued within three to four working days.

According to Decree No. 481 of 2004, the Medicines Review Commission (MRC) at INVIMA may authorise the importation of a VUM for groups of patients. The application must contain:

- a justification of the quantities of the VUM needed – this import will be authorised for a maximum of three to six months of treatment and documentation supporting the number of patients is helpful;
- a certificate of incorporation of the entity requesting the import authorisation;
- a World Health Organization certificate for the pharmaceutical product; and

- a certificate of analysis.

This authorisation may take from 15 days to two months to be issued. However, during the VUM import application assessment, the MRC may require the applicant to apply for pharmacological evaluation first, which may take up to four months.

VUMs and supplies for treating the covid-19 pandemic were subject to a special proceeding whereby these products were exempt from the marketing authorisation requirement (Resolution No. 385 of 2020 modified by Resolution No. 844 of 2020, Resolution No. 522 of 28 March 2020, and subsequent related regulations).

Law stated - 26 September 2023

Compassionate use

What rules apply to the establishment of compassionate use programmes for unlicensed products?

Decree No. 481 of 2014 allows the importation and manufacture of VUMs (including orphan medications for rare diseases or for clinical emergencies, the use of which may include compassionate use) for an individual patient, a specific group of patients or in a clinical emergency without the need for a prior granted marketing authorisation, thus allowing for faster market entry, provided that the following conditions are met:

- the active pharmaceutical ingredient has already proven its safety and efficacy in other countries, and is not under clinical research;
- the drug is not being marketed or is in insufficient supply in the country; and
- there is no therapeutic substitute for the drug.

Medicines under clinical research cannot be used to treat patients in Colombia (unless they are deployed within an approved clinical trial in the territory). The review of Decree No. 481 of 2014 was included in the Ministry of Health's regulatory agenda a few years ago, but no specific date for publication has been given.

Law stated - 26 September 2023

SALE AND SUPPLY

Regulation

Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

Decree No. 780 of 2016 , which incorporated Decree No. 2200 of 2005 and Resolution No. 1403 of 2007, contains regulations for appropriate storage, handling and supply requirements for medicines and medical devices that any pharmaceutical facility should meet.

Prescription medicines can be sold only in pharmaceutical facilities (ie, pharmacies and drug wholesalers). Over-the-counter medicines may also be sold in supermarkets provided that the establishment complies with the minimum requirements for guaranteeing the quality of the medicinal products.

Importers of medical devices must obtain a certificate of storage and conditioning capacity for medical devices.

Law stated - 26 September 2023

Online supply

What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

Law stated - 26 September 2023

Pricing and reimbursement

What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

According to Law No. 1571 of 2015 , the Ministry of Health and Social Protection has the responsibility, among other things, to maintain a financially sustainable national pharmaceutical policy that includes medicine price controls (for monopolistic or high-cost medicines), unified benefits plans (collective protection plus individual protection), benefits plan exclusions, health technology assessment for the entry into the Colombian market (front door assessment) and centralised purchasing.

Through Decree No. 705 of 2016 , the Ministry of Health delegated the pricing of medicinal products to the National Pricing Commission for Medicinal Products and Medical Devices (NPCMPMD). The NPCMPMD has structured different methodologies for the calculation of the maximum sales value of high-cost products, including the direct control regime, and for the reimbursement of those products not included in the benefits plan. The NPCMPMD also monitors medicinal product prices reported to the Drug Price Information System by marketing authorisation holders, medicine sellers and buyers. In general, there are two regimes for the price control of medicines:

- surveilled freedom, which allows sellers to determine the price of their product, but said prices must be periodically reported and are monitored by the NPCMPMD; and
- the government direct control regime, which includes most high-cost medicines and the government sets a maximum sales price.

Maximum prices for medicines under direct control are most commonly determined based on international comparisons (international price referencing (PRI)). However, there are some medicines within direct control whose price is determined by other methodologies not based on PRI. PRI is mandatory and applies to institutional and trade channels.

Other medicines without PRI but that were the subject of reimbursement in the past had a maximum reimbursement value (VMR) calculated by the government. Although not mandatory (for invoicing), this value is the maximum value that could be reimbursed by the Administrator of Resources of the General System of Social Security in Health (ADRES) or that is considered for maximum capped fee calculations.

Medicines within the benefits plan (collective protection) are covered by a per capita unit, which is transferred from the ADRES to each health maintenance organisation (HMO) per affiliate. Medicines not covered by the capitation payment unit (UPC) were previously reimbursed by the ADRES at a VMR but, as of 1 March 2020, they are paid with a maximum capped fee (paid in advance to each HMO, according to historic reimbursements for therapies not covered by the mentioned UPC). New regulations also established how HMOs should manage said capped values (for technologies

considered individual protections, see, for example, Resolutions No. 2481 of 2020, 243 of 2019, 205 of 2020, 206 of 2020, 2152 of 2020, and 586 of 2021).

The Ministry of Health also has the faculty to establish mechanisms to undertake centralised negotiations and to directly purchase medicines, supplies and devices. The first regulation for centralised purchasing is Resolution No. 1962 of 2017 , which establishes the criteria, distribution and supply of medicines for chronic hepatitis C. This practice is likely to be extended to other high-cost medicines.

In addition, a cost-benefit evaluation performed by the Institute of Technology Assessment in Health (IETS) will assign a therapeutic value category to new technologies. The price will depend on health outcomes and a set comparator (ie, standard of care). Circular 016 of 2023 of the National Committee for Medicines Prices defines the methodology the National Commission on Drug and Medical Device Prices establishes the maximum selling price of new medicines in the country, which in turn depends on the therapeutic value category established by IETS. This methodology will start to apply as soon as a resolution regulating the conditions and terms for the pricing procedure for new medicines is issued and enters into force.

In 2022, the National Committee for Medicines Prices, for the first time, was given the power to control prices for vital unavailable medicines in Circulars No. 11 and 12 of 2022.

Law stated - 26 September 2023

UPDATE AND TRENDS

Forthcoming legislation and regulation

Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

Legislation

The Front Door Regulation (cost-benefit assessment for price suggestion against a comparator) has already been issued. However, this regulation is not yet in force because of ongoing administrative proceedings. The government issued Resolution No. 2152 of 2020 , by means of which a technology assessment was determined for new chemical entities that are not included in the maximum capped fee for technologies and are not covered by the universal product code.

Draft regulations for the amendment of Decree No. 677 of 1995, which regulates the marketing authorisation proceeding for medicines, are currently under review by the government and interested stakeholders. Different workshops will be held during the coming months to discuss, among other things, relevant proposals that could impact the procedure and its timeline (eg, recognition of high surveillance approvals to expedite evaluations and automatic renewals), and the processes for pharmacological evaluation.

An amendment to Decree No. 481 of 2004 has been on the agenda of the Ministry of Health and Social Protection since 2018. However, no draft has been disclosed to the public yet.

A comprehensive care model for people with a diagnosis of an orphan disease was proposed in 2018 through Resolution No. 651 of 2018 . However, its implementation is still ongoing. In addition, Resolution No. 205 of 2020 , amended by Resolution No. 586 of 2021 , establishes that the Ministry of Health must identify in detail the people who are being treated with a diagnosis of orphan diseases and the drugs used in multidisciplinary treatment. It also guarantees the financing of the medicines defined by the Ministry of Health that are required by patients who are diagnosed for the first time with an orphan disease.

On 16 June 2021, Bill No. 372 of 2020 (the Pharmaceutical Safety Law) was approved during a first debate. The

Pharmaceutical Safety Law seeks to prevent and control pharmaceutical product shortages in Colombia.

A draft decree on anatomic components, organ transplants, human component donations and marketing authorisation for products (medical devices) based on human components was issued in June 2022.

Finally, a draft circular has been issued by the National Commission for Medicines containing the methodology for determining the price, based on therapeutic value, of new drugs and therapies.

A resolution regulating the conditions and terms for the pricing procedure for new medicines is to be issued to determine the entry into force of Circular 016 of 2023.

Guidelines determining the entry into force of Decree 334 (ie, the guidelines to determine the type of quality and safety and efficacy amendments) are expected to be published in the third quarter of 2023.

Amendments to Resolution 4320 of 2004 are expected by the first quarter of 2024.

Intellectual property litigation

Colombian procedural law provides ample opportunities for discovery through pre-litigation discovery motions for site inspections, document production (including confidential information) and depositions. In 2021, the Judicial Division of the Superintendence of Industry and Commerce (SIC) granted at least eight preliminary discovery motions (PDMs) where a pharmaceutical company that requested the exhibition of documents related to marketing authorisations applications for a global exchange company that may be infringing pharma patents. These PDMs related to secondary patents such as formulation patents, salt patents and process patents for obtaining active pharmaceutical ingredients.

These PDMs allow innovators to disclose certain data under suspicion of infringement, which becomes particularly important for secondary patents where obtaining evidence of infringement may be difficult. For a judge to admit PDMs in patent infringement cases, it is important to highlight a possible trigger of imminence of infringement for the judge, such as a shipment importation of the active pharmaceutical ingredient contained in the patent or a marketing authorisation application filed for a product that may be infringing the innovator's patent.

The SIC, where the Colombia Patent Office resides, has become the principal venue for patent infringement matters and, regarding PDMs, it usually takes the SIC from one to three months to admit and collect the requested evidence.

Global exchange companies have reacted to these motions by indicating that the information required is a trade secret. One such company has filed an unfair competition action. Therefore, if a global exchange company chooses to use this procedural tool, it must expressly indicate the purpose and the subsequent action for which this evidence may be collected.

As a result of these PDMs, some of the companies have confirmed non-infringement situations and one case is pending a decision of injunctive relief.

Judicial decision regarding cease-and-desist letters

In 2022, the SIC rejected the claims of a generic company against an innovator, arguing that sending letters requesting evidence of non-infringement constituted unfair competitive behaviour. The generic company intended to prevent the innovator from sending letters requesting evidence related to the pharmacological dossier filed by the generic for a product containing a compound potentially covered by the patent.

The SIC indicated that sending notice letters to any party in the market is not, in and of itself, an act of unfair competition. On the contrary, the patent owner has the legitimate right to use and can avail itself of all discovery mechanisms that are available in Colombia to ensure compliance, even when such inquiries concern confidential documentation. The decision was affirmed on appeal.

Compulsory licensing

In June 2023 and by means of Resolution 881, the administrative procedure of declaration of public interest (DPI) was initiated for patents of medicines that have the active pharmaceutical ingredient dolutegravir. The DPI procedure is the first, and a pivotal, step towards the issuance of a compulsory licence.

During the term established for this DPI procedure, those holding patents and interested third parties submitted comments and the Association of Pharmaceutical Research and Development Laboratories (AFIDRO) requested the resolution be revoked.

On 18 August 2023, the Interinstitutional Technical Committee (ITC), led by the Ministry of Health, rejected the revocation request and ordered the evidence for the procedure to be submitted. On 5 September, the ITC issued its final report, recommending that the Ministry of Health declare a DPI to create compulsory licences for two Colombian patents for dolutegravir.

The ITC's recommendation was based on an increasing number of HIV/Aids cases in Colombia has created a need to provide dolutegravir to specific populations to prevent the disease from having a greater impact in the country. The ITC also indicated that it was very difficult to obtain licences from dolutegravir's patent holders under terms that would allow the government to handle the HIV/Aids situation. However, the ITC's recommendation does not include or provide evidence of problems accessing medicines covered by these patents in Colombia.

The parties involved had until 19 September 2023 to submit comments on the ITC's recommendation. Subsequently, the Ministry of Health will analyse the ITC's recommendation and any submitted comments, before issuing a Resolution on whether a declaration of public interest should be issued to create the compulsory licences. If the Ministry of Health declares there is a public interest in these patents, the patent holders may be able to protect their patent rights through administrative proceedings and legal actions, such as annulment actions or non-compliance actions, at the Andean Community level.

Ethics and compliance

In External Circular No. 2022151000000053–5 of 2022 , the National Superintendency of Health stated it required supervised entities to implement transparency and business ethics programmes (PTEEs) to prevent corruption and promote legality, responsibility and integrity in the management of public health resources.

The circular establishes that health promotion entities, prepaid medicine companies, prepaid ambulance companies, generators and collectors of health resources, and health service providers must adopt PTEEs that establish policies, principles and values for their employees to follow in their roles, ensuring good governance. Additionally, PTEEs must include measures to prevent and mitigate the risks of corruption and bribery and define the principles and values that each entity must consider in order to carry out ethical, transparent and honest operations.

Consequently, supervised entities must take appropriate actions against individuals who violate the entity's PTEE including administrators, associates and employees. Furthermore, the entity must ensure its PTEE is communicated and disclosed to employees, associates, contractors and the general public.

In Press Release 067 of 2023, the National Superintendency of Health mandated that health service providers must complete a self-assessment survey on the implementation of PTEEs and other risk management systems. Additionally, health service providers are required to formulate work plans to address any identified unfulfilled requirements. This survey enabled the Superintendence to request supporting evidence regarding the implementation of PTEEs and risk management systems and for the imposition of penalties for non-compliance.

Law stated - 26 September 2023

Jurisdictions

Australia	Clayton Utz
Austria	Preslmayr Attorneys at Law
Brazil	Kasznar Leonardos
China	East & Concord Partners
Colombia	OlarteMoure
Denmark	Accura Advokatpartnerselskab
European Union	DLA Piper
Germany	Ehlers Ehlers & Partner
Greece	PotamitisVekris
India	ANA Law Group
Israel	Pearl Cohen Zedek Latzer Baratz
Italy	Avvocati Associati Franzosi Dal Negro Setti
Japan	Atsumi & Sakai
Kazakhstan	Baker McKenzie
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
Serbia	BDK Advokati
South Korea	Lee & Ko
Spain	Faus Moliner
Sweden	Advokatfirman Hammarskiöld
Switzerland	Wenger Vieli Ltd
Taiwan	Formosa Transnational Attorneys at Law
Thailand	Baker McKenzie
USA	DLA Piper