COUNTRY COMPARATIVE GUIDES 2024

The Legal 500 Country Comparative Guides

Colombia

LIFE SCIENCES

Contributor

Dentons Cárdenas & Cárdenas

Luz Helena Adarve

Partner for Life Science and Intellectual Property | luz.adarve@dentons.com

Mónica Bonnett

Partner for Life Science and Intellectual Property | monica.bonnett@dentons.com

This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Colombia.

For a full list of jurisdictional Q&As visit **legal500.com/guides**

COLOMBIA
LIFE SCIENCES

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

Colombia has an extensive and complete legal framework for medicinal products, biologicals, medical devices, food and food supplements. The rules for each of these products have the following structure: scope of the rule, definition of general terms that are in the rule, requisites for the filing of the health registration application, time frame of the prosecution, prosecution process, advertisement, health security measures and sanctioning process. Most of the rules application depend on the Health Regulatory Authority INVIMA practice. The following are the rules for each of the mentioned products:

Medicinal Products:	Decree 677 of 1995 general rule for health registrations for chemical sinthesys products and biologicals Decree 334 of 2022 modifies Decree 677 of 1995 regarding renewals, amendments, and no commercialization of medicaments. Decree 1474 of 2023, medicaments amendments and undefined life term. Decree 426 of 2009 Decree 1782 of 2014 biological products pharmacological evaluations. Decree 335 of 2022 Good Manufacturing Practice Certificates.
Medical devices	Decree 4725 of 2005 Health sanitary registrations requisites and applications, commercialization, amendments and renewals. Decree 582 of 2017, modifies Decree 4725 regarding automatic amendments.
Food	Resolution 2674 of 2013 Health sanitary registrations and applications, commercialization, amendments and renewals Decree 810 of 2021 (labeling) Decree 2492 of 2022 (labeling) Resolution 254 of 2023 (labeling).
Food supplements	Decree 3249 of 2006 Decreto 3863 of 2008

It is important to mention that the Ministry of Health issued Decree 1474 of September 8th, 2023, according to which there were some amendments regarding the important aspects of medicaments health registrations, the pharmaceutical industry duties when a medicament is taken out from the market and the health registration for medicaments filing and prosecution. Right now, in Colombia, the life term of a medicament health registration is undefined. For those medicaments which already had health registration at the moment the new rule was issued, its life term will be undefined under which the health registration was approved are maintained. Also, with this new rule the inspection, vigilance and control of the medicament made by the Health Regulatory Authority (INVIMA) is expected to be increased considering that the health registration of a medicament does not have a renewal. Thus, this is the way INVIMA would assure that the product complies with the regulatory rules.

Regarding the medicaments that are going to be taken out from the market, after the six-month period granted by INVIMA, “the holder of the health registration will request the loss of enforceable force of the administrative act that granted the health registration and/or its renewal, or will report the continuity of marketing of the corresponding product”. If the health registration holder does not carry out this procedure, either to block the marketing of his or her drug, or to request continuity, INVIMA will proceed to cancel the health registration.

The intentions of not marketing the product temporarily must also be notified to INVIMA, within a period of no more than 30 calendar days following the situation of the incident that requires non-marketing.

According to the decree, this is done “in order to carry out a risk analysis, which allows minimizing the negative impacts of cases due to the impact or temporary interruption of the marketing of the products subject to this decree and generate a timely and efficient response to avoid a possible market shortage.”

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

R&D of medicinal products has a robust legal frame, which main purpose is to protect humans in these activities. R&D activity has to follow Resolution 00840 of 1993, which establishes: (i) the duty of having an Ethic Committee for the investigation in humans, who will be in charge to solve any issue regarding ethic aspects of the investigation in humans; (ii) the classification of the clinical studies according to the risk; (iii) defines the informed consent which has to be signed by the patient who will participate in the clinical study, (iv) describes the requisites which have to be complied in the clinical study, (v) establishes the conditions of this sort of studies for communities, minors, pregnant women, disables, etc; (vi) defines the pharmacological investigations and the biosecurity of the researches and the cases in which said investigations can be developed in Colombia. There are other important rules which regulate that medicaments investigation projects should be evaluated by INVIMA (Colombian Health Regulatory authority) (Resolution 3823 of 1997) and Good Clinical Practices that must be observed by the institutions who carry out investigation in humans. Resolution 2378 of 2008 establishes the need of the Certification of Conditions under the qualification of the Unique System for investigations in humans that apply when medicaments are used. The Research Centers should comply with the procedures and conditions of inscription of health providers (Resolution 2300 of 2014).

Once the investigation stage is done, next step is the marketing authorization that in Colombia starts with the filing of the application and is followed by a series of verification authorities of quality and harmlessness conditions, the tracking of health effects and the development of intervention actions in the production chain. This, to guarantee the control and tracking of the products in order to minimize any risk in human health. Health Registrations for medicaments have the following cathegories: (i) Chemical Synthesis and biological, (ii) Phitotheraputics and Homepathics. If there is a condition such as a new chemical entity or new ingredients/elements in the medicament, before applying for the approval of the health registration it must me necessary to obtain the opinion and approval of said new chemical entity/element issued by INVIMA Medicaments Revision Room (“Sala Revisora especializada en Medicamentos”). Once said Room issues its approval, the health registration process can start. Health registration process for medicaments is made up of: (i) Filing of the application; (ii) issuance of an action indicating any technical or legal questions or doubt that INVIMA´s examiner may have, (iii) resolution granting or denying the health registration. Against the decision issued by INVIMA rejecting the granting of the health registrations there is the possibility to file a reinstatement action and reconsideration appeal. The term to obtain a health registration in Colombia could take at least a year and a half. Right now, in Colombia, Health Registrations for medicaments do not have to be renewed as they are granted undefined.

INVIMA is very active in vigilance after a health registration for a medicament is granted. Moreover, right now, after issuance of Decree 1474 of 2023, as health registrations for medicaments are granted indefinitely. Thus, INVIMA considers that this circumstance makes more important to increase vigilance over medicaments in the Colombian market. Vigilance is made up of systematic activities to verify the quality and harmlessness conditions, the tracking of the effects of medicaments over the population health. INVIMA has an internal organism called GURI which is in charge to check in the market the labels of the medicaments, the advertisement and the social networks, and also, they can make a visit to a manufacturing facility to check if the conditions under which the health registration was granted is being complied. If GURI detects the infringement of a sanitary rule, they will pass a report to the Sanitary Responsibility Unit of INVIMA, who would issue a health security measure which purpose is to stop the infringement of a rule. In any case, after a health security measure is issued, INVIMA could decide to open a sanctioning process.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

Food supplements in Colombia are considered high risk food health registrations. Thus, in the practice, INVIMA tends to have the same standard as the medicaments. If the food supplement has an ingredient that has not been accepted by INVIMA, the health registration applicant has to consult before the INVIMA Phitotherapeutic Medicaments, Homeopathics and Food Supplement Revision Room (“Sala Revisora especializada de Medicamentos Fitoterapéuticos, Homeopáticos y Suplementos Dietarios”), if said ingredient would be accepted. Once said Room has approved the new

ingredient (in case it has to be done), the applicant can file the health registration application.

Health registration process for a food supplement is made up of: (i) Filing of the application; (ii) issuance of an action indicating any technical or legal questions or doubt that INVIMA´s examiner may have, (iii) resolution granting or denying the health registration. Against the decision issued by INVIMA rejecting the granting of the health registrations there is the possibility to file a reinstatement action and reconsideration appeal. The term to obtain a health registration in Colombia could take at least a year and a half.

INVIMA is very active in vigilance for food supplements as there is a big market of this kind of products in Colombia through multi levels. Thus, INVIMA tends to keep tracking in the social networks and internet to check the advertisement. Advertisement for food supplements needs to be approved before it is delivered to the public. Vigilance is made up of systematic activities to verify the quality and harmlessness conditions, the tracking of the effects of food supplements over the population health. INVIMA has an internal organism called GURI which is in charge to check in the market the labels, the advertisement and the social networks, and also, they can make a visit to a manufacturing facility to check if the conditions under which the health registration was granted is being complied. If GURI detects the infringement of a sanitary rule, they will pass a report to the Sanitary Responsibility Unit of INVIMA, who may issue a health security measure which purpose is to stop the infringement of a rule. In any case, after a health security measure is issued, INVIMA could decide to open a sanctioning process.

Rules for food supplements are the following: Decree 3249 of 2006 and Decree 3863 of 2008.

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

Regarding medicaments and medical devices, the holder of a health registration has the following obligations after the marketing authorization has been approved:

– To record before INVIMA any amendment of the health registration holder, the manufacturer, or the distributors information.

– To use the labels with the legal and technical information approved in the health registration.

In some cases, medicaments, after approval of their health registration, may have changes or variations due to several causes, among which are the change in the capacity of manufacturing equipment and production efficiency, improvements in manufacturing processes, maintenance of product consistency, adjustment of specifications or analytical methodologies, optimization in the supply of raw materials and materials, minimization of errors in use, among others. All of them are the result of permanent quality monitoring programs and continuous improvement, corrective/preventive actions, business strategies, compliance with regulatory standards or legal, and harmonization to regional and/or global guidelines.

Depending on the complexity of the changes that occur in chemically synthesized medications and gases medicament products, could have a greater or lesser impact on the quality, safety, or efficacy of the product. Thus, the variations that arise must be regulated by INVIMA. Consequently, the health registration holder must inform these changes to INVIMA.

In medicaments field, it is also necessary: (i) that the holder of the health registrations files a monthly report of sales made by customers of medicines to the Ministry of Health, (ii) the filing of a semi-annual report on Transfers of Value between the actors of the health sector and the pharmaceutical industry, which consists of the delivery in cash or in kind of goods or services to the Ministry of Health, (iii) preparation and filing of reports of Adverse Events of Drugs with Sanitary Registration before INVIMA.

In case of medical devices, the holder or importer of the health registration, marketing permit or his authorized distributor must obtain the UDI-DI at the code issuing agency that carries out the association to the attributes of the standard. The holder or importer of the medical device, marketing permit or his authorized distributor, will report to INVIMA the technical information indicated in Resolution 1405 of August 5, 2022. INVIMA will validate the report of the information on the medical device used human or in vitro diagnostic reagent, as appropriate.

For all medical devices under the regime of monitored control, a monthly report of sales made by customers should be filed before the Ministry of Health.

For coronary endovascular and contraceptives medical devices, prices report before the Ministry of Health should be filed by manufacturers or distributors. The report must include the sales or supply prices of the medical devices included in the probation regime, as well as the ID of the medical device, the month, channel, minimum price, maximum price, total sales, total

reporting units, the invoice number of the minimum and maximum price, and the NIT of the purchasing entities at minimum and maximum price.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

INVIMA (INSTITUTO NACIONAL DE VIGILANCIA DE MEDICAMENTOS Y ALIMENTOS INVIMA) is the technical and scientific institute which is part of the Ministry of Health, who applies the Government policies made for inspection, vigilance and sanitary control based on the potential risk of the products in order to take care of the public health. Thus, INVIMA is the competent authority who has the regulatory oversight over medicinal products, medical devices, food, and food supplements.

INVIMA has the main responsibilities: (i) granting and prosecution of health registrations; (ii) vigilance and inspection, (iii) sanctioning in case of infringement of the sanitary rules.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

In Colombia, administrative procedure is applied to health registration prosecution. Thus, all the administrative rules of CPACA (Código de Procedimiento Administrativo y de lo Contencioso Administrativo) are applied to any health registration prosecution category (medicinal products, medical devices, and food supplements). When INVIMA rejects a health registration, the applicant has 10 days counted as from the rejection notice notification, to file a reinstatement action and a reconsideration appeal. Both must be filed at the same moment and in the same brief: reinstatement action will be decided by the same official who makes the rejection and in case the decision confirms the rejection, as the appeal has also been requested in the same brief, it automatically will be studied by the superior officer. If the appeal confirms the rejection, the applicant will have four months counted as the notification to file a Nullity Action before the Council of State.

The reinstatement action and a reconsideration appeal must be filed in a brief and once they are filed it would take at least six months to have a final decision. There are just two stages: filing of the brief and final decision. Nullity action has to be filed before the Highest Administrative Court, the Council of State: a claim has to be drafted. Once the claim is admitted, there will be three hearings: initial hearing, evidence hearing and final decision hearing. A process in the Council of State could take at least eight years until there is a final decision.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

Clinical Trials in Colombia legal framework in Colombia is robust. Main rule is Resolution No. 008430 of 1993 “by which scientific, technical and administrative standards are established as requirements for the development of health research activity.” These are the key points of this rule: (i) Institutions that carry out research on humans must have a Research Ethics Committee in charge of resolving all issues related to the topic, as well as the ethical aspects of research on human beings; (ii) Research risk is the probability that the research subject will suffer some harm as an immediate or delayed consequence of the study (classifies studies according to the type of risk); (iii) It also defines informed consent and describes the requirements that must be met in the process. Establishes the conditions for carrying out studies in communities, in minors, subordinate or disabled groups, women of childbearing age, pregnant women, during labor, puerperium, breastfeeding and newborns, use of embryos, deaths and fetuses and in cases of artificial fertilization, research on organs, tissues and their derivatives, or new prophylactic, diagnostic, therapeutic and rehabilitation resources. (iv) Lastly, it defines pharmacological research and the biosafety of research and the cases in which this research can be carried out in the country.

Resolution No. 3823 of 1997 established that drug research projects must be evaluated by the National Institute for Food and Drug Surveillance – INVIMA and subsequently Resolution No. 2378 of 2008 was issued “by which Good Clinical Practices are adopted to “the institutions that conduct research with medicines in human beings” and in which INVIMA is delegated the responsibility of certifying and ensuring that the clinical studies that are carried out in the country are conducted in the research centers in accordance with national and

international standards. It describes the requirements and evaluation processes that must be met by institutions that carry out clinical research in human beings, considering the ethics committee, researcher, sponsor and clinical laboratory in order for each institution to obtain certification that allows it to conduct clinical studies.

Resolution No. 2378 of 2008 establishes that institutions where research with human beings is carried out, through the application and use of medications, must have the certification of conditions of the Single Habilitation System. This implies that research centers must also comply with the provisions of Resolution No. 2300 of 2014 “which defines the procedures and conditions for the registration of Health Service Providers and the authorization of health services”, the Decree No. 2200 of 2005 “by which the activities and/or processes of the pharmaceutical service are regulated”, Resolution No. 1403 of 2007 “by which the Management Model of the Pharmaceutical Service is determined, the Manual of Essential Conditions is adopted and procedures and other provisions”, Resolution No. 0444 of 2008 “by which the Instrument for Verification of Compliance with Good Practices for the Preparation of master preparations is adopted and other provisions are dictated” and Decree No. 351 OF 2014 “by which regulates the comprehensive management of waste generated in health care” and Resolution No. 1995 of 1999 that “establishes the standards for the management of clinical history.”

Resolution No. 2011020764 of 2011 establishes the processes and periodicity of reporting adverse events in the clinical research phase with drugs in humans and applies to the reporting of Adverse Events associated with the safety of drugs in research with human beings.

The following are the main aspects of clinical trials procedure: The first step to carry out a clinical trial, is to write a clinical protocol, which must be prepared by an experienced principal investigator – who may be a doctor, a scientist or both -, for its subsequent evaluation by the clinic or IPS (Institución Prestadora de Salud – Health Provider Services Institution) that will carry out the investigation.

Every clinic or IPS must have research and/or medical-clinical committee, where they evaluate the protocol and say whether it is viable or not. After it is approved by the institution and it is decided to participate in the research, whether it is a new drug or an existing one, but for which a new clinical use could be studied, the protocol must be sent to INVIMA.

INVIMA continues with the evaluation from a specialized room or committee that is responsible for evaluating clinical protocols. If INVIMA approves the safety of the protocol, a copy of this authorization and the approval of the clinical committee of the institutions that are going to participate in the research must be attached, and sent as a final step to an Institutional Review Board (IRB, for its acronym in English), which can be from a university entity or private. These committees are made up of a health professional, a scientist, a person from the social area with experience in ethics, and a community representative specialized in evaluating research studies. They value that the protocol complies with all guidelines, especially with the four principles of bioethics: autonomy, beneficence, non-maleficence and justice.

It must be evaluated that there are no adverse effects that threaten the patient’s life, and the biological, psychological and social safety of the study as a whole must be assessed. This IRB committee reviews the protocol, informed consent and approves them. Afterwards, the test is complete for execution. Each patient who enrolls must sign the informed consent, and a copy remains for him or her and the original for the research files.

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

Yes, there is a Colombian Government link, called Gov.co “Datos Abiertos”, where it is found a list of documents related with clinical investigations protocols such as: Invetigator manuals, annual reports, final reports which were filed before INVIMA for revision and approval: https://www.datos.gov.co/Salud-y-Protecci-n-Social/DOCUMENTOS-RELACIONADOS-CON-PROTOCOLOS-DE-INVESTIG/egdv-j34n/data

There are no specific rules for the publication of clinical trials.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

Individuals must be treated with respect from the moment they are asked for possible participation even if they refuse to participate in a study during their participation and after their participation ends. This includes: Respect privacy and keep the private information as confidential. There is the duty to inform the participants of a clinical trial as about what was learned from the investigation. There is also the duty that the person under the clinical trial will not be identified. This is established by Resolution 8430 of

1993.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

In Colombia, health technology has become an important tool to improve the prevention and treatment of diseases. To this end, several mobile applications and online platforms have been developed, such as APPs that allow users to access their medical records, schedule medical appointments, and receive reminders and medications sent from institutions that have such information systems. Even tough, there are no specific legislative proposals in Colombia for digitalizing clinical trials, it most probable that the companies who are carrying out the clinical trials are developing AI, APPs or process to digitalize the clinical trials process. COVID 19 pandemic triggers the development of the Health Tech and data analytics in Colombia. Most probably the Clinical Trial industry in Colombia is using Health Records, Medical Record and Personal Health Record as a second generation in intelligent information systems of second generation.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

In general, the requisite for the authorization of manufacturing plants for medicinal products, medical devices, food and food supplements is the Good Manufacturing Practice Certificate. Said document certifies the infrastructure conditions and procedures established for all production and control processes, with the aim of guaranteeing the quality and safety of said products according to internationally accepted standards.

The applicant should file a petition before INVIMA requesting a visit. In said petition the applicant should comply with some documentation that will be necessary for obtaining the date of the visit. Said visit will be made by technical experts in each product and they will check according to technical conditions that are set in the rules if the manufacture facility complies with the technical and legal requirements. INVIMA will issue (i) a concept indicating that the manufacturing facility complies with all the requirements or (ii) a concept conditioning the issuance of the Good Manufacturing Practice Certificate until the technical conditions are complied, or (iii) a concept indicating that the manufacturing facility does not comply with the technical conditions.

In case of imported medicaments, INVIMA recognizes technical reports from other authorities that will be basis for issuing a Good Manufacturing Practice Certificate. INVIMA will accept the Certificate of Compliance of Good Manufacturing Practices – GMP, or its equivalent, as long as it is specified the manufacturing areas, or the production processes, or pharmaceutical forms, or type of product or products, granted by the competent authority of the United States of America, Canada, Switzerland, United Kingdom, Germany, France, Denmark, Holland, Sweden, Norway, Japan, South Korea, Australia and other member countries of the European Medicines Agency (EMA), to laboratories located inside and outside its territory, or by whom have signed mutual recognition agreements with these countries. This is the case of Mexico and Colombia for medicaments. In this way, the cooperation measure that in the first instance applies to the National Institute for Food and Drug Surveillance INVIMA, of Colombia, and the Federal Commission for the Protection against Sanitary Risks – Cofepris-, of Mexico, contributes to the efficiency of health regulation and the facilitation of regional trade by reducing the times and costs of issuing documentation. It is important to clarify that the initiative covers only chemically synthesized medicines and excludes biological, biotechnological, herbal or phytotherapeutic, homeopathic, as well as food/dietary supplements.

For the medicinal products there are three kind of certificates: (i) Good Elaboration Practice Certificate, (ii) Good practice Certificate for laboratories and (iii) Good Manufacturing Practice Certificate. Decree 335 of 2022 establishes the requisites, procedures, and legal aspects to obtain any of those certificates. This rule also applies for food supplements which will have the same procedure to obtain the certificate as medicinal products.

GMP is an important enhancement to food safety management system, increasing customer’s confidence in your commitment to selling and producing safe, high-quality food.

Compliance with GMP requirements involves procedural requirements applicable to all food processing establishments. Many companies in the food industry have implemented the food processing certification program as a policy, upon which they have developed and implemented other quality and food safety management systems, including HACCP, ISO 22000, SQF and ISO 9001. For food, INVIMA has a guide for the

process of certification of manufacturing facility in case of foods of high risk of animal origin located in a foreign country different from Colombia.

For medical devices, the establishments dedicated to manufacturing, semi-manufacturing, packaging and packaging devices for their operation, must comply with Good Health Practices. Decree 41225 of 2005 indicates that for medical devices there are two kind of certificates: (i) Good manufacturing practices certificates; (ii) Storage capacity and conditioning certificate for medical devices. All importing establishments and Marketers of medical devices must comply with the requirements of storage and conditioning capacity. There are specific rules for cases such as manufacturing and adaptation of tailor-made medical devices of external orthopedic technology which is established by Resolution 00001319 of 2010.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

The process of distributing medicinal products, begins from the moment of the order request, followed by the preparation, transportation and dispensing to the different services and ends with the respective movement in the system.

The distribution chain for this sort of products is: Pharmaceutical Industry, wholesale industry, Pharmacy, Pharmacy Services and Hospitals.

The systems to distribute medicaments is the following: 1) the distribution system by stock in the different services (also called floor stock or floor or service warehouse), 2) the distribution system by individualized prescription (transcribed or direct), and 3) mixed or combined distribution system, which uses both.

Regarding food supplements, as they are of free sale and they do not have a restriction to its commercialization said products can be sold by drug stores, pharmacies, natural food stores, retail stores or any other form. In Colombia, it is very common that food supplements are sold by multilevel systems.

With respect medical devices, its distribution and commercialization depend on the risk of the product. Medical devices are classified in Colombia by Decree 4725 of 2005, depending on the risk: low risk, medium risk and high risk. Low risk medical devices can be sold by drug stores, pharmacies, natural food stores, retail stores or any other form. For medical devices of medium and high risk it should be considered the following: (i) for very specific medical devises such as human body prothesis the only channel of distribution would be directly from the manufacturer to a specialized distributor and then to the hospital or doctor; (ii) for those medical devices such us diagnosis devices, the only chain of distribution would be from the manufacturer to the hospital.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Law 81 of 1988 provides that the exercise of the pricing policy of various products, including medications and devices medical, may be exercised by the competent authorities under the following modalities: i) Direct control regime; ii) Regime of regulated freedom and iii) Probation regime.

The National Commission for Prices of Medicines and Medical Devices – CNPMDM is a tripartite entity made up of a delegate of the Presidency of the Republic of Colombia, the Minister of Commerce, Industry and Tourism and the Minister of Health and Social Protection. Said commission fixes the prices for medicines and medical devices. The Commission has the function of setting and adopting the general guidelines for the formulation and regulation of the pricing policy of medicines and medical devices, based on criteria of (i) technical nature and economical that, according to its competence, it considers convenient or necessary the Ministry of Commerce, Industry and Tourism, or (ii) of a technical nature related with the health sector that, in accordance with its competence, the Ministry of Health and Social Protection considers convenient or necessary, or (iii) technical studies presented for consideration by the technical secretariat of the Commission.

There is a list of medicaments with maximum price by commercial presentation for being sold to the public and which is publicly disclosed. There is also another list by unity for each relevant market. Said list is also public.

Regarding the medical devices, their price is part of the freedom supervised regime, according to which any member of the distribution chain can fix the price of a medical device, but the Secretariat Technical Comission could request to any member of the distribution chain any information to make an inspection over the medical devices prices. Details to fix prices for medical devices are established in Circular number15 of 2023.

Food supplements prices are under free market or liberal market price system, according to which the price of the food supplement is agreed upon by consent between sellers and buyers, through the laws of supply and demand.

Regarding reimbursement of medicinal products, medical devices and food supplements, our system recognizes the expenses a patient has made in the terms of article 14 of Resolution 5261 of 1994. The expenses will be recognized if they are part of emergency care in case of service in an IPS that does not have a contract with the respective E.P.S., when it has been expressly authorized by the E.P.S. for specific care and in case of disability, impossibility, unjustified refusal or demonstrated negligence of the Promoting Entity of Health to cover the obligations towards its users. The refund request must be made within fifteen (15) days following the patient's discharge and will be paid by the Entity Health Promoter within thirty (30) days following its presentation, for which the the claimant must attach the original of the invoices, certification by a doctor of the occurrence of the event and its characteristics and a copy of the patient's medical history. The economic recognitions will be made at the rates established by the Ministry of Health for the public sector. In our health system the reimbursement is not expressly for a medicament, but it is recognized for the entire service which maybe includes the medicaments. For medical devices and food supplements, it has to be demonstrated that they are part of the scenarios already mentioned.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

Each product has its own legal framework.

The regulations applicable to the advertising of medicines in Colombia are summarized in Decree 677 of 1995, which establishes the requirements for the advertising of medicines for sale with a medical formula, and Resolution 4320 of 2004, for over-the-counter medicines.

The regulations establish that advertising, in any case, must comply with the provisions of the product's health record, guide proper use of the product and not generate deception or error in the consumer. Prescription medicines can only be advertised in media aimed at health professionals, with information of a technical-scientific nature. For their part, those for free sale can do so in mass media, but taking into account requirements such as not attracting the attention of minors, including the health legends established by law and having prior approval from INVIMA to advertise.

According to 4725 of 2005 Scientific, promotional or advertising of controlled technology medical devices and biomedical equipment, will be carried out in accordance with the conditions of the respective health records or marketing permits and current legal technical standards and must adhere to the truth, with scientific evidence that demonstrates it and consequently, they will not be able to exaggerate the benefits that its use may offer. In any case, it will not be possible to carry out advertising of medical devices and controlled technology biomedical equipment, in the following cases: a) When the general rules regarding health education are not applied therapy; b) In those that lead to deception or error; c) When it is imputed, defamed, causes harm or pejorative comparison to others brands, products, services, companies or organizations. Medical devices that are part of class I may be advertised in mass media considering the specifications of the automatic health registry. Medical devices and biomedical equipment of classes IIa, IIb and III intended for use exclusively by health professionals or prescribed by them, they can only advertise or promote them in scientific or technical publications.

Food Supplements advertisement is established by Decree 3249 of 2006. Advertising of dietary supplements will comply with the benefits attributed to each of the characteristic ingredients of the composition and must be previously approved by INVIMA. In the label and/or label and in the advertising of dietary supplements, no information must be presented that confuses, exaggerates, or deceives as to its composition, origin, effects and other properties of the product, nor show indications preventive, rehabilitative or therapeutic.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

Decision 486 of the Andean Community is the general law which establishes trademark and patents provisions.

Products, processes, or products by processes could be patented. Thus, if the inventions of medicinal products, medical devices or food supplements can be included in any of those categories and they have novelty, industrial applicability, and inventive level, they can be protected by patent.

Trademarks for medicinal products, medical devices, and

food supplements can be registered under the same conditions of any other trademark. It is important to take into account to follow these suggestions in order to make a distinctive mark: (i) non use of generic expressions, (ii) avoid the use of descriptive expressions, (iii) a trademark should use evocative signs.

There are no specific rules for these sectors medicinal products, medical devices, and food supplements regarding patents or trademarks.

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Infringement action can be used by a legitimate patent holder. Said action can only be used when a patent has been conferred. This action cannot be used for patent applications. In case an infringement happens during the patent application prosecution, what could be done is to file the infringement action once the patent is granted and to roll back the effects of the infringement at the moment of the publication. Medicinal products and medical devices can use a patent infringement action if these are inventions protected by a granted patent.

In Colombian market, there would be more medicinal products infringement cases than medical devices. Probably, because the pharmaceutical market is bigger than the medical devices in our country.

In Colombia, we have two possibilities to start an infringement process, different from filing a sue: (i) the holder of the patent can request an anticipated evidence with which the infringement can be demonstrated. If the anticipated evidence is enough to demonstrate the infringement the patent holder can start the infringement action; (ii) the patent holder can request seizure measures against the infringer asking to stop the acts; the judge confers seizure measures and order, for instance, to stop the commercialization and production of the medicament or medical device and to pick up each medicament or medical device of the market. This will provide a strong position to the patent holder to start a process and would make the patent infringer to considerate a possible conciliation instead of getting in a long and costly process.

It is also important to consider a 360 degrees protection of a medicinal product or a medical device, i.e. the trademark, the industrial design, the patent as in the Andean Community (from which Colombia is part) the Andean Tribunal of Justice has considered the whole protection of a product with all the figures of the industrial property as a Trade dress protection. This will make stronger the possibilities to defend a medicinal or medical device protected by a patent in a potential infringement trial.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Regarding the restrictions on the use of trademarks for medicinal products, these should be adjusted to terms of scientific moderation. Therefore, in no case shall names be admitted which, without any connection with the real effects of the product as determined by the health authority, use words such as: tonic, comforting, vigor, energetic, life, extra, super, best, ideal, beautiful, wonderful and unique, either as a name or brand name or simply as an explanation.

With respect to medical devices, the scientific or advertising information on medical devices must be truthful, with scientific evidence to prove it, and the benefits that their use may offer may not be exaggerated. Neither may medical devices be advertised when they are imputed, defamed, cause damage or pejorative comparison to other trademarks, products, services, companies or organization.

With respect to dietary supplements, it must be used a trademark or name that does not mislead or deceive the consumer. These products may not be labeled as foods, medicines, phytotherapeutic products, or as pharmaceutical preparations based on natural products or alcoholic beverages.

Lastly, there are not specific restrictions on the use of trademarks for food products. However, there is a general restriction for labels of food for human consumption, in the sense that the name of the product shall not describe or present the packaged foodstuff in a manner that is false, misleading or deceptive or likely to create an erroneous impression regarding the nature or safety of the product in any respect.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

In Colombia, the liability regime for defective products is regulated in the Consumer Protection Statute. In the

case of medications, drug safety is defined as “The characteristic of a medication according to which it can be used without greater possibilities of causing unjustifiable toxic effects.”

Regarding medical devices, safety is the characteristic of a medical device, which allows its use without greater possibilities of causing adverse effects.

The Consumer Protection Statute indicates that defects in a product can have different origins, whether manufacturing, design, information, or packaging.

Civil liability for medical-health products can be framed in a regime of objective civil liability for defective products, in which there is a presumption of liability on the part of the producer or supplier, in such a way that the consumer who is the victim of the defective medicine or device only has to demonstrate the causal link and damage.

To attribute liability to the manufacturer of a defective product, the elements of civil liability must be configured, such as damage, a factor for attributing responsibility and the causal link.

The producer or distributor may be exonerated from liability if he proves that:

– The defect did not exist at the time of production or marketing of the product.

– The defect was caused by the consumer.

– The defect was caused by an event beyond the control of the producer or distributor.

The state of the scientific technique at the time of production or marketing of the product did not allow the defect to be detected.

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

In Colombia, civil liability will follow the general rules of our Civil Code. According to civil liability in Colombia there is an obligation to repair or compensate damages that could be caused over a person. For medicinal products, medical devices and food supplements, there are no cases law regarding civil liability based on which a laboratory or pharmaceutical company has been forced to respond for the damages caused to consumers. The costs that may cover a compensation due to declared civil liability are the following: medical expenses, funeral costs, and loss of income incurred as a result.

Criminal liability is the duty to face the criminal consequences of a crime. These consequences generally involve the imposition of a sentence, security measures or a punishment proportional to the crime committed. Criminal liability of defective products is novel topic that is quite important as there is the discussion how to make charges due to the death of a person or personal injury for the use of a defective product such us medicinal products (including biologicals), medical devices, foods, and food supplements. In those cases, the crimes would be homicide or personal injury.

Administrative liability in Colombia are based on the consumer actions and the regulatory administrative actions. Consumers have the possibility to file a claim due to defective product before the Consumer Colombian Authority (División de Consumidor de la Superintendencia de Industria y Comercio) and before INVIMA. The Consumer can file the claims at the same time or if it is filed only at the Consumer authority, the authority can inform the facts of the claim to INVIMA and the health regulatory authority can open an investigation for the infringement for the any of the rules. In both cases a money sanction can be imposed.

Consumer and health regulatory actions are effectively enforceable in Colombia, considering that they are issued by an authority imposing most of the times a penalty, and they tend to take care of the consumer health. Criminal and Civil actions would work too, and they have reasonable enforceability, but it takes time for a final decision.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Colombia has no specific regulation with regards to health applications. However, the following may be applicable:

– Telemedicine / telehealth: provided health apps may render health and/or medicine services to end users, telemedicone regulation may be applicable. Specifically, note that under COVID, the Colombian government issued Reolution no. 2654 of 2019, which aims to establish provisions for telehealth, and parameters for

the practice of telemedicine, its categories, the use of technological means, the quality and security of care, as well as of information and data.

– Personal data collection and processing: Considering health apps may be processing personal data – specifically health-related information-, which is considered as Sensitive Data in Colombia, personal data regulations may be applicable. Specifically, Law 1581 of 2012 and Decree 1377 of 2013.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

Decree 1474 of 2023 has been important for Colombia in its effort to address challenges in the supply and availability of essential medicines.

This addressed the medicament supply concerns directly. The decree also strengthens INVIMA's response capacity in the face of public health emergencies. With greater powers, INVIMA can act quickly to ensure that essential medicines are available in critical situations.

Other measures include streamlining processes for minor risk changes in records and promoting national production of medicines in public servants. These actions not only seek to prevent shortages, but also to strengthen the national pharmaceutical industry.

With this Decree, medicinal health registrations do not need to be renewed. Thus, the health registration will not be a burden at the moment of importing or commercializing a medicament.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

There are specific compliance legal rules in the pharmaceutical sector:

– Transparency and Ethics Code from the Pharmaceutical Chambers of ANDI (Colombian Entrepreneurs National Association). This code will be binding for the Pharmaceutical Companies which have signed the Transparency Pact.

– Compliance Program Implementation Guide from the Superintendencia de Industria y Comercio (SIC). It is not compulsory to follow it. It is voluntary its application.

– Law 1949 of 2019 strengthens the role of Superintendencia Nacional de Salud (Government Health Industry Authority) and makes more drastic the sanctions for the Health and Pharmaceutical sector.

There is a general trend of the industry to follow the best compliance practices in the companies and to acknowledge transparency. In Colombia, a group of laboratories decided to create an ethics code and some guidelines of ethics and compliance. This is the case of AFIDRO (Investigation Laboratories Association) ethic code. There is a registry of transactions between the pharmaceutical and health technology industries. Colombian government is also concerned regarding the transparency, reason why they issued Resolution 2881 of 2018 which establishes the value transfer rules in the Health Sector.

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

From a regulatory perspective, we have some important key cases. We prepared and requested before the Ministry of Health the adjustment of the draft Circular 013 of 2022, the withdrawal of the drug SOLUFOS 500 mg from the relevant market.

In a subsidiary manner, the separation of the relevant market into two subgroups was requested, differentiating granules and tablets for oral administration, by the salt of the active ingredient, since they present clear differences in effectiveness, bioavailability, adherence, cost structure and pharmaceutical form. It was possible to separate the relevant markets, creating the relevant market Fosfomycin Calcium, composed solely of the drug Solufos.

The Health Authority issued an order to initiate a sanctioning process against a very important pharmaceutical for the alleged violation of health regulations related to the advertising of medicines. We advised the client on how to deal with the authority's visit, removing immediately all advertisements with possible infringement. We were able to withdraw the process due to lack of evidence.

The legal framework for patenting life forms is often

complex and varies between jurisdictions. Different countries have different rules and standards for patenting living organisms, leading to inconsistencies and uncertainties in the legal landscape. Prosecuting life science technologies in Colombia, particularly patenting technologies that involves living beings, requires an extra effort because, due to various limitations in Colombia by law (e.g., limitations for patenting therapeutic methods or living matter), it requires an extra support in adapting the non-allowed matter in order to obtain a suitable protection.

We prosecute the patent applications in Colombia whose patent involved polymorphs, wherein, besides the typical patent prosecution, our role in prosecuting these sorts of applications is to adapt applications to comply with Colombian practice and law. The importance of this matter to our client relies on our capacity to adapt inventions related to polymorphs into non-obvious patentable matter. Additionally, the patented technologies of our client are important because they are related to pharmaceutical products that improves patient's life quality.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

Colombia still has no comprehensive regulation on AI, or any specific initiatives on the use of AI in the life sciences sector. However, there are general initiatives and proposals which aim to integrate new technologies and innovations within the public sector – including the use of AI -, which may involve local halthcare systems.

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

During pandemic, and as a consequence of the lock down, the Health Care Industry had to develop new strategies to provide services to their users. Thus, a tendency of digitalization in the health industry started from 2020 up to these days. Today is possible to request appointments through a platform, to collect data from patients and to use software and AI to make diagnostics which would help to detect, prevent and treat health problems in a more efficient way. This new way to provide services, has open a door to a new market and to face challenges for the data protection and technology practices which are also part of the life sector.

Since 2016, when scientific and medical use was legalized in 2016 with the approval of Law 1787, hemp started to be seen as an agricultural product that represents opportunities for the Colombian producers and the cannabis industry. The industrial and scientific use of cannabis is allowed by Law 2204 of 2022, according to which if the purpose of the crop corresponds to the production of flowering or fruiting tops of the plant and its derivatives with a percentage greater than 0.3% of THC, the licenses should be requested. Righ now in Colombia, there is a proliferation of cannabis products made up of industrial hemp from which there is a big expectation.

In our country there is an ecosystem made up of innovation and technology which purpose is to build solutions in the health care industry and to provide services. In Colombia, there are more or less 300 hundred health tech companies who are providing services in Colombia, Latin America, United States and Europe

Contributors

Luz Helena Adarve
Partner for Life Science and Intellectual Property
luz.adarve@dentons.com

Mónica Bonnett
Partner for Life Science and Intellectual Property
monica.bonnett@dentons.com