Chapter 10
Pharmaceutical Policy in Colombia

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Abstract This chapter aims to provide an overview of Colombia's pharmaceutical sector from 1993 to 2016. The 1993 Colombian Health Sector Reform was a radical change and led to the implementation of a compulsory social health insurance scheme covering essential medicines and use of generic products and International Nonproprietary Names for prescription and dispensing. This chapter provides valuable information about current country pharmaceutical achievements and challenges in the implementation of the General System of Social Security in Health (SGSSS). Over the past 22 years, health insurance coverage expanded from less than 20% in 1993 to over 97% in 2015. However, access and rational and effective use of health services and medicines are still burdened by inequality and inefficiency. Ensuring effective access to medicines in so-called scattered areas is one of the country's major challenges. The Government is currently working on developing a special health model for these areas. The 2012 National Pharmaceutical Policy has promoted positive scenarios of specific policies such as pricing system, biologics regulation, and interesting joint initiatives between the health sector and research on drug use, which may provide useful future interventions in the rational use of

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medicines. In 2015, a Statutory Law was also enacted to ensure the fundamental right to health. Currently, shifting to an implicit approach that involves the definition of an explicit exclusion list instead of the explicit inclusion list has become the medicines coverage challenge for the health system.

10.1 General Context

Colombia is located in South America and has a surface of 2,070,408 km^2, with an estimated population of 48.2 million (2015). More than 75% of its inhabitants live in urban areas [1, 2]. Colombia is a unitary, decentralized Republic consisting of 32 departments currently comprised of 1101 municipalities and districts [3].

Colombia's epidemiological transition has witnessed predicted increases in chronic, noncommunicable diseases. However, the burden of communicable diseases persists. Health improvements were observed nationally, but with large regional gaps. For example, the infant mortality rate (IMR) has been declining nationally, reaching 17.23 in 2014. However, the largest IMR is over four times higher in the Amazon department (48.96) compared with the Quindío department (11.83) [4].

Colombia is significantly affected by global economic changes and blatant inequalities. Colombia is classified as an upper middle income country. Its Gross Domestic Product (GDP) was US$ 292.08 billion in 2015 [5]. Monetary poverty and extreme monetary poverty levels show reductions at the national level during the period 2005–2014, from 45.0 to 28.5% for monetary poverty and from 13.8 to 8.1% for extreme monetary poverty, but with large regional gaps. In 2014, poverty incidence in rural areas was 1.7 times greater than the urban areas, and extreme poverty incidence was 3.5 times greater [6]. Moderate income distribution improvements were measured by the Gini index, from −0.557 in 2005 to 0.538 in 2014, but large inequalities remain [6], as the wealthiest 1% of the population accounts for 20% of revenue and about 40% of total wealth [7].

10.2 Health in Social Protection: The Policy Context

In 1991, Colombia's new constitution states that the social security is a public service to be provided under the coordination and control of the State, subject to efficiency, universality, and solidarity and under the terms established by the Law. Social security may be provided by public or private entities and resources allocated to these institutions may not be used for other purposes [8].

In 1993, the National Health System (1974–1993) was radically reformed; the General System of Social Security in Health (SGSSS) began to operate as part of the Comprehensive Social Security System. In 2007 and 2011, incremental changes were introduced to the SGSSS. In 2015, Colombia established health as fundamental

right, whose protection has to be regulated and established by designing and implementing mechanisms to structure national health benefits [9–12].

The SGSSS developed the "Structured Pluralism Model", which is based on managed competition with financing for a comprehensive package of personal health services [13]. Colombia was the first Latin American country to implement this model in its entirety in the 1990s. Published as a World Bank document, this model is recommended and promoted the main agencies and international organizations as the most effective model to attain the best levels of efficiency and equity in health systems [14–17]. However, its implementation has been a long and complex process with controversial results [18–21].

SGSSS key features can be described considering three parts [3, 13, 17]. First comes public financing, based on universal health insurance, which has two schemes. The "*Contributory Scheme* – RC" includes people with paying capacity: formal sector employees, informal sector workers, and freelance workers. Health insurance is mandatory for them. RC is funded by nontax resources, from compulsory employer and employee contributions. The other insurance scheme is the "*Subsidized Scheme – RS*", covering people with no paying capacity. Low-income individuals are identified by a means test. Its funding derives from fiscal, national, departmental, and nontax solidarity funds.

There is also another segment called "Noninsured low income individuals – PPNA". They are people with no paying capacity who are not affiliated with RS or RC and cared for by public health service providers. Their care is financed only from fiscal, national, and departmental public resources. The SGSSS does not apply to some other population segments. They are the so-called Exceptional and Special Schemes – R.E.E., such as military, workers of the Colombian state-run oil company – Ecopetrol, and teachers.

The second part is the institutional design with four separate health system functions: *modulation, financing, coordination, and delivery*. *Modulation*[1] is separated from financing and delivery of health services. Since 2012, the Ministry of Health and Social Protection (MoHSP) is the only legally responsible agency for SGSSS modulation [22]. *Financing* is separated from delivery of services with the establishment of the National "Solidarity and Guarantee Fund – FOSYGA". Funds are collected and solidarity is ensured between the schemes (RC and RS).

The delivery of health services gathers private and public "health service providers – IPS". Public health service providers are also called "*Social State Enterprises – ESEs"*. In both cases, they are funded by the sale of services (contracts). Actually, for many reasons, mainly or only ESEs are in place in many municipalities and departments, due to difficult geographic access and low population [23].

[1] Modulation is a broader concept: it involves setting, implementing, and monitoring the rules of the game for the health system, as well as providing it with strategic direction, according to Londoño and Frenk [13] p.8. During the period 1993–2012, two extinct boards were in charge of this function: the National Council of Social Security in Health – CNSSS (1993–2007) and the Health Regulation Commission – CRES (2007–2012).

Entities responsible for the *coordination* of services are separated from the delivery of services. Currently, there are public, private and mixed "Health Promotion Enterprises – EPSs". Legally, vertical integration between EPS and IPS is limited to 30% of the insurer's total expenditure [10]. In 2011, the EPS was called "Benefit Plans Management Entities – EAPB" [24]. The EAPBs have to ensure health services delivery, including medicines, through coordination and risk management with healthcare providers. EAPBs of the contributory scheme are responsible for collecting nontax contributions and retaining the "*Per-capita Payment Unit – UPC*" established by the SGSSS to offer the "*Individual Services Package – POS*". EAPBs of the subsidized scheme receive the "*UPC-S*" established by the SGSSS to finance the *individual beneficiaries' services package (POS-S).*

The third key feature is the definition of SGSSS benefit packages. Actually, there are four types of benefit plans [25]. The first one is the *Public Health Plan of Collective Interventions (PIC)*, defined as "basic care for all citizens", and has to be offered on a free and compulsory basis, it is financed by fiscal and public funds. The second is the individual services plan called *POS*, financed by the UPC. At the beginning of the SGSSS there were two plans, a contributory scheme (POS) and a subsidized scheme (POS-S). A single POS has been in place since 2012, while the definition of UPC is still being assessed [26, 27]. In 2015, the MoHSP initiated a 2-year pilot study for the temporary equalization of "pure premium", which corresponds to the premium net of administrative expenses of the per capita Payment Unit amount (for RC and RS) [28, 29].

The other healthcare plan is for accidents and catastrophic events for the entire population; it is financed by the compulsory insurance for road traffic accidents and the EAPBs, or by FOSYGA. The last plan is for urgent care and is for all citizens; it is financed by POS (RC and RS) via the EAPBs or other funds.

In the period 1993–2014, Total Health Expenditure (THE) ranged from 6.3 to 7.2% of GDP; individual out-of-pocket healthcare declined from 43.7 to 15.5% of THE in the same period, one of the lowest figures in Latin American region [30–32]. In 2014, health expenditure per capita was US$ 569 [33]. Over the past 21 years of SGSSS operation, the population's health insurance coverage expanded from less than 20% in 1993 to over 96.6% in December 2014, practically achieving universal coverage: 48% of the population under the subsidized scheme and 43.6% in the contributory scheme; it is estimated that 5% belongs to the R.E.E. However, inequalities and inefficiencies related to access, rational, and effective use of health services and medicines remain [28, 30, 34].

10.3 Pharmaceutical Policy Context

All the paramount health rules have involved direct or indirect changes related to the pharmaceutical sector. For example, in 1993, Law 100 states that "essential generic medicines" are part of benefit packages defined by the SGSSS and has been crucial for the promotion of essential medicines, use of generic products, and International

Non Proprietary Names (INN) for prescription and dispensation and subsequent efforts to establish a National Pharmaceutical Policy (NPP).

Laws have been the political and technical opportunity to create institutional arrangements (the National Institute of Food and Medicines Surveillance – INVIMA in 1993; and the Institute of Technology Assessment in Health – IETS in 2011). Similarly, in 1993, the MoHSP would again participate in the definition of a Medicines Pricing Policy with the creation of the National Commission on Medicines Prices (NCMP).

Thus, two NPPs were structured. In 2003, the MoHSP published the first NPP 2003–2008, focusing on rational use, essential medicines selection, and promoting competency [35]. However, it was not officially adopted and did not incorporate funding, monitoring, and evaluation mechanisms.

The approved NPP 2012–2021 had an intersectoral approach [36]. It identified issues related to nonrational use of medicines, inefficient spending, information problems, poor supply and dispensing system, and monitoring and stewardship weaknesses. It aimed at achieving equitable access to effective medicines and provision of quality pharmaceutical services under the principle of shared responsibility between sectors and stakeholders. Ten strategies were set to achieve these goals: reliable and timely information; governance; pharmaceutical human resources; pricing regulation; environmental sustainability and leverage biodiversity; strengthening inspection, monitoring, and control; design of pharmaceutical services networks; improved access to special medicines programs; and adapted medicines programs supply.

Currently, the Directorate of Pharmaceuticals and Health Technologies at the MoHSP created in 2011 is responsible for leading intersectoral NPP's monitoring and evaluation [37]. Important advances were achieved on pricing regulation, improving information, and regulatory framework for biotechnological medicines. The MoHSP also worked on an off-label use model in order to allow access and on the design of a medicines centralized bargaining mechanism.

Colombia has a specific approach to define SGSSS-financed benefit packages, which is the explicit inclusion list for individual healthcare services, including the list of medicines covered by POS and PIC. Recently, in 2015, shifting to an implicit approach that involves the definition of a specific exclusion list instead of an explicit inclusion list has become the medicines coverage challenge for the SGSSS [12, 38]. The MoHSP is currently designing the process to introduce this change without affecting rational use. This should be monitored by the NPP.

10.3.1 Pharmaceutical Market and Industry

In 2007, the NCMP legally defined two "channels" for the medicines market, considering the characteristics of the health sector [39]. The institutional channel represents all sales made by the institutions that comprise the SGSSS and R.E.E. The commercial channel represents all sales made by the commercial sector.

The size of these channels is not accurately established. However, recognizing that fact, the current NPP refers to estimates that can be made based on two sources [36]: (1) Intercontinental Marketing Services – IMS and (2) the Medicines Information System (SISMED) of the MoHSP.[2] IMS monitors the pharmacy and drug store market through standardized sampling. SISMED captures transaction reports for each medicine (in values and units) that sellers and buyers are required to make [40].

On the one hand, IMS estimated and characterized the domestic pharmaceutical market in December 2011 at approximately Colombian pesos (COP) $ 5.94 billion, or US $3.3 billion, the commercial or private channel at US $ 2.2 billion (COP $ 3.96 billion) and the institutional channel at 50% of the market, i.e., US $ 1 billion (COP $ 1.98 billion). The extrapolation and sampling methodology used by IMS in their estimates is characterized by uncertainty [36]. On the other hand, SISMED estimated the domestic pharmaceutical market at more than COP$ 8 billion. These data are not comparable with IMS estimates; it includes in-patient sector and real transaction reports from various stakeholders of the Colombian pharmaceutical supply chain [41].

The pharmaceutical industry sector in Colombia has approximately 143 industrial plants that are GMP-certified by INVIMA, 133 of which belong to national businesses and ten are foreign-owned laboratories. There is just one public manufacturer, which is part of the National Health Institute (NHI) and produces snake antivenom immunoglobulins [42].

The pharmaceutical industry represented 2.31% of industrial GDP and directly employs 22,264 people [43]. Both domestic and foreign laboratories mainly formulate medicines. Many of these medicines have been on the market for many years. There is no research or development of new molecules [44].

In 2011, domestic manufacturers reached a market share of 42% in terms of value, while their share in terms of volume produced (units) was 75% [45]. Colombia is highly dependent on pharmaceutical imports (both finished products and APIs, as well as, chemical, biological, and biotechnological products). Its deindustrialization process is reflected by the reduced value added to pharmaceutical production, total industrial and nonindustrial economic activity, as well as reduced net foreign investment in the pharmaceutical industry and loss of participation of foreign capital establishments in the domestic production of medicines [46].

In 2009, pharmaceutical products exports represented just 1.19% of total exports, while pharmaceutical products imports reached 3.36% of total imports. For that same year, total country imports and exports of APIs, excipients, and finished and semifinished products were US$ 1.105 billion and US$ 391.21 million, respectively, showing a foreign trade balance deficit of US$ 714 million. Regarding these totals,

[2] SISMED is part of the Integrated Information System for Social Protection - SISPRO. SISPRO is a tool for obtaining, processing and consolidating necessary information for decision-making for policy development, regulatory monitoring and management services in each of the levels and essential processes in the sector: insurance, financing, supply, demand, and service use. This information is available to all citizens http://www.sispro.gov.co/.

APIs and excipients represented roughly US$ 234 million of imports and US$ 19.3 million of exports, respectively. Finished and semifinished pharmaceutical products imports were US$ 656 million and US$ 214 million, respectively, whereas finished and semifinished products exports reached US$ 370 million and US$ 1.5 million, respectively [43].

10.4 Medicines Regulatory Environment

The *MoHSP* is the highest level health authority. The *National Health Superintendent-Supersalud* is the head of SGSSS Inspection, Monitoring and Control (IMC). Two of SGSSS' seven areas are specially relevant for medicines as regards Supersalud's role: insuring the population and providing individual and collective healthcare [47]. Surveillance agencies for the production of goods and services for use and human consumption, supplies, facilities, and processes across the production chain are divided into three categories: health authorities, producers, and suppliers and consumers of these goods and services. Health authorities are the Ministry of Health and Social Protection, National Narcotics Fund-UAE, INVIMA, NHI, and the Territorial Entities (ETs) through the Territorial Directorates of Health (DTS).

The *National Health Institute – (INS)* is an autonomous entity linked to the MoHSP. It is responsible for epidemiologic surveillance. Since 2011, it is classified as a National Institute of Science and Technology of the General System of Social Security in Health and the Science, Technology and Innovation System. The INS also promotes, guides, implements, and coordinates scientific research in health and biomedicine; it is a national reference laboratory and manufactures biological products of interest to public health. The National Health Observatory is part of the INS and is responsible for the surveillance of public health information and provides policy recommendations [48].

The *National Institute of Food and Medicines Surveillance*, *INVIMA*, is an autonomous entity linked to the MoHSP. It is responsible for implementing IMC for medicines and other supplies that may impact individual and collective health. INVIMA has the power to issue regulations to develop the regulatory frameworks established by the MoHSP.

The *Territorial Directorates of Health – DTS* (departmental, district, and municipal level) is required by INVIMA to perform IMC of distributors and retailers of medicines establishments, such as pharmaceutical specialty agencies, warehouses, pharmacies, drug stores, and health food stores. Under the SGSSS Obligatory System for Quality Assurance in Health (SOGCS), the DTS is also in charge of IMC for health service providers (IPS and ESE), including pharmaceutical service providers.

The *Institute of Technology Assessment in Health (IETS)* is a nonprofit corporation with mixed public and private participation and own assets. Among their main functions is conducting health technology assessments based on scientific evidence, taking into account issues of safety, efficacy, effectiveness, and economic impact;

developing recommendations, guidelines, protocols, and generating information to facilitate decision making in the health sector, all at the request of the MoHSP [49].

10.4.1 Medicines Regulatory Authority

INVIMA is in charge of marketing authorization; it regulates advertising and conducts postmarketing surveillance throughout the lifecycle of health products. It ensures the traceability of medicines from production to final consumption to prevent counterfeiting and drug smuggling. As part of postmarketing surveillance, the pharmacovigilance program examines efficacy, safety, adverse events, and contraindications. In addition, INVIMA certifies Good Manufacturing Practices, Good Clinical Practices for medical research in humans, and operates the country's quality control reference laboratory.

In 2010 for the first time and in 2016 for the second one, INVIMA was recognized as a reference national regulatory authority (NRA) for the Americas [50, 51]. It means INVIMA adequately performs its regulatory functions to ensure efficacy, safety, and quality of medicines. It is one of the six reference NRAs in the region. This section offers an overview on some of the main medicines regulatory functions, according the regulatory assessment tool [45]. Colombia has made important progress in the strengthening of regulatory systems for medicines and other technologies. Nevertheless, local improvements are required in specific areas such as pharmacovigilance.

10.4.1.1 Good Clinical Practices

Legal provisions are in place for biomedical research mainly to protect human rights and welfare of enrolled individuals. Clinical trials require prior authorization and approval of an ethics committee and must be reported in INVIMA's clinical trials database. Research sponsors have to meet Good Clinical Practice standards and healthcare providers involved must have certified health service quality standards. INVIMA oversees every instance involved in this type of research. Information about clinical trial requests and approvals for the period 2008–2016 and other related document are available at the institutional website.

10.4.1.2 Medicines Licensing

Specific marketing authorization criteria are publicly available, as are exemptions, such as special imports, donations, emergency, orphan drugs, among others. There are no foreign license recognition mechanisms. Following the current government's development plan, the MoHSP and INVIMA are analyzing the medicines authorization process in order to include IETS inputs. In 2011, there

were about 17,000 pharmaceutical products licensed by INVIMA. The institutional website provides current technical information about approved products in Colombia [45].

10.4.1.3 Quality Control

In Colombia, legal provisions ensure the quality of pharmaceutical products as per GMP standards. INVIMA has a national reference laboratory for medicines quality control where inspectors collect samples for quality testing in postmarketing surveillance.

A local program called "Demuestra la Calidad" (Demonstrate Quality) has been in place, since 2004, in which samples are collected at wholesalers and retail pharmaceutical establishments. As of 2011, more than 765 samples had been collected and 22.5% did not meet quality standards [45].

10.4.1.4 Pharmacovigilance

The country's pharmacovigilance network is led by INVIMA, with important results in monitoring adverse drug reactions (ADRs) and medication error notifications. In 2011, INVIMA's database included 35,398 ADR notifications. New efforts are required on risk management and regarding decision making.

Worth highlighting are some specific efforts made according to strategies of the current NPP (2012). A recent study describes medication errors reported to a pharmacovigilance system by 26 hospitals for patients in the Colombian healthcare system from 2008 to 2013: there were 9062 medication errors in 45 hospital pharmacies. Real errors accounted for 51.9% of the total, of which 12.0% affected the patient and caused harm to 17 individuals. The main error-prone process was prescription, followed by dispensation, transcription, and administration. Administration-related errors were 45.2 times more likely to affect patients [52].

Another study following ADR associated with the use of disease-modifying antirheumatic drugs in patients with rheumatoid arthritis recommends patients monitoring to reduce the risks observed. The highest numbers of ADRs were reported following the use of tocilizumab, rituximab, and infliximab, and the most frequently reported ADRs were elevated transaminase levels and dyspepsia. Overall, 73.2% of patients who experienced an ADR stopped taking their drugs [53].

10.4.1.5 Generic Medicines

Generic medicines policies in Latin America have aimed to improve access to medicines by promoting competition in the pharmaceutical market; there is scarce evidence about the effect of these strategies in the region since the 1990s. Furthermore, for other subregions, and even for the United States and Canada, policies promoting

generic drugs are mainly focused in replacement policies restricted to deprescription conditions and dispensing of generic versions of a specific pharmaceutical product, and these concessions are strictly related to the guarantee of equivalence between the competitors and innovators. Colombia does not have any registration, financial or deprescription incentives to promote the use of generic medicines [54].

Generic drug-use policies have been in place in Colombia since the late 1980s. In 1991, during the National Health System, the Ministry of Health established the mandatory use of INNs for the prescription of medicines [55]. This has been reinforced in all regulations on medicines coverage since the beginning of the SGSSS to date [56]. NPPs medicines supply chain rearrangement strategy have been the promotion of generic drugs competition in the pharmaceutical market.

Perception studies on generic medicines continue to show controversial outcomes. A recent study showed a good level of perception in a sample of prescribers in Bogotá: 5 out of 5 questions were answered as "adequately perceived" by more than 50% of cases. Outcomes for this realm coincided with Shrank, in which 45.8% of individuals who stated that generic and brand drugs are equally effective. Actually, INVIMA has structured an advertising campaign about myths and realities about generic medicines [57–59].

10.4.1.6 Patents and Data Exclusivity

Since the 1970s, patent protection has been regulated in Colombia through the Andean Community Decisions. Because of its membership, decisions directly affect the country. The World Trade Organization TRIPS Agreement (Trade-related Aspects of Intellectual Property Rights) was incorporated in 2000 by Decision 486 [44]. Colombia has been a WTO member since 1995 and has never exercised the right to use any TRIPS flexibility (e.g., parallel imports or compulsory license) or the Doha Declaration (2001) as safeguards to protect public health from patent rights' holders abuse. Instead, Colombia introduced data protection for an exclusivity period by Decree [60]. This is a controversial decision because of its impact on the generic market: it delays the entrance into the market of competitors of the protected product, regardless of the patent protection's status. Subsequent free trade agreements celebrated by Colombia with the United States and EU adopted the same standard, laying down an obligation to provide for a 5-year term of regulatory test data exclusivity. The Decree has established a highly effective entrance barrier [44].

Only two processes have requested drug compulsory licenses (Kaletra® started in 2008 and Glivec® in 2014); both initiatives stemmed from civil society organizations and none of them has resulted, in a compulsory license so far. Fortunately, Kaletra® process achieved a price reduction of around 80% due to a price control mechanism ordered by a judge to the Government. Glivec® process is still ongoing [61] (Fig. 10.1)

Kaletra® and Glivec® processes have contributed to improve stakeholders' understanding and technical capacity to increase access to medicines in Colombia. Civil society will continue to insist on the need and urgency to use the compulsory license mechanism for Glivec®, knowing that a favorable outcome is difficult to obtain.

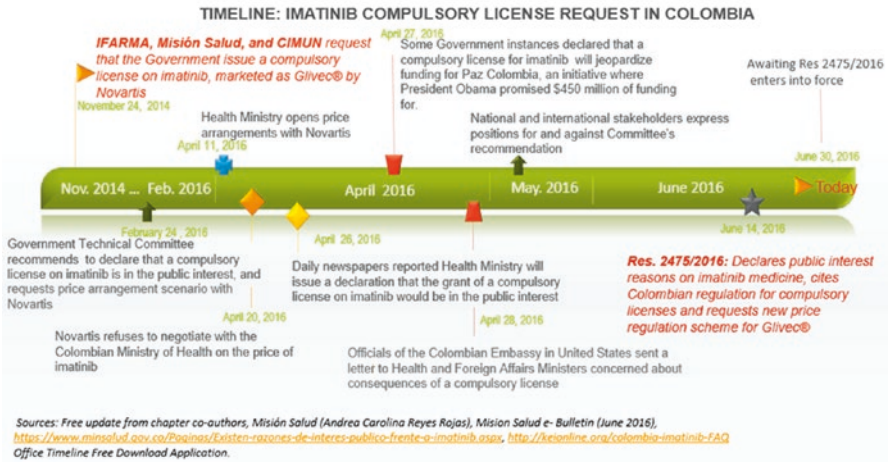

Fig. 10.1 Timeline: imatinib compulsory license request in Colombia, 2014–2016 (Source: Elaborated by authors)

Thus, Government's support is needed, and future initiatives to grant compulsory licenses will evolve from the Government. This would help to achieve lower prices for those medicines. [61].

10.5 Medicines Supply System and Pharmaceutical Services

In general, there are three medicine supply systems: the institutional sector, the private sector, and the Government supply for diseases and conditions of public health interest and controlled medicines.

10.5.1 Institutional Sector

This sector corresponds to the marketing and distribution of medicines in the institutions that compose the SGSSS and the R.E.E. There is no single network for supply chain distribution within the country. The chain network consists of three groups with specific roles.

The first group is composed by *manufacturers and importers*. They manufacture or import medicines as a finished product. They are responsible for registering the product at INVIMA. Then we have *distributors and retailers*, they act as brokers purchasing directly to agents in Group 1 or other distributors and sellers of the same group, to sell to the IPS (public or private). It is important to note that it has not been possible to establish the level of intermediaries in the supply chain or the approximate

number of stakeholders. This is because Colombia lacks mechanisms to measure registration of companies and organizations whose purpose is to purchase, sell, and/or distribute medicines.

The existence of companies generically called "logistics operators" in Colombia is also highlighted here. These companies have outsourced pharmaceutical services of the public (ESEs) and private IPSs and contracted insurers (EPS) for dispensing medicines to members of the SGSSS (in RC and RS). For the Adapted Entities (EA), they dispense medicines to the R.E.E. Logistic operators even perform other types of assistance activities at the hospital and outpatient areas. Some of them are Third Party Logistics (3PL) and Fourth Party logistics (4PL) operators. 3PL outsources one or more logistical processes, while 4PL outsources logistical strategy design and its processes. These operators integrate pharmaceutical processes, including logistic and pharmaceutical operations like compounding, pharmaceutical care, and other clinical activities.

Decreased direct purchases by health service providers (IPSs) – private and public (ESEs) – to Group 1 stakeholders has been observed. Actually, purchases by insurers (EPS) via intermediaries and pharmaceutical outsourcing services have been increasing. For example, in the case of cancer medicines, in 2009, 85% of oncological IPS were purchased directly, while it fell to 52% in 2012 [62]. This occurs especially in the contributory regime of the SGSSS and R.E.E. in large cities. In 2014, approximately 72% of the population in the contributory regime received their outpatient medicines from the large EAPBs or outsourced major logistics operators (*source based on* [63]). The situation of the subsidized scheme differs between capitals and other municipalities. In capitals, there is a similar pattern of intermediation, but EAPBs contracts are with small intermediaries or hospital cooperatives[3] (or other types of cooperatives); in cities or intermediate and small municipalities, contracts are made according to accessibility or availability – with intermediaries, the public hospital (IPS-ESE), or drug store (private).

Private and public health service providers in charge of dispensing medicines form the third group. For hospitalization, IPSs contract pharmaceutical services with the EAPBs directly or via outsourcing (partial or whole service). Those agreements follow the same practices described above or they also buy its products from agents of the first or second group depending on its financial capability. In this area, a new type of outsourcing appears, namely, the "Compounding center", which also has become important in facilitating compliance with defined quality standards for pharmaceutical services in the Obligatory System for Quality Assurance in Health (SOGCS).[4]

Very few services perform the full technical processes for dispensing medicines. In most cases, they are simply limited to medicines delivery, without providing information to patients or meeting the quality standards established by pharmaceutical service regulation.

[3] Public hospital Department cooperatives are organizations under private law where public hospitals (currently called ESE) collaboratively purchase medicines and devices [62].

[4] Principles and requirements for the provision of quality health services were established from the beginning of the SGSSS and are regularly reviewed. SOGCS currently consists of four components: Training, Auditing, Accreditation and Information System for Health Quality.

The distribution of SGOCS pharmaceutical services is heterogeneous; they are concentrated in the capitals. Only 38% of the municipalities in the country have SGOCS-compliant pharmaceutical services [65]. This, in part, is due to geographical barriers and poor road infrastructure (Grade 2/7) [66].

Contract rules are governed by type of medicine product; those included in the benefit packages and ambulatory supplies (excluding high-priced medicines) are contracted by capitation: the EAPBs deliver a fixed amount on a regular basis, the IPS is contracted to cover supply for a period of time, regardless if the user requests them or not [67]. High-priced and hospital medicines are purchased per event. In recent years, for certain health conditions, contracting is done comprehensively, including medical care, provision of medicines, and other health technologies, as well as providing complementary services such as pharmaceutical care with payments through fee for service and diagnostic related groups (for both outpatient and inpatient) [67]. This is commonly seen for the treatment of diabetes, chronic heart disease, breast cancer, and hemophilia.

10.5.2 Medicines Managed by Government

Through the MoHSP, the national government performs centralized management of the medicines supply for the following diseases of public health importance: malaria, leishmaniosis, Chagas disease, and tuberculosis. In addition, there are vaccines and supplies through the Expanded Immunization Program. The Public Health Plan of Collective Interventions (PIC) provides guidelines and the MoHSP directly performs the supply, storage, purchase, and distribution of these medicines and vaccines.

The MoHSP uses international procurement mechanisms such as PAHO Strategic Fund for the purchase of medicines (TB, malaria, Chagas, and leishmaniosis) and PAHO Revolving Fund for vaccines and syringes. In some cases, the MoHSP makes local purchases. The level of compliance with quality standards for the processes of demand management, storage, distribution, and dispensing is homogeneous within each department; however, there are large differences between departments. The development of these processes is influenced by local government policies. Some departments show significant improvements regarding processes and human resource stability; in others, there is a high turnover of human resources, which does not allow for continuity in quality compliance [68].

Despite efforts of national and territorial authorities, poor coordination between central level and departments is an issue that impact supply; which, therefore, impacts access to medicines. During the implementation of the SGSSS, public health indicators related to vaccination coverage and management of diseases of interest to public health (i.e., malaria, tuberculosis, Chagas disease, and leishmaniosis) also suffered significant deterioration.

The lack of an information system that makes real time and traceable information available for medicines is clear [68]. Given the geographic diversity of rural versus urban and low and highly populated areas, it is important to establish

a decentralized logistics model with different distribution centers to optimize supply [69].

10.5.2.1 Medicines Under Special Control

"Special control" medications are managed by the Government through the National Narcotics Fund, UAE-FNE. Departmental Narcotics Revolving Funds (FRE) were legally created to ensure availability in the country. The network involved the UAE-FNE, the FRE, wholesalers, IPSs, ESEs, drug stores, and other pharmaceutical establishments that are legally authorized to manage these types of medicines. One of the access-related challenges is the weak coordination between central and departmental levels, the lack of resource allocation at department levels for the FREs and the lack of pharmaceutical services or drug stores trained to handle these medicines in remote areas [70].

10.5.3 Private Sector

This sector includes large drug store chains and cooperatives that sell medicines. In this case, there is only one supply chain: the laboratory, chain, or cooperative drug store. The State, through the Territorial Health Entities, conducts inspection, monitoring, and control (IMC) on products and processes. The end user (patient) purchases medicines via out-of-pocket expenditures.

Some of these chains also operate in the institutional channel, with the same infrastructure and human resource processes, but with different sales prices. There is no official source stating the number of medicine stores. In 2011, 12,441 drug stores and 178 pharmacy drug stores were reported in 20 of the 36 Territorial Health Entities, according to the MoHSP [45]. In 2014, 10,945 drug stores were registered nationally, which corresponded to 2.5% of all companies in the country [71].

Colombia has regulations on standards for the provision of pharmaceutical services, specifically for the selection, purchase, storage, distribution, and dispensing of medicines. However, the application, interpretation and strictness of regulators actually vary across regions and type of stakeholders [70].

Ensuring effective access to medicines in so-called scattered areas is one of the country's major challenges. Population dispersion stems from the country's poor infrastructure and geographical, socioeconomic, and cultural characteristics. The Government is currently working on developing a special health model for these areas. The idea is to have a single operator in charge of insurance and service delivery in all municipalities [72].

There are large gaps in infrastructure and technology for supply chain management between territorial entities and institutions. Few services are automated or have comprehensive and robust information. Most services are performed manually with intermediate-level information systems, such as Kardex manuals. The challenge

is also to articulate supply chain management with appropriate standards and rational use.

Throughout the implementation of the SGSSS there have been many attempts to develop a negotiation strategy [11] for centralized procurement. Although legislation exists for certain high-priced medicines for HIV/AIDS, cancer, or orphan diseases [73], the government has not been able to implement centralized procurement. The principle of risk sharing has prevailed among insurers against consolidation of needs and centralized procurement. By 2016, the Government will renew this initiative to legislate and implement a centralized bargaining process [74].

10.6 Medicines Financing

All medicines covered by the SGSSS are financed according to the benefit packages rules (POS and PIC). There is a special authorization process for medicines nonpart of POS (non-POS). The current benefit packages consist of 673 medicines and 13 pharmacological groups; this represents about 710 active principles. The subgroup of medicines for Public Health Special Programs (under PIC) represents 25 products and about 19 active principles [56]. Most medicines included in "WHO Model Lists of Essential Medicines" are included in the current list.

Besides the extension of benefit packages, the big challenge for the government is to ensure rational use of medicines. It considered that the prescription will be established under the principles of doctors' self-regulation and transparency.

The provision of medicines for the PIC is free-of-charge through all the SGSSS and the R.E.E. For the CR, POS medicine prescription requires user rates according to individual income. There are no user rates for the RS. Amounts collected from this matter are EAPBs. User rates are not considered a financing mechanism, but this payment at the point of service could be considered a barrier for access.

The authorization process for non-POS medicines is changing, due to the transition from an explicit plan of benefits to an implicit plan with exclusions, as referred to in Sect. 10.3. EAPBs is responsible for this procedure until September 2016, then after this period it would go through an online prescription system without any special authorization [75].

One last consideration is the judicial order for non-POS medicines, which is a dramatic situation. The MoHSP estimates that between 1997 and 2000, reimbursement requests for medications not included in PB totaled 387 and there were 701 judicial orders that mandated the reimbursement of medication not included in PB. By November 2009, the health system received 1,412,462 requests for non-POS medication reimbursements and 945,406 judicial orders. In an attempt to accommodate the increased request for non-POS medicines, the Colombian Government enacted a new law to increase POS coverage. The

Constitutional Court, however, ruled it as unconstitutional as it favored only certain parts of the population [44]. In 2014, there were 36,510 judicial orders to supply medicines: this constituted 62.82% non-POS orders, while the rest were POS 37.18% related orders [76].

Contributory scheme expenditure had a noticeable rise from 2009 to 2011, mainly due to increased members, but also due to the significant growth in payments by FOSYGA to the EPSs regarding reimbursements of non-POS medication. In addition, FOSYGA lost several lawsuits[5] initiated by patients for medicine reimbursements. The amount of reimbursement payments (in billions of Colombian pesos) in 2009 was 1925.4, 2429.0 in 2010, and 2154.8 in 2011 [77].

Subsidized scheme expenditure has grown much more than any other area. According to the MoHSP, this has occurred due to government decisions to expand scheme membership, as well as POS (RS and RC) equalization, which began gradually in 2009. This was in order to implement the Constitutional Court decision (ST-760-CC) [77]. This MoHSP report does not show the breakdown of reimbursements or lawsuits related to RS expenditures. The studies have also shown that the number of reimbursements and lawsuits are much less among subsidized schemes, compared to the contributory scheme due to (among other reasons) patients' lack of knowledge of their rights [78].

10.6.1 Medicines Pricing

High medicines prices were observed in Colombia when compared with other countries. Consequently, national pharmaceutical expenditure showed increase in prices during the 2008–2011 period [79]. This scenario was addressed during the NPP formulation. As a result, external and internal reference pricing methodologies were implemented in 2013, which are described in detail in Fig. 10.2.

Following external reference pricing policy, as of March 2015, 1086 medicine prices have been regulated given their market power and national average price (higher than setting reference prices). Andia et al. [80] demonstrated in 2014 that average price reductions due to price regulation was 41% and regulated medicines represent 80% of expenditure from one of the main financing mechanism.

[5] Lawsuits allow anyone to state their case before a judge; this legal action serves to immediately protect the individual's fundamental constitutional rights when they are violated or threatened by the action or omission of any public authority. The protection consists of an order to the public authority in question to act or refrain from doing so. The ruling is immediately enforceable and can be contested before a competent judge. The maximum time allowed by law for an entity to respond to a lawsuit is 10 days from the date of receipt thereof (Colombia, 2000). This is an important mechanism created by the current Constitution in force (1991). For example, 89,762 lawsuits occurred in 2010 to demand services not included in the POS. Ombudsman, 2011 (Defensoria del Pueblo, 2011).

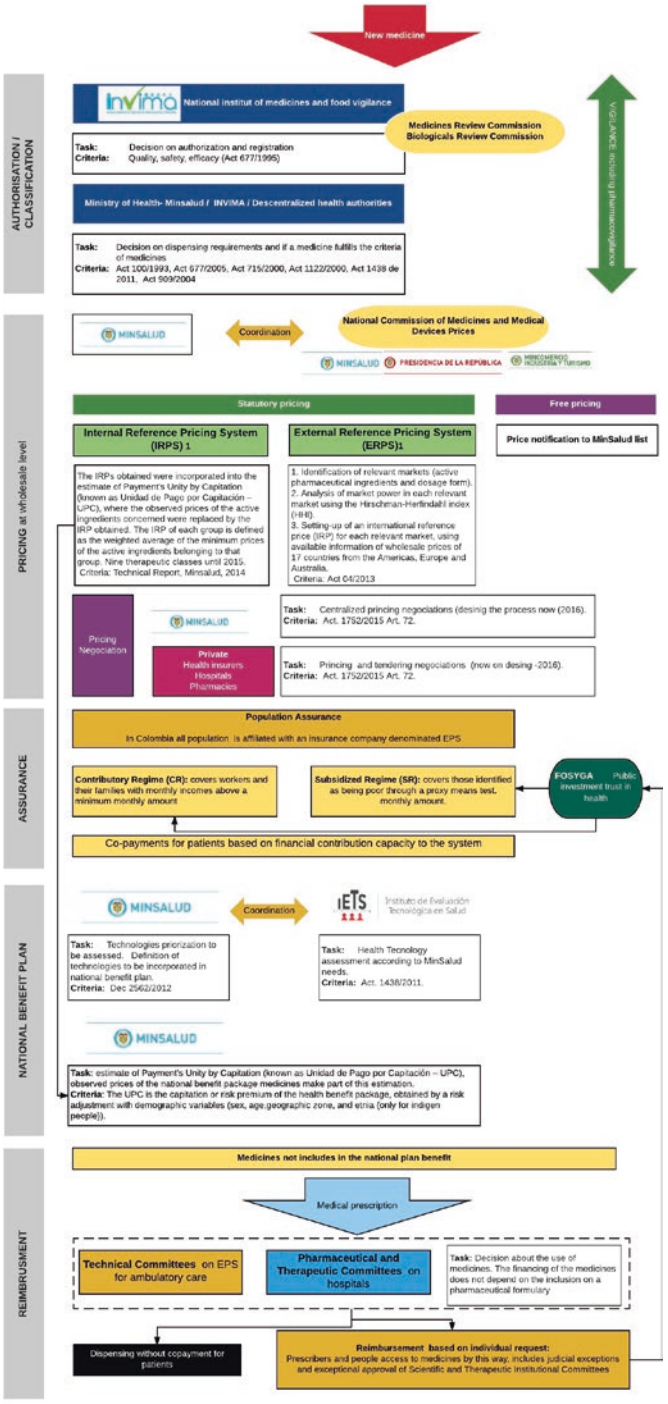

Fig. 10.2 Pricing and reimbursement policies scheme in Colombia

Adapted from: Third Pharmaceutical Pricing and Reimbursement Policies Meeting: Challenges beyond the Financial Crisis (12–13 October 2015, Vienna, Austria). Acosta A. Rapid Oral Presentation.

However, policymakers are aware of the short-term impacts of these policies, therefore, MoHSP has identified other strategies to implement other pricing policies, such as Risk Sharing Schemes and Value-Based Pricing.

10.7 Rational Medicines Use

The rational use of medicines and other health technologies have to consider all levels and stakeholders, including the end users, the consumer. Essential medicines' concepts and the definition of a national list of medicines were established by the SGSSS, but were not sufficient to ensure the incorporation of good practices and rational use of medicines by key stakeholders (health workers, IPS, EAPB, consumers, and communities) in the health system.

At the national level, it is important to note that the institutional arrangements to ensure an appropriate selection process of medicines covered by the SGSSS suffered many modifications and hardships between 1993 and 2015. However, the list of essential medicines has been periodically updated and it was last updated in December 2015. The current challenge is to shift the approach from explicit to implicit National Benefit Package (as described in Sect. 10.6).

In 2012 the NPP diagnosis the lack of information on prescription patterns in Colombia, and scarcity evidence about appropriate use of medicines. Since then to nowadays a significant progress has been made, more specifically from a pharmaceutical service provider and a pharmacoepidemiology research group joint with access to a representative database of different health centers from all the country [81–89].

Since 2015, the MoHSP is implementing activities in order to set up a National Program, including the participation of INVIMA and IETS; the program considers the establishment of the National Formulary, pharmaceutical advertisement regulation and antimicrobial resistance control [49]. Nevertheless, it is relevant to note that, with the NPP, public-private initiatives started to target rational use of medicines strategies [52, 53]. Fifty national Clinical and Therapeutic Guidelines have already been published and some are currently being developed.

Box 10.1 illustrates the pharmaceutical regulatory framework that covers diverse fields and regulations (Box 10.1)

Box 10.1 Legal Bases and Stakeholders (Authorities, Market and Health System Players of the Pharmaceutical Sector), Colombia, 2015

Field	Legal basis	Scope	Authority	Actors
Market authorization	Law 100/1993, art 245 Dec.677/1995 and main modifications	Decision on medicines authorization and registration under quality, safety and efficacy criteria	MSPS Invima	Pharmaceutical manufacturers and importers, holders of market authorization

Field	Legal basis	Scope	Authority	Actors
Medicines coverage by the Health System (SGSSS) Financing and reimbursement	Law 100/1993. Title III Decree 806/1998 Res. 5592 /2015	Medicines coverage by the benefit packages for: (1) individual services, UPC financed (POS); (2) special Programs (for PIC), MSPS funded. Description by active ingredient (INN), strength and dosage form. A specific use included on case basis	MSPS	Mix, and private health insurers – EAPB, public, and private healthcare providers (IPS, ESE) Prescribers and health workers
	Law 1122/2011, art. 33 Res. 518/ 2015	Directions on Public Health management and PIC operation (focus on coordination: Territorial entities, EAPB and IPS). Medicines for PIC described by Public Health program, INN, strength, and dosage form	MSPS	EAPB, IPS, ESE; prescribers and health workers; MSPS and Territorial Health Directorates (Department and Municipal)
	Decree 2562/2012	MSPS legal mandate for SGSSS key components definition (e.g., BP and financing)	MSPS	MSPS, IETS, and other stakeholders based on MSPS request
	Law 100/1993, art 187; Law 1122/2007 art 14 Cuervo CNSSS 260/2004 and 365/2007 Acuerdo CRES 30/ 2011 Circular 16/2014	Copayments and user rates User rates values include medicines prescription Exception for copayments and user rates based on regime (RS) or legal protection or criteria (e.g., displacement population, indigenous)	MSPS	EAPB, IPS, ESE; prescribers and health workers
	Res. 5395 de 2013	Legal procedure to claim medicines not included in the benefit plan package (POS)	MSPS	EAPB, IPS, ESE

(continued)

Field	Legal basis	Scope	Authority	Actors
Pricing	Law 04/2013 Res. 5592 de 2015	External Reference Pricing System (ERPS) Internal Reference Pricing System (IRPS)	NCMP	Manufacturers and importers, holders of market authorization, wholesalers, logistic operators, EAPB; IPS, ESE; prescribers and health workers
Purchasing	Laws 80/1993, 1150/2007 Decree-Law 4170/2011	Regulation on Public purchases and contracts Colombia efficient purchasing		ESE, mix EAPB, MSPS, Invima, ETs
Distribution	Decrees: 919/2004, 1950/1964, 2200/2005	Medicines donations, medicines storage, commercialization, distribution, dispensing	MSPS, Invima	ET's, EAPB, IPS, logistic operators, wholesalers and retailers.
Human resources	Law 212/1995, Decree 1945/1996	Provisions related to chemical pharmacist profession in Colombia	MSPS	Health professionals
	Law 485/1998 Decree 3616/2005	Provisions on other types of workers in the pharmaceutical field: "Tecnólogo en Regencia de Farmacia" – TRF and technicians (Auxiliar en Servicios Farmacéuticos)		Technologists and technicians professionals
Postmarketing surveillance	Laws 100/1993, 715/2001, 1122/2007, 1438/2011, Law 909/2004. Decree 677/1995	Dispensing requirements, pharmacovigilance and compliance of medicines quality criteria	MSPS, Invima, ETs	Pharmaceutical companies, holders of Market authorization Wholesalers, Logistic Operators, Health insurers, Health care providers, Hospitals, Pharmacies, Prescribers

Field	Legal basis	Scope	Authority	Actors
Services provision Surveillance	Decree 1011/2006, Res 1403/2007; Decree 2200/2005	Directions on the Obligatory System for Quality Assurance in Health (SOGCS) & IMC; pharmaceutical services	MSPS Supersalud	ETs public and private IPS-ESE pharmaceutical services
Intellectual property and public health	Andean Agreement Law Decisions 486/2000; Decree 2085/2002 Decree 1313/2010	WTO TRIPS Agreement adopted by Andean countries; data exclusivity; medicines parallel importing for SGSSS (TRIPS flexibility)	Andean Community; MSPS, SIC	Invima Manufacturers and importers. Holders market authorization, wholesalers, EAPB, IPS, ESE

Sources: Elaborated by authors based on regulation of MSPS and Invima; Supersalud and SIC. R.E.E. specific regulations not included

10.8 Final Considerations

This chapter provided an overview of the key features of the health system reform that Colombia implemented, and also presented the main progress and challenges of the country's pharmaceutical policy.

Achieving universal coverage for "nominal" healthcare of the Colombian population in 2014 and equalization of the subsidized and contributory schemes of the *Individual Services Package* – POS must be recognized together with the persistent challenges of equity, quality and sustainability. It is encouraging to know that the Statutory Law on the right to health opens the possibility of a renewed debate for all sectors involved to define a health policy and structure that responds to the characteristics of the country and the population.

The right of access to medicines as part of the right to health is a big challenge for the current pharmaceutical policy of the SGSSS, since there is a gap between nominal insurance coverage and the actual use of medicines. The valuable lists of essential medicines coverage by the SGSSS, along with Colombian low rates of out-of-pocket expenses, are elements favoring access to medicines.

The country has taken great strides in medicines regulation, through the strengthening of INVIMA. The local capacity for pharmaceutical manufacture has to be reinforced; there are competent human resources, but challenges persist to formulate and apply an industrial policy considering research, development, and production of medicines to meet population and health sector needs.

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