

What you need to know about key stakeholders and P&MA dynamics in Colombia for 2023 and beyond



Part 5 of 7

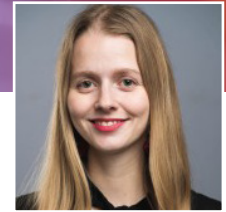
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Colombia

Colombia is the third-largest pharmaceutical market in Latin America. The country provides near-universal health coverage with 97% of the population receiving care under the public health service (SGSSS). Healthcare coverage operates under 2 schemes:

- 1) **Contributory:** For employees and/or persons who are able to pay for coverage, financed through contributions from the persons and their employers
- 2) **Subsidised:** For persons who are not able to pay and/or vulnerable populations, financed via cross-contributions from the contributory sector and national/regional taxes

In contrast with many other countries in the region, all drugs in Colombia are subject to an HTA by the National Commission for Health Technology Assessment (IETS), which is performed simultaneously with the regulatory assessment and considers the drug's safety, efficacy, efficiency, usefulness, and economic impact. The non-binding IETS recommendation informs the pricing decision by the National Commission for Pricing of Medicines and Medical Devices (CNPMDM), with 2 possible outcomes in terms of price setting depending on the drug's inclusion in the national compulsory health plan (POS). Products that the MoH includes in the POS are subject to a maximum wholesaler selling price. Non-POS therapies approved by the regulatory agency (INVIMA) are subject to free pricing, though since 2019 a price cap based on IRP has been established for non-POS products to limit pharmaceutical expenditure. Healthcare is provided via nearly 70 different public health insurers, which are obliged to provide all medical services/treatments within the POS. Premium innovative drugs are usually excluded



from the POS, but the Ministry of Health provides public health insurance plans (EPS) with a set annual budget to finance non-POS therapies.

Healthcare reforms in Colombia over the past 2 decades have been associated with rapid reduction in out-of-pocket expenditure and improvement in access to care. There is also a strong incentive to provide broad and equitable access to medicines and medical technologies to promote health across the country. Unified regulatory and HTA process creates opportunities for manufacturers to simplify and speed up access to patients by removing the obstacle of multiple payers and

Table 5: Key market access stakeholders in Colombia

| RESPONSIBILITY | STAKEHOLDER | | ROLE |
|---------------------------|-------------|---|--|
| Policy | MINSALUD | Ministerio de Salud y Protección Social–Ministry of Health and Social Protection | Responsible for national health policy |
| Regulatory | INVIMA | Instituto Nacional de Vigilancia de Medicamentos y Alimentos–Colombia Medicine Agency | National regulatory agency |
| HTA | IETS | Instituto de Evaluación Tecnológica en Salud– National Commission for Health Technology Assessment | A decentralised, private-public HTA entity that has brought credibility to the health technologies evaluation since its inception in 2011; it is also responsible for developing treatment guidelines, horizon scanning and early scientific dialogues |
| Pricing | CNPMDM | Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos– National Commission for Pricing of Medicines and Medical Devices | Entity responsible for the establishment and control of prices for pharmaceuticals |
| Payers/ Providers/ Others | SGSSS | Sistema General de Seguridad Social en Salud de Colombia–National Health System | Regulates essential primary care public health for the general population. There are 2 coverage systems: the contributory regimen for those with enough income, and the subsidiary regimen for those with limited resources |
| | EPSs | Entidades Promotoras de Salud–Health-Public Health Insurance | Responsible for the affiliation, the collection of contributions, and providing healthcare through the Plan Unico de Protección Integral (POS) from the Ministry of Health and Social Protection |
| | IPSs | Instituciones Prestadoras de Salud–Health Provision Institutions | Hospitals, clinics, and laboratories, among others, in charge of providing healthcare services |
| | ADRES | Administradora de los Recursos del Sistema General de Seguridad Social en Salud–Health System Fund Management Entity | Its objective is to guarantee the adequate flow of resources of the General System of Social Security in Health (SGSSS) and implement the controls |

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