

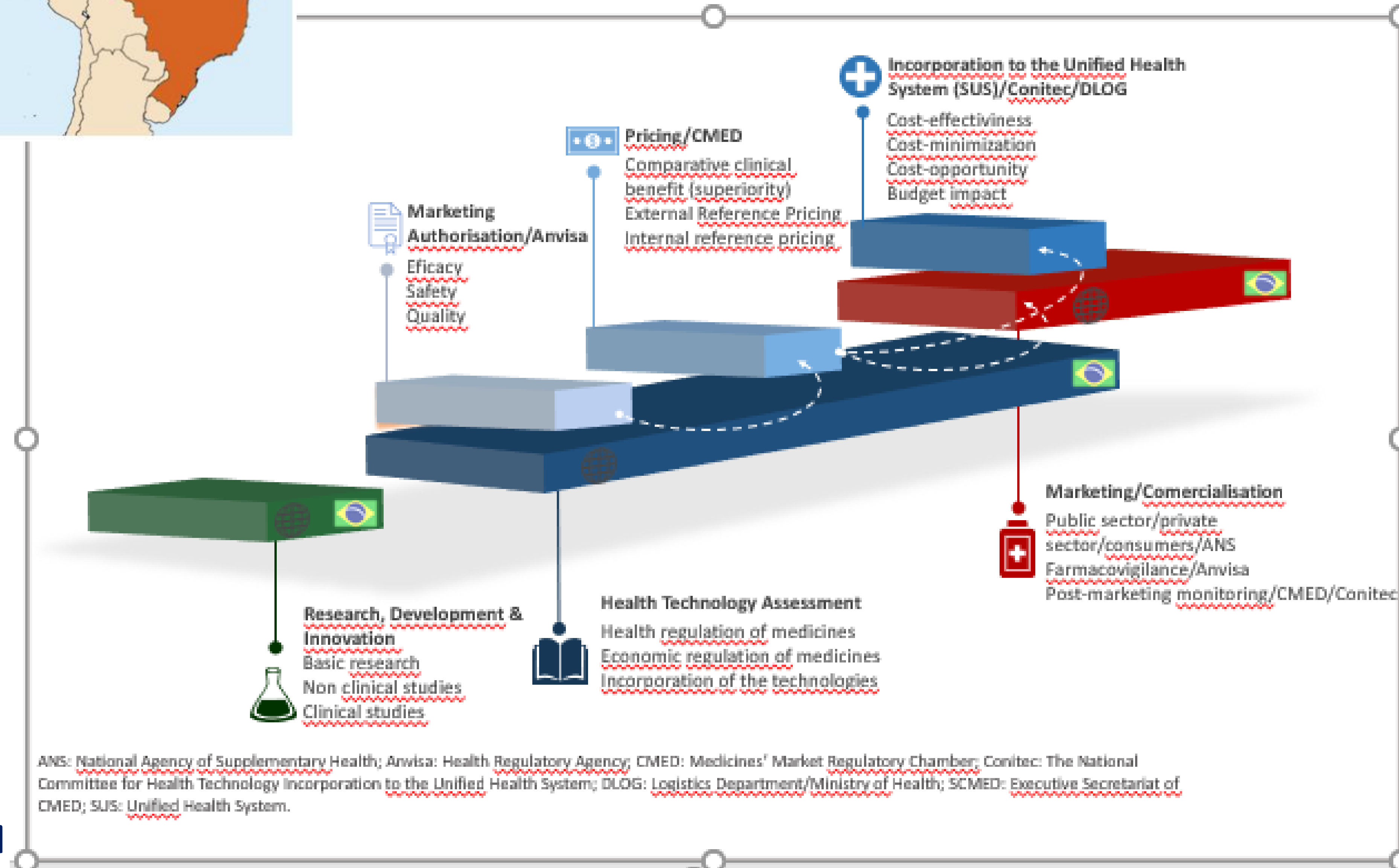
# Pharmaceutical pricing and reimbursement policies

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Total population (2016)	207,653,000
Gross national income per capita (PPP international \$, 2013)	14,750
Life expectancy at birth m/f (years, 2016)	71/79
Probability of dying under five (per 1 000 live births, 2017)	15
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2016)	194/91
Total expenditure on health per capita (Intl \$, 2014)	1,318
Total expenditure on health as % of GDP (2014)	8.3

Source: WHO (2019)



## PRICING OF MEDICINES – PRIVATE AND PUBLIC SYSTEM

Medicines' Market Regulation Chamber (CMED) was established in 2003. It is a cross-government body with representatives from the Ministry of Health (President), the Presidency's Office (Casa Civil), the Ministry of Economy and Ministry of Justice and Public Security and its Executive Secretariat at the Brazilian Health Regulatory Agency (Anvisa). The decision-making levels are the Ministerial Council, the Executive Technical Committee (CTE) and its Executive Secretariat (SCMED), a technical body for supporting the decision making and implementing its decisions and for monitoring the pharmaceutical market.<sup>2</sup>

Pricing mechanisms in Brazil are applicable to all medicines entering in the Brazilian market (out-patient and in-patient; public and private sector).

**Pricing policies for medicines:** The price authorisation by CMED is a mandatory requirement for all medicines entering in the Brazilian market. The pricing policy interventions include:

- **price cap** based on health technology assessment (HTA), using external reference pricing (ERP) (innovative medicines) and internal reference pricing (IRP) with generic medicines at 65% of the reference medicine prices;
- **mandatory discounts for public procurement (PMVG):** Price Adequacy Ratio (CAP) refers to a mandatory minimum discount, updated annually, that should be applied whenever medicines are procured by the public administration (Federal government, the States, the Federal District and the Municipalities). The CAP is applied to the Ex-factory Price - PF, resulting in the Maximum Government Selling Price (PMVG).
- **annual prices adjustments:** Adjustment ratios are calculated on the basis of three main factors: productivity factor, intra-sector relative price adjustment factor share and inter-sector relative price adjustment factor share;
- **tax exemptions:** these are the taxes on medicines: (i) Tax on transactions relating to the movement of goods and on the provision of interstate and intercity transport and communication services (ICMS); and (ii) contribution to the social integration and public equity programs (PIS/Pasep) and the contribution to the financing of social security (Cofins). The presumed credit grant of PIS/Pasep and Cofins is applied to prescription medicines from companies that adhere to the credit (positive list),
- **Price list publicly available:** updated electronic price lists are available online for outpatient medicines. Medicines for hospital use only don't have the prices published;<sup>7</sup>
- **monitoring of the pharmaceutical market:** there is an electronic system - Medicines' Market Monitoring System of Medicines (SAMMED) with mandatory annual communication of commercialisation data
- **mechanisms of compliance and enforcement:** non-compliant companies are fined (administrative law).
- **Wholesale remuneration (e.g. margins):** The distribution margin is 12% (informally negotiated);
- **Pharmacy remuneration (e.g. margins):** average margin between wholesaler and maximum consumer's price (PMC): 38%

For more information: [www.portal.anvisa.gov.br/cmcd](http://www.portal.anvisa.gov.br/cmcd)

## MEDICINES IN THE PUBLIC SYSTEM

### The National Committee for Health Technology Incorporation (CONITEC)

Provides therapeutic assistance and health technology incorporation into the Brazilian Public Health System (SUS). The purpose of CONITEC (part of the MoH's structure) is to advise the MoH in their duties related to the incorporation (uptake), disinvestment or alteration of health technologies by SUS, as well as the development or changes in Clinical Protocols and Therapeutic Guidelines (PCDT).

Medicines are provided free of charge at the Unified Health System (SUS) (out-patient and in-patient)

### Positive list / formulary

Brazil has positive lists of medicines to be provided in the Unified Health System (SUS): National List of Essential medicines (Rename) and Clinical Protocols and Therapeutic Guidelines - PCDT

**Timeframe:** The decision-making period of 180 days (extendable for an additional 90 days);

**Criteria:** includes evidence-based analysis, taking into account aspects such as technology efficacy, accuracy, effectiveness and safety, as well as comparative economic benefit assessment and costs in relation to existing technologies (marketing authorisation at Anvisa is a requirement for the technology to be evaluated for incorporation into the Unified Health System).

For more information: <http://conitec.gov.br/en/about-conitec>