

# BRAZIL

TOTAL POP. (2022): 203 MILLION  
POP. DENSITY (2022): 23.86 PER KM2 (4.51 – 91.77)  
GDP PER CAPITA (2022): US\$ 8,917

HEALTH SYSTEM: SUS – UNIVERSAL COVERAGE, TAX-FUNDED  
PRIVATELY FUNDED INSURANCE COVERAGE (25% POP.)  
HEALTH EXPENDITURE (2019): 9.6% OF GDP.

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## BRAZILIAN PUBLIC HEALTH SYSTEM (SUS)

### FUNDAMENTAL PRINCIPLES

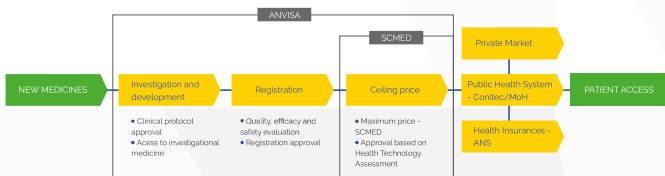
- Universal Coverage;
- Integrality;
- Equity;
- Social participation.

### CHALLENGES

- To provide free and universal assistance to more than 200 million inhabitants.
- To formulate national health policies in a country with large regional differences.

The Federal Constitution stipulates health as everyone's right and duty of the State, guaranteed through social and economic policies.

## ACCESS TO NEW MEDICINES IN BRAZIL



## PRICING: CMED (DRUG MARKET REGULATION CHAMBER)

- CMED Resolution No. 02/2004 approves the criteria for defining the prices of new products and new presentations of medicines. Statement No. 09/2016 discloses the pricing criteria for not-new biological drugs.
- The Brazilian model is based on PRICE CAP using internal and external price referencing.
- Regulatory Challenges: pricing of new therapies with rapid innovations (advanced therapy products, nano medicines, personalized treatments, orphan drugs); implementation of new pricing models in the face of increasingly higher proposed values, which may make the public and private health system unsustainable;

regulatory fragmentation derived from Resolution No. 02/2004: significant increase in cases characterized as omitted: pricing of drugs registered on a fast track basis, whose safety and efficacy evidence is precarious.

- Next steps: implementation of the Strategic Planning, aiming, through thematic groups, to update the normative framework of CMED, in particular the revision of CMED Resolution No. 02/2004, with the definition of criteria for the pricing of advanced therapies, products subject to incremental innovation and biosimilars.

## PROCUREMENT

### PUBLIC SECTOR:

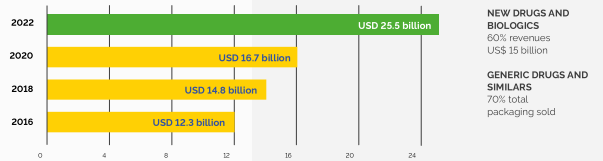
- Tendering based on RENAME, by Federal, State and Municipal Government
- Popular Pharmacy Programme (co-payment for primary care medicines)
- All medicines made available after assessment (HTA)

### PRIVATE SECTOR:

- Decentralized purchasing, different co-payment schemes
- Inpatient medicines must be covered
- Outpatient oncology medicines covered after assessment (HTA)

## BRAZILIAN DRUG MARKET

### BRAZILIAN DRUG MARKET REVENUE



source: <https://www.gov.br/anvisa/pt-br/contato/departamento/publicacoes/medicamentos/cmcd>

## PRICING

- External reference pricing system
- Health technology assessment
- Pharmacoeconomics analysis

### External reference pricing system

Australia, Greece, Canada, Italy, New Zealand, Spain, USA, Portugal and France, country of origin of the product

Ceiling price

### Internal reference pricing system

Cost of treatment, 95% discount - generics

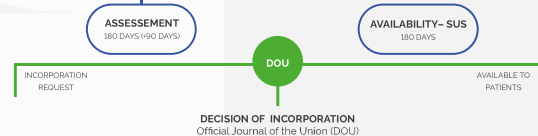
## REIMBURSEMENT AND COVERAGE

### SCIENTIFIC EVIDENCE

(Efficacy/safety/reticiveness)

### ECONOMIC EVALUATION

STUDIES (Cost-effectiveness)



Conitec opens public consultation in all demands.

Conitec considers multifactorial parameters, including cost-effectiveness threshold - 76 - 22.8 thousand dollars (around 1 to 3 GDPpc).

## DRUG PRICE CONSULTATION PANEL

The medicine price consultation panel was recently launched by CMED to help the population consult the prices of medicines authorized in Brazil. In this way, every citizen can contribute to monitoring the pharmaceutical market, in order to avoid overpricing in the country.



## TRANSPARENT RESPONSE TO SOCIETY

### PRICES ESTABLISHED BY CMED



### CONITEC EVALUATION PROCESS



### PRICES IN PUBLIC PURCHASES

