

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



## Part 2 of 7

Salvador Alvarez Rio, Dilyana Dimitrova  
& Dominika Meszarosova | PRECISIONadvisors



Salvador Alvarez Rio



Dilyana Dimitrova



Dominika Meszarosova

## Brazil

Brazil is the largest pharmaceutical market in Latin America with an estimated population of approximately 214 million. In 2019, 9.59% of the GDP was spent on healthcare with 20.5% of this being on pharmaceuticals and medical devices.

Brazil has a public health system predominantly represented by the Unified Health System (Sistema Único de Saúde, SUS) that covers every person legally living in the country. SUS is decentralised with funding by the Ministry of Health (MoH), states, and municipalities. Healthcare administration is handled regionally, leading to a lot of disparity in quality and access to care. Additionally, one-third of Brazilians have private health insurance regulated by the National Regulatory Agency for Private Health Insurance (ANS), which amounts to about 58% of the total healthcare expenditure.

The Brazilian Health Regulatory Agency (ANVISA) is responsible for the marketing authorisation of medicines based on their efficacy, safety, and quality. Once approved, a medicine is subject to price negotiations with Medicine Regulation Chamber (CMED) for maximum price approval (price cap). For drugs considered to be innovative, maximum wholesaler price is set using international reference pricing (IRP), while all other drugs are priced in line with the existing alternatives. Public reimbursement is contingent on the inclusion in the national list of medicines (RENAME), which is published by the MoH and takes into consideration the assessment by the national HTA body, National Committee for Technology Incorporation (CONITEC). The HTA process focuses on 3 key aspects: 1) effectiveness and safety vs existing drugs; 2) cost effectiveness, cost utility, or cost-benefit studies if therapeutic benefit is claimed and if there are additional costs compared to existing products; and 3) budget impact.



Despite having a national health system and a well-established HTA process, Brazil has one of the largest private health insurance markets in the world. Although the formation of CONITEC was associated with improvements in terms of time to access and transparency of the HTA process, most innovative and high-cost treatments tend to only be available through the private sector due to public budget constraints, further contributing toward disparities in access to care. Nevertheless, opportunities for manufacturers may arise as pharma-friendly policies are expected with the recent election of Luis Inácio Lula da Silva as president. Some of his goals are to increase healthcare spending and to strengthen the ANVISA workforce, which could lead to faster medicines approval.

**Table 2:** Key market access stakeholders in Brazil

RESPONSIBILITY	STAKEHOLDER		ROLE
Policy	MoH/MS	Ministério da Saúde –Ministry of Health	Responsible for national health policy
Regulatory	ANVISA	Agência Nacional de Vigilância Sanitária–Sanitary Vigilance National Agency	National regulatory agency
HTA	CONITEC	Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde–National HTA Commission	Responsible for advising the Brazilian Ministry of Health in the inclusion of health technologies into the SUS and development of clinical guidelines
Pricing	CMED	Câmara de Regulação do Mercado de Medicamentos–Medicine Regulation Chamber	The inter-ministerial body responsible for the economic regulation of the pharmaceutical market in Brazil. It also establishes limits for drug prices and sets and monitors the application of the mandatory minimum discount for public purchases
Payers/ Providers/ Others	SUS	Sistema Único de Saúde–Single Health System	Provides universal health coverage to the population. It is financed from the national, state, and municipal budgets and is conformed by public and private clinics (through agreements with the government)
	Privado	Seguro Privado–Private Insurance	Multiple hospital chains and national and international private health insurance companies operate in Brazil

**For further information, contact our market access strategy experts:**

**Salvador Alvarez Rio**  
 Senior Engagement Manager  
 PRECISIONadvisors  
[Salvador.AlvarezRio@precisionvh.com](mailto:Salvador.AlvarezRio@precisionvh.com)  
 Madrid, Spain

**Dilyana Dimitrova**  
 Consultant  
 PRECISIONadvisors  
[Dilyana.Dimitrova@precisionvh.com](mailto:Dilyana.Dimitrova@precisionvh.com)  
 London, UK

**Dominika Meszarosova**  
 Engagement Manager  
 PRECISIONadvisors  
[Dominika.Meszarosova@precisionvh.com](mailto:Dominika.Meszarosova@precisionvh.com)  
 London, UK

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