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OBJECTIVE

The Brazilian Universal Health System (BUHS) enact several policies to reduce access barriers to biological medicines, favoring biosimilars. After seven years since the authorization of the first biosimilars, we investigated the major gaps that hinders a greater participation of these products in the market.



METHODS

Through systematic regulatory review and expert interviews, a sustainability assessment of each policy area was conducted to provide a "sustainability rating". To inform a consistent application to rank a scorecard, which summarizes the potential benefits of biosimilars for various stakeholders, it was first developed based on existing literature and validated with experts in biosimilar policies. The holistic dimensions assessed were Regulatory Approval, Pharmacovigilance, HTA Requirements, Contracting, Reimbursement, Medical Education, and Prescribing Behavior, using a 5-point Likert scale regarding the extent to which current policies allow various stakeholders to perceive benefits to be achieved with biosimilars.



RESULTS

	Health Technology Assessment	Private ★★★★★	Public ★★★★★ High-cost Bx Low-cost Bx
	Regulatory Approval	★★★★☆	
	Manufacturing and R&D	★★★☆☆	
	Prescribing	★★★★☆	
	Contracting	Private ★★★★☆	Public ★★★☆☆
	Dispensing	★★★☆☆	
	Monitoring	★☆☆☆☆	
	Pricing & Reimbursement	★☆☆☆☆	
	Biosimilar Education & Understanding	★☆☆☆☆	

Marketing Authorization and Health Technology Assessment were evaluated as the most sustainable aspects in relation to biosimilars policies. Dimensions with mixed results were industrial policy to foster local production, contracting (public centralized tender diminish hospital formulary inclusion lowering competition and private payers reduced the ability of payers to pressure for switch can limit cost savings) and absence of consensual policies to promote (by incentives) or regulate(compulsory or not) biosimilars prescription. Less sustainable aspects valued by all stakeholders as pharmacovigilance monitoring, no broad educational efforts in medical education and lack of specific pricing policies for biosimilars.

Key biosimilar policy priorities listed to achieve long-term sustainability in Brazil are developing transparent pricing guidelines specific to biosimilars, which understand their differences compared to generics and account for their benefits to the system; implementing broad educational campaigns to target all stakeholders involved in the biosimilars lifecycle; and establishing clear and transparent pharmacovigilance guidelines to ensure proper monitoring of biosimilars.

Table 1. Evaluated Policy Area and 5-point "star rating" scale.



CONCLUSION

These findings reveal the potential to further improve policies designed to expand access to complex biological medicines across health system to improve local production, competition, and entrance of this products in the market, simultaneously overcome challenges related to medical education and absence of specific parameters to price biosimilars, to improve Health System sustainability and ultimately improve access for Brazilian patients.



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