Brazilian investments in medicines for poverty-related diseases: strategies to ensure access

Investimentos brasileiros em medicamentos para doenças relacionadas com a pobreza: estratégias para garantir o acesso

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ABSTRACT

Introduction: Financing the access to medicines has been one of the greatest challenges facing health systems all around the world. For diseases that attract lower levels of interest and medicine offers across the market, that challenge gets bigger. This study investigates the main strategies adopted by the Brazilian government to guarantee access to medicines for diseases identified as "poverty-related".
Methods: We analyzed acquisitions made by the Brazilian federal government over 10 years (2005 to 2014) sourced from the database of the Ministry of Health, indicating three main strategies to face the difficulties of guaranteeing access to these medicines. (I) Centralization of the financing and acquisition for the great majority of the medicines; (II) Acquisition via multilateral organizations and (III) Production of medicines by official laboratories.
Results: 132 medicines are included in the National List of Essential Medicines (RENAME in force, used in order to prevent and treat poverty-related diseases. More than a half (55.3%) of the items have only one national producer or are not registered and therefore can only be obtained through international acquisition to attend consolidated health programs such as tuberculosis, leprosy, malaria or even for disease prevention of nutritional actions and for immunization actions. However, the findings from this study document ways to approach access to medicines for poverty-related diseases.

Conclusions: The observation of these strategies enables us to verify the advances and improvement points of the Brazilian Pharmaceutical Policy, in view of preventing setbacks during moments of crisis and guaranteeing assistance to populations.

Keywords: Poverty, Neglected Diseases, Access to Medicines, Inequities in Health.

RESUMO

Introdução: O financiamento do acesso aos medicamentos tem sido um dos maiores desafios enfrentados pelos sistemas de saúde em todo o mundo. Para doenças que atraem níveis mais baixos de interesse e ofertas de medicamentos em todo o mercado, esse desafio se torna maior. Este estudo investiga as principais estratégias adotadas pelo governo brasileiro para garantir o acesso a medicamentos para doenças identificadas como "relacionadas à pobreza".

Métodos: Analisamos as aquisições feitas pelo governo federal brasileiro ao longo de 10 anos (2005 a 2014) com origem no banco de dados do Ministério da Saúde, indicando três estratégias principais para enfrentar as dificuldades de garantir o acesso a esses medicamentos. (I) Centralização do financiamento e aquisição da grande maioria dos medicamentos, (II) Aquisição via organismos multilaterais e (III) Produção de medicamentos por laboratórios oficiais.

Resultados: 132 medicamentos estão incluídos na Lista Nacional de Medicamentos Essenciais (RENAME em vigor, utilizado para prevenir e tratar doenças relacionadas à pobreza. Mais da metade (55,3%) dos itens tem apenas um produtor nacional ou não estão registrados e, portanto, só podem ser obtidos através de aquisição internacional para atender programas de saúde consolidados como tuberculose, hanseníase, malária ou mesmo para a prevenção de doenças de ações nutricionais e para ações de imunização. Entretanto, os resultados deste estudo documentam formas de abordar o acesso a medicamentos para doenças relacionadas à pobreza.

Conclusões: A observação destas estratégias nos permite verificar os avanços e pontos de melhoria da Política Farmacêutica Brasileira, com vistas a prevenir recuos durante momentos de crise e garantir assistência às populações.

Palavras-Chave: Pobreza, Doenças Negligenciadas, Acesso a Medicamentos, Desigualdades em Saúde.

1 BACKGROUND

In times of economic crisis, the health sector is always threatened through discourses on financial cuts and actions of fiscal austerity. However, at such moments, social protection policies, such as the Unified Health System (SUS) in Brazil, have a strategic role to play in facing the increasing prevalence of conditions related to the mental suffering, certain chronic conditions and poverty-related diseases. The contingent of people, who no longer have resources to pay private care or health insurance plans, causes an increase in the demand for health care provided by the State. Furthermore, inappropriate use of medicines by the poor could exacerbate health

disparities, since poverty is associated with poor health and the need for more medicines[1]. International experiments have also shown that countries in crisis that have maintained their investments in health were able to overcome the difficulties faster and there was less impact on social welfare indicators compared to other countries that imposed cuts in this area [2,3].

If the global investment in health is threatened at such times, maintaining access to medicines with less market interest tends to be even more critical, especially for diseases that are identified as poverty-related. These diseases, disorders and injuries result in and contribute to the perpetuation of poverty condition and social vulnerability. This scenario has already established a permanent picture of minimal research in medicines and also difficulties to adopt available measures to advance the health system. They are often characterized by requesting older and less expensive drugs for the health system. In Brazil, these drugs are covered by the public program entitled Strategic Conditions Component of the Pharmaceutical Assistance [4,5]. In this country, poverty-related diseases are particularly important health issues. They are the result of poor living conditions, insufficient access to adequate and healthy food, clean drinking water, medical care and education [4–7]. Some infectious diseases such as HIV, considered to be related to poverty globally, in Brazil are not classified as neglected or poverty related. Particular healthcare facilities and medicines are available and accessible for people living with HIV.

Poverty-related diseases are responsible for 13.8% of the global disease burden, but receive only 1.34% of global health-related research and development expenditure. This exposes the two-way relationship between the persistence of these diseases and the social and economic development of countries, transferring the responsibility of their eradication to governments [4,5,8,9].

The definition of financing policies for diseases related to poverty is configured as equity strategy on access to health care. The current Brazilian scenario shows the clear reduction of investment in research on equity actions on health as well as the prevalence of economic studies that are more restricted to certain clinical outcomes to the detriment of studies that evaluate costs and expanded benefits, including parameters of social determinants about health [10].

Stevens [11] proposes that the lack of access to a great part of the medicines for poverty-related diseases cannot be attributed only to the low amount of clinical research carried out or investments in industries, but also the failures in mechanisms to

define public policies on management, financing and access to medicines that are already available. It is necessary to ensure access to medicines in different parts of the country, at a sustainable cost, avoiding shortage, forgeries, quality deviations and the adoption of proper guidance [11–13].

This article analyses the investments in medicines for poverty-related diseases in Brazil, the world's fifth most populous country, with 207 million people. It is a federal republic and its political system is composed of several political parties and three levels of autonomous government: federal government, 26 states and one district and 5,563 municipalities. The Brazilian health system (the Unified Health System - SUS) is under the shared responsibility of the federal government, states and each municipality, highlighting its governance complexity.

The SUS is committed to offering health care to the entire population, including the distribution of essential medicines free of charge aimed at treating the most prevalent diseases and expensive medicines to treat rare diseases [14]. SUS provides access to medicines and pharmaceutical services at both primary and specialized public health facilities, which includes the selection, acquisition, distribution and dispensing of medicines. Currently, free access to medicines for the treatment of chronic diseases occurs to a significant portion of the Brazilian population, especially for the poorest ones, indicating decreased socioeconomic inequalities in access to medicines. A national survey revealed that about half of adults who have been diagnosed with a chronic disease in Brazil obtained all required medicines for free. Nevertheless, some differences between regions and between some types of medicines can still be observed [15].

Brazilian policies have also indicated the need to invest in health through industrial and technology policies with the aim of national autonomy in producing key materials. Several strategies for improving access to medicines, including investments in science, technology and innovation in the national efforts for economic, social and sustainable development to reducing vulnerabilities can be found in Brazil’s national health plans and industrial policies [13].

Giving a series of financing conflicts and the definition of priorities in public health policies, this article intends to contribute to an analysis of the Brazilian strategy for financing and supplying medicines for diseases related to poverty. In addition, it highlights the importance of paying attention to the “equity” factor in access to medicines.

2 METHODS

This is an exploratory study, with descriptive-analytical aspects and a methodological process organized in three phases.

In the first phase, a review was performed of the drugs included in the National List of Essential Medicines (RENAME) indicated for prevention and treatment of diseases and aggravated diseases related to poverty[16].

As there are disagreements in the definition of these conditions, the authors adopted the classification of previous studies [4,5], based on the adaptation of concepts adopted by the World Health Organization (OMS) and Doctors Without Borders (MSF), categorizing them as diseases and aggravated diseases: (I) Global non-transmissible, (II) Global transmissible and (III) Related to poverty [6,7].

Having identified the list of medicines for diseases and worsening related to poverty of the RENAME, the second phase consisted of a search in the database records of the National Agency of Sanitary Surveillance (Anvisa) and the Regulation Chamber of Medicines Market (CMED), with the intent of verifying the availability of active records of pharmaceutical laboratories for production and national commercialization.

In the third phase, there was accomplished budget data collection and acquisition processes of these medicines at federal level between January 2005 and December 2014. For this purpose, internal records of the Pharmaceutical Assistance Department of the Ministry of Health, information from the Strategic Inputs Information System (SIES) were also used from this Ministry as well as information on the contracts signed between the Ministry and its suppliers. Authentic information was collected from the contracted supplier/producer (official laboratories, laboratories and multilateral organizations) and contracted values. The evolution of expenditures was compared to the evolution of budgets for the HIV/AIDS program; the Specialized Component of Pharmaceutical Assistance; and expenses with drug trials.

All figures were updated according to annual average of the Broad Consumer Price Index (IPCA) of the Brazilian Institute of Geography and Statistics (IBGE) in 2018 [17]. This index was chosen because it is used by the federal government to update medicine prices [18]. The prices were converted from Brazilian Real (BRL) to United States Dollar (USD). In the international contracts that presented values of acquisition in dollars, the conversion was performed using the standard conversion values defined in the contracts.

Based on this data, three main strategies performed by the Ministry of Health with the objective of guaranteeing the access to medicines for poverty-related diseases were identified and are described below.

3 RESULTS

One hundred and thirty-two medicines we identified in the RENAME in force, used in order to prevent and treat poverty-related diseases. With the survey of companies registered in the country in relation to these medicines, it is possible to observe a limited number of pharmaceutical companies registered. More than a half (55.3%) of the items have only one national producer or do not have a registration and therefore can only be obtained through an international acquisition to attend consolidated health programs such as tuberculosis, leprosy, malaria or even for disease prevention of nutritional actions and for immunization actions (see Table 1).

Table 1 – Medicines for diseases of poverty and their number of companies registered in Brazil on August 2016

Poverty Diseases	Records	No Records	01 Record	02 Records	03 Records	04 or + Records	Total
Infectious Diseases Immunopreventable	2.28	05	09	06	02	04	26
Infectious Diseases Not Immunopreventable	3.41	16	34	08	09	25	92
Other Poverty Diseases	2.61	03	06	00	01	04	14
Total	**3.05**	24(18.2%)	49(37.1%)	14(10.6%)	12(9.1%)	33(25%)	132

It is understood that the existence of only a few national pharmaceutical companies generate a picture of insecurity in the supply of products, since regulatory and production problems in Brazil or in the country of origin can generate shortages.

Botelho et al. showed that the last drugs registered in the country are characterized by items that are not in agreement with the Brazilian disease burden, with only 17% of them classified as important therapeutic innovation [19]. Santana et al. also advance that despite the expansion of the medicines supply for diseases of poverty in RENAME in recent years, the scarcity of records for these technologies jeopardizes the sustainability of SUS strategic programs [5]. Both affirm that strategies for guiding drug research to meet

national needs and promoting the registration of medicines with little commercial appeal should be actions of public health policies [5,19].

Strategy 01 – Centralization of the financing and acquisition

On the 132 drugs identified in the RENAME 2017 edition, 79% (105) have federal government funding for acquisition. The resource comes basically from the so-called Strategic Component of Pharmaceutical Services, established by Ordinance nº. 204/2007, which defines the financing blocks of SUS. This component is intended to guarantee access to medicines for diseases and aggravated diseases with an endemic profile, with epidemiological importance, socioeconomic impact or that affect vulnerable population, included in SUS strategic programs [20,21].

In other developing countries, about 50-90% of essential medicines need to be purchased by the patient himself/herself, which may be unviable when dealing with diseases affecting vulnerable populations and for the cost of new treatments for tuberculosis, HIV/AIDS or malaria, for example [22].

Federal government accountability for the acquisition of most medicines for poverty-related diseases is a successful strategy that may inspire other countries to formulate similar policies or structuring regional collaborations, since the demand for the production of such medicines is not always cost-effective for an industrial scale gain.

The centralization of financing, planning and concentration of demand and single flow of care to the Ministry of Health is a crucial strategy for public laboratories to meet the needs of this type of treatment.

Souza et al. demonstrate that this strategy of financing centralization, information and demand in the Ministry of Health contributes to the effective delivery of medicines to SUS through official public laboratories, with the federal agency as the main client. Failure to structure an adequate flow of information on demand and distribution channels may justify the fact that this same success is not achieved to meet the demands of medicines for states and municipalities [23].

Strategy 02 – Acquisition of medicines by multilateral organizations

For an immediate solution to access medicines that are not registered or produced in Brazil, the country uses the import strategy through multilateral organizations.

The entry of medicines without registration in the country is based on regulations such as Law No. 9,782 of 1999 which states, referring to Anvisa:

> "The Agency may exempt from registration immunobiologicals, insecticides, drugs and other strategic inputs when purchased through international multilateral organizations for use in public health programs by the Ministry of Health" [24].

Law nº. 10,191 of 2001 further corroborates that these acquisitions "may be performed through international multilateral organizations, of which Brazil is a party and will obey the procedures adopted by them" [25].

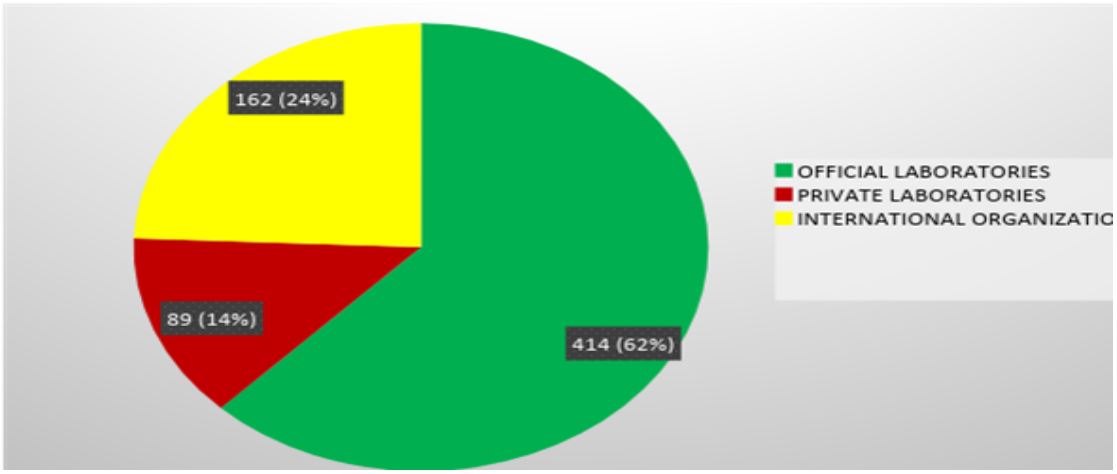
For imported items, the main form of acquisition is via technical cooperation with the Pan American Health Organization (PAHO), which uses the so-called Strategic Fund for Medicines, responsible for the acquisition of vaccines, antiretroviral and treatment of poverty-related diseases in the Americas [26].

Strategy 03 – Strengthening and using official laboratories

In Brazil, actions to strengthen public laboratories were essential to guarantee the supply of medicines for diseases of poverty. For items produced in the country, the offer is essentially guaranteed by the network of official laboratories. In 2014, for example, these public laboratories were responsible for supplying 50% (35) of purchases made by the Ministry of Health for diseases of poverty.

As can be seen in Figure 1, the official laboratories were responsible for handling almost two-thirds of the purchases made by the Ministry of Health during a period of 10 years between 2005 and 2014.

Figure 1 – Drug supply routes for Poverty Illness between 2005 and 2014, by number of acquisitions.



Prepared by the authors

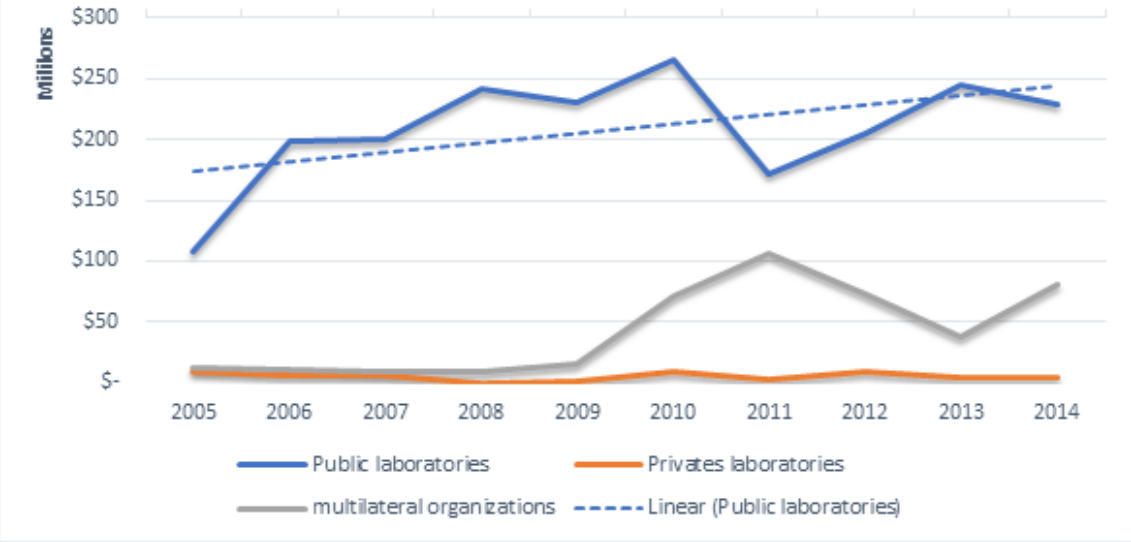
Since 2000, with the organization of Brazilian Network of Public Production of Medicines and the structuring of the procurement mechanism centralized by the Ministry of Health, it was possible, at the same time, to invest in the integration and technological capacity of official laboratories and also to adequately measure the national demand of medicines for care [27].

The small percentage of private laboratories in providing medicines for diseases related to poverty (14%) contrasts sharply with the large share of high-cost drugs in the Specialized Component of Pharmaceutical Services, for example. In 2014, private laboratories accounted for 68.7% [28] of centralized drug purchases for this component.

The research investment of private laboratories is centered on health care programs that use high-cost drugs, especially for non-communicable chronic diseases such as cancer and rheumatoid arthritis, or even transmissible with a chronicity profile and great governmental institutionalization such as HIV/AIDS and viral hepatitis [4].

The contrast of participation of private laboratories and public laboratories can also be observed in relation to the expenditures of the Ministry of Health over these years, as shown in Figure 2.

Figure 2 – Routes of medicines supply for Poverty Diseases between 2005 and 2014, by resource volume.



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It can be observed that the participation of private laboratories in the volume of resources destined to this group of medicines is constant and not very expressive, representing less than 2% (USD 36 million) of the acquisitions made during the period.

The acquisitions of multilateral organization accounted for almost 23% of the acquisitions (USD 477 million), characterized by oscillations of growth and a decrease in

the percentage of purchases, depending on the demands for incorporation of different medicines. This is on account of the fact that the acquisition by import is usually the strategy used when there is inclusion of a certain technology in SUS, not yet produced in the country. The percentage of this acquisition route is reduced when production is developed by a national public laboratory. The impact of the incorporation of the vaccine for the prevention of meningococcal meningitis C in the vaccine calendar from 2010 and 2011, obtained by PAHO at the time, can be clearly observed in Figure 2.

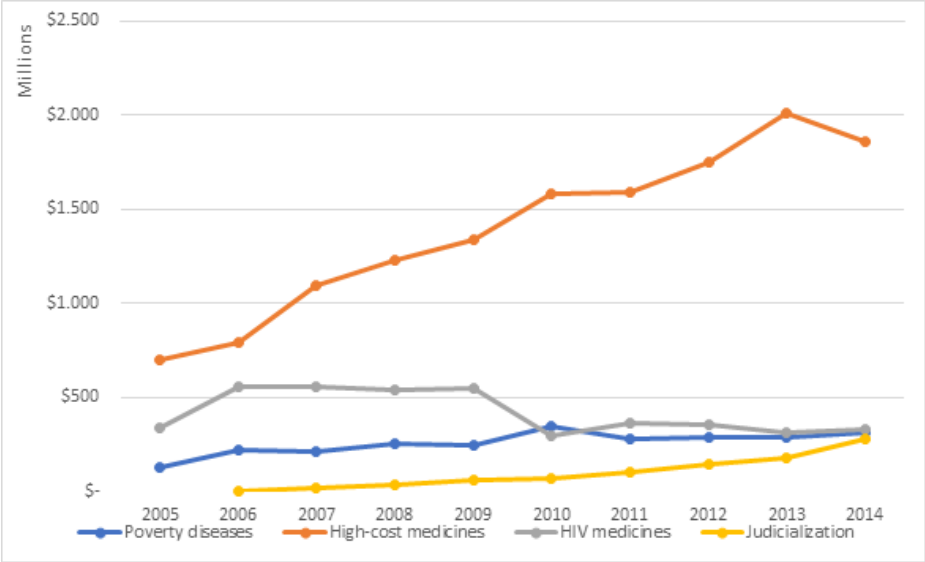
The participation of public laboratories also presents some oscillations, but with a general tendency of growth, representing about 75% of the total acquisitions during the period of evaluation (USD 1.6 billion).

Contradictions in the division of the budget: a threat to the sustainability of funding? Some discussion

Even with the strategy of the Brazilian Pharmaceutical Policy for poverty-related diseases, it is not possible to escape the reproduction of social contrasts when the spending on sets of medicines is observed.

Figure 3 shows the sharp increase in the budget for high-cost medicines (Specialized Component), already reaching the mark of 2 billion annually and, therefore, each year, surpassing the expenses of a decade of acquisitions of poverty-related diseases medicines.

Figure 3 – Comparison of the medicines costs evolution for diseases of poverty, and HIV/AIDS budgets, high cost and litigations demand.



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In 2013 and 2014, the average medicine costs for each patient of the Specialized Component was already higher than USD 1,193.3 [22,26]. However, recent incorporations of new medicines have had a significant impact on the budget, such as new treatments for chronic viral hepatitis C and arthritis. Although it is considered an example of good negotiations if compared to other countries, Brazil still spends between USD 11 and USD 22 thousand per hepatitis treatment [29]. A public laboratory has developed the generic medicine for hepatitis C, however, a court decision has impeded its registration.

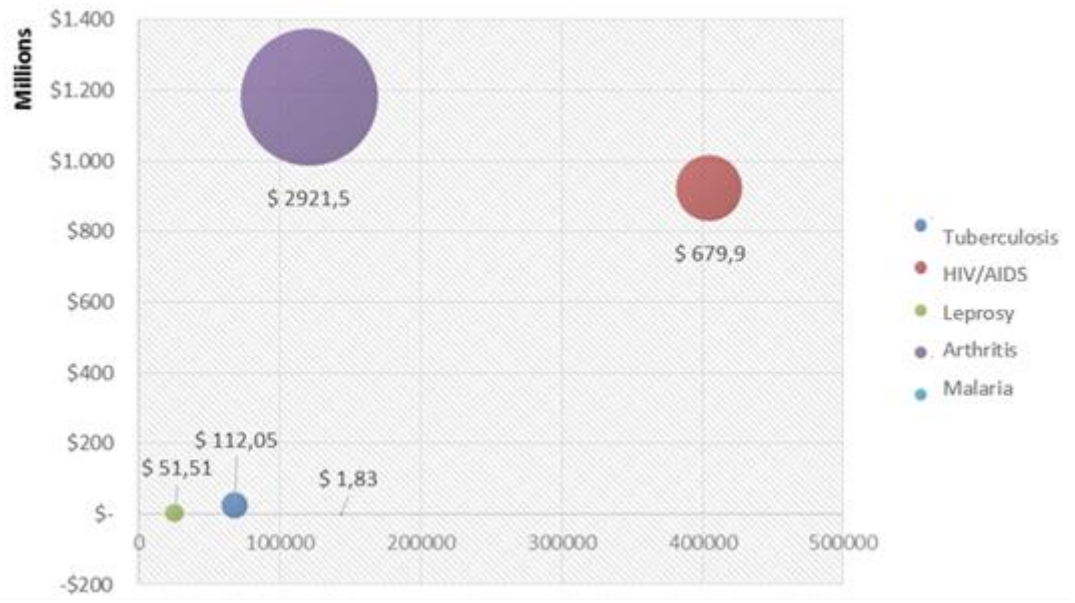
Likewise, the growth in expenses with litigations to access high cost medicines also represents risks [30], since there is no planned budget which forces the government to reallocate resources from other programs and investments. This unplanned reallocation is expensive for health policies, as demonstrated by Chieffi and Barata [31] in the experience of the state of São Paulo, where the average cost per patient in the judicialization represented almost 10 times the cost of one patient of the high cost program. This calls for a debate on issues of equality in pharmaceutical services and decision-making in health technologies affordability [30].

The acquisition expenditures on antiretroviral medicines for HIV/AIDS patients, reaching close to USD 300 million per year, outweigh the annual expenses on medicines for poverty-related diseases (USD 239 million per year).

Previous studies by the Applied Economic Research (IPEA) had shown this discrepancy, noting that treatment costs for tuberculosis, leprosy, malaria and leishmaniosis accounted for only 4.6% of annual expenditure on HIV/AIDS antiretrovirals, although the number of cases of the first four diseases is 3.4 times higher than HIV cases [32].

Figure 4 shows the dispersion of the investment discrepancy by served population (per capita). Malaria, for example, which in 2014 had a number of people (143,552) close to the population treated for rheumatoid arthritis (120,483), has per capita investments with medicines (USD 1.83) that are much smaller than the latter (USD 2,921.5) [33,34].

Figure 4 – Comparison between the served population (x), medicine costs (y) and per capita value (ball size).



Prepared by the authors

This difference can be explained by the dynamic of public and private investments in the area of medicines. Since diseases related to poverty have involve a low percentage of innovation, they are characterized by old treatments and mostly produced by public laboratories or acquired by importation. Medications for diseases such as rheumatoid arthritis, HIV/AIDS or viral hepatitis have great investments in innovation, continuous launches of new products with patents and little national production by public laboratories [29,32,35,36].

4 CONCLUSION

The findings of this study enable us to verify that different strategies were adopted by the Brazilian government in the last decade in order to overcome deficiencies in the supply of medicines for diseases related to poverty.

The use of collaboration with multilateral organizations enabled the access to medicines unavailable in the country and often without any interest of production by the national pharmaceutical industry.

The centralization of financing by the Ministry of Health and the use of public laboratories enable the sustainability of access, since the acquisition of inputs in reduced quantity and low-cost inputs is hampered in a context of decentralization for states and municipalities, as there is no interest for private pharmaceutical companies.

The use of these strategies for other types of medicines should be considered in resource saving strategies to avoid competition over budgetary resources from damaging successful actions of the pharmaceutical care policy. Adjusting Brazilian commercial and economic policies to guarantee access to poverty-related disease drugs is an important strategy for the protection and promotion of human rights.

REFERENCES

1. Wirtz VJ, Hogerzeil H V., Gray AL, Bigdeli M, de Joncheere CP, Ewen MA, et al. Essential medicines for universal health coverage. The Lancet. 2017.

2. Instituto de Pesquisa Economica e Aplicada (IPEA). Nota Tecnica nº 26 - Crise econômica, austeridade fiscal e saúde: que lições podem ser aprendidas? Disponível em: http://www.ipea.gov.br/portal/images/stories/PDFs/nota_tecnica/160822_nt_26_disoc.pdf. 2016. p. 34.

3. Kruger TR. Stuckler D, Basu S. A economia desumana: porque mata a austeridade. Lisboa: Bizâncio; 2014. Saúde em Debate. 2019;

4. Santana RS, Leite SN. Prioridades da pesquisa clínica com medicamentos no Brasil e as doenças da pobreza. Rev Panam Salud Publica. 2016;40(5):355–61.

5. Santana RS, Lupatini E de O, Leite SN. Registro e incorporação no SUS: Barreiras de acesso a medicamentos para doenças da pobreza? Cien Saude Colet. 2017;22(5):1417–28.

6. Médicos Sem Fronteiras. Desequilibrio fatal: a crise em pesquisa e desenvolvimento de drogas para doenças negligenciadas. Geneva: Grupo de Trabalho de Drogas para Doenças Negligenciadas, Médicos Sem Fronteiras. 2001.

7. World Health Organization. Global report for research on infectious diseases of poverty. 2012. 1–184 p.

8. WHO. Integrating Neglected tropical diseases into global health and development: fourth WHO report on neglected tropical diseases. World Health Organization. 2017.

9. von Philipsborn P, Steinbeis F, Bender ME, Regmi S, Tinnemann P. Poverty-related and neglected diseases – an economic and epidemiological analysis of poverty relatedness and neglect in research and development. Glob Health Action [Internet]. 2015 Dec 21 [cited 2018 Aug 29];8(1):25818. Available from: https://www.tandfonline.com/doi/full/10.3402/gha.v8.25818

10. Mclntyre D, Mooney G. Aspectos econômicos da equidade em saúde. Fiocruz, editor. Rio de Janeiro; 2014. 348 p.

11. Stevens P. O combate às Doenças da Pobreza. Porto Alegre: Sul Editores; 2008. 303 p.

12. Hunt P, Khosla R. The human right to medicines. Sur - Int J Hum Rights. 2008;(8):99–115.

13. Thorsteinsdóttir H, Ovtcharenko N, Clare Kohler J. Corporate social responsibility to improve access to medicines: the case of Brazil. Global Health. 2017;13(10).

14. Paim J, Travassos C, Almeida C, Bahia L, Macinko J. The Brazilian health

system: history, advances, and challenges. Lancet. 2011 May;377(9779):1778–97.

15. Tavares NUL, Bertoldi AD, Mengue SS, Arrais PSD, Luiza VL, Oliveira MA, et al. Factors associated with low adherence to medicine treatment for chronic diseases in Brazil. Rev Saude Publica. 2016;50.

16. Brasil. Ministério da Saúde. Secretaria de Ciência Tecnologia e Insumos Estratégicos. Relação Nacional de Medicamentos Essenciais: Rename 2017. Disponível em:http://bvsms.saude.gov.br/bvs/publicacoes/relacao_nacional_medicamentos_rename_2017.pdf. 2017. p. 210.

17. IBGE. Índice Nacional de Preços ao Consumidor Amplo. Disponível em: https://www.ibge.gov.br/estatisticas-novoportal/economicas/precos-e-custos/9256-indice-nacional-de-precos-ao-consumidor-amplo.html?=&t=o-que-e. 2020.

18. David, G.; Andrelino, A.; Beghin N. Assessment of expeditures on medicines within the federal scope of SUS between 2008 - 2015. Brasília: Inesc, 2016. http://www.inesc.org.br/library/publications/right-to-medicines. 2016;

19. Botelho SF, Martins MAP, Reis AMM, Botelho SF, Martins MAP, Reis AMM. Análise de medicamentos novos registrados no Brasil na perspectiva do Sistema Único de Saúde e da carga de doença. Cien Saude Colet [Internet]. 2018 Jan [cited 2018 Aug 29];23(1):215–28. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S141381232018000100215&lng=pt&tlng=pt

20. Marques RM, Piola SF, Roa AC. Sistema de Saúde no Brasil: organização e financiamento. 2016. 260 p.

21. Agência Nacional de Vigilância Sanitária. Resolução RDC nº 204 de 14 de novembro de 2006 que estabelece as Boas Práticas de Distribuição e Fracionamento de Insumos Farmacêuticos. Disponivel em: http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2006/res0204_14_11_2006.html. 2006.

22. Organización Mundial de la Salud. Acceso equitativo a los medicamentos esenciales: un marco para la acción colectiva. Perspect políticas la OMS sobre Medicam. 2004;8:1–6.

23. Souza ALP de, Pitassi C, Bouzada MAC, Gonçalves AA. A Rede Brasileira de Produção Pública de Medicamentos na perspectiva da gestão de cadeias de suprimentos: o papel das TIC. Rev Adm Pública. 2015 Jun;49(3):615–41.

24. Brasil. Presidência da República. Lei nº 9.782 de 26 de janeiro de 1999 que define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. Disponível em: http://www.planalto.gov.br/ccivil_03/leis/L9782.htm. 1999.

25. Brasil. Presidência da República. Lei nº 10.191 de 14 de Fevereiro de 2001 que dispõe sobre a aquisição de produtos para a implementação de ações de saúde no âmbito do Ministério da Saúde. Disponível em:

http://www.planalto.gov.br/ccivil_03/leis/LEIS_2001/L10191.htm. 2001.

26. Horst MML de L, Soler O. Fundo Estratégico da Organização Pan-Americana da Saúde: mecanismo facilitador para melhorar o acesso aos medicamentos. Rev Panam Salud Pública. 2010 Jan;27(1):43–8.

27. Magalhães JL De, Antunes AMDS, Boechat N. Laboratórios farmacêuticos oficiais e sua relevância para saúde pública do Brasil. Reciis. 2011;5(1):85–99.

28. Brandão CMR, Guerra Júnior AA, Cherchiglia ML, Andrade EIG, Almeida AM, Dias da Silva G, et al. Gastos do Ministério da Saúde do Brasil com Medicamentos de Alto Custo: Uma Análise Centrada no Paciente. Value Heal. 2011 Jul;14(5):S71–7.

29. Andrieux-Meyer I, Cohn J, de Araújo ESA, Hamid SS. Disparity in market prices for hepatitis C virus direct-acting drugs. Lancet Glob Heal. 2015 Nov;3(11):e676–7.

30. Vargas-Peláez CM, Rover MRM, Leite SN, Rossi Buenaventura F, Farias MR. Right to health, essential medicines, and lawsuits for access to medicines – A scoping study. Soc Sci Med [Internet]. 2014 Nov [cited 2018 Aug 29];121:48–55. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25306409

31. Chieffi AL, Barata RB. Judicialização da política pública de assistência farmacêutica e eqüidade. Cad Saude Publica. 2009 Aug;25(8):1839–49.

32. Garcia LPEA. Epidemiologia das doenças negligenciadas no Brasil e gastos federais com medicamentos. IPEA Textos para discussão. 2011.

33. Brasil. Ministério da Saúde. Secretaria de Ciência Tecnologia e Insumos Estratégicos. Componente Especializado da Assistência Farmacêutica: inovação para a garantia do acesso a medicamentos no SUS. Brasília: Ministério da Saúde; 2014. 163 p.

34. Brasil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Malária: Monitoramento dos casos no Brasil em 2014. Bol Epidemiológico. 2015;46(25):1–5.

35. Duarte PS, Ramos DG, Pereira JCR. Padrão de incorporação de fármacos antiretrovirais pelo sistema público de saúde no Brasil. Rev Bras Epidemiol. 2011;14(4):541–7.

36. Barros, DSL. Cuidado farmacêutico ao paciente com hanseníase Pharmaceutical care for leprosy patients. Brazilian Journal of Development. 2020;12(6): 96967-77.