

# Moving toward improved access to medicines and health technologies for cardiovascular disease\*

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**Suggested citation** Giron N, Lim C, Vallini J and Hallar K. Moving toward improved access to medicines and health technologies for cardiovascular disease. *Rev Panam Salud Publica*. 2023;47:e93. <https://doi.org/10.26633/RPSP.2023.93>

## ABSTRACT

The objectives of this article are to describe the interventions carried out by the Strategic Fund of the Pan American Health Organization to facilitate access to and availability of antihypertensive medicines and devices for measuring blood pressure across the Region of the Americas as part of the HEARTS initiative, and to present the preliminary results of price analyses of antihypertensive medicines.

The study methodology included a review of reports made by the Strategic Fund between 2019 and 2020, an evaluation of modalities of procurement, a review of the public procurement databases for five antihypertensive medicines, and a comparison with the price obtained by the Strategic Fund. Differences in price ranging from 20% to 99% were identified, indicating significant opportunities for savings. The study also presents interprogrammatic actions that can support the HEARTS initiative, such as the inclusion of antihypertensive medicines recommended by the World Health Organization, consolidation of regional demand and competitively-priced long-term agreements to manage the procurement of quality generic products, and the definition of technical specifications and regulatory requirements to support the procurement of devices to measure blood pressure. This mechanism will enable Member States to reduce their costs significantly, while extending treatment and diagnostic coverage to more people.

## Keywords

Access to essential medicines and health technologies; antihypertensive agents, Strategic Fund; medicine cost.

Ensuring equitable and universal access, improving availability, and enhancing the affordability of safe, effective, and quality-assured antihypertensive medicines is the fundamental role of the Strategic Fund (SF). Within the framework of implementation of the HEARTS Initiative (1), a variety of interventions have been carried out to support the diagnosis, care, and management of hypertension.

The Strategic Fund was established in 2000 by the Pan American Health Organization (PAHO) (2) to address critical gaps in access to medicines and health supplies for priority public health programs in the Region of the Americas. The SF offers technical cooperation in supply management, provides lines of credit to

make procurement feasible, and promotes the use of quality-assured generic medicines at affordable prices. This mechanism has been used by Member States to increase access to quality-assured health care and strengthen the sustainability of health systems.

The objectives of this article are to describe the interventions carried out by the PAHO Strategic Fund to facilitate access to and availability of antihypertensive medicines and devices for measuring blood pressure, to present the preliminary results of price analyses carried out by the SF, and to consider the impact of prices on increasing the availability of these medicines in the countries that have implemented the HEARTS Initiative in the Region of the Americas.

\* Official English translation from the original Spanish manuscript made by the Pan American Health Organization. In case of discrepancy, the original version shall prevail. Access to original manuscript: <https://doi.org/10.26633/RPSP.2022.156>.

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## METHODS

Reports were reviewed by the Strategic Fund between 2019 and 2020, procurement methods were evaluated, public procurement databases for five antihypertensive medicines were reviewed, and a comparative price analysis was conducted.

## RESULTS AND DISCUSSION

Over the past two years, the SF has developed a series of actions within the framework of the HEARTS Initiative to collaborate with countries to incorporate timely interventions recommended by the World Health Organization (WHO) that support the sustainability of public policies to ensure and increase access to essential health technologies (3).

An effective strategy to rapidly improve hypertension control rates is to implement standardized medicine treatment protocols and ensure the availability and affordability of quality-assured antihypertensive medications. In 2019, the 21st WHO List of Essential Medicines (4) included fixed-dose combination (FDC) medicines for the treatment of hypertension. Such products have demonstrated efficacy and safety in controlling blood pressure, increasing adherence, and reducing (mitigating) side effects and adverse events in monotherapy (5). That same year, new antihypertensive medicines were added to the SF list, including single medicines and FDC, in various pharmacological categories such as diuretics, angiotensin-converting enzyme inhibitors, and angiotensin II receptor blockers, described in Table 1.

The Strategic Fund has evolved to respond to countries' needs and improve the availability of medicines for noncommunicable diseases. Within the framework of the implementation of the HEARTS Initiative, regional demand for antihypertensive medicines was consolidated for 18 formulations in 2020, with the participation of six countries of the Region. This process concluded with an international tender in compliance with the eligibility criteria and quality standards defined by PAHO and WHO (6). Offers were obtained for (multisource) generic antihypertensive medicines with regulatory approval by PAHO and WHO Reference Regulatory Authorities. These established competitive prices with long-term agreements that are accessible to Latin American and Caribbean countries (7).

The interprogrammatic strategies of the SF include developing price comparison studies and analyzing national supply systems in the different countries participating in the initiative.<sup>1</sup> These efforts help to identify barriers and opportunities for strengthening access to antihypertensive medicines and medical devices for measuring blood pressure. For this, we used information from institutional public procurement prices for 2020 and 2021, validated by each country. These reflect unit prices without other associated costs and correspond to products without a valid patent in the countries, allowing comparisons to be made.

Regional challenges identified by the Strategic Fund include increased demand for antihypertensive medicines, limited budgets, fragmentation of health systems, and decentralization of public procurement, all of which impact the consolidation of

**TABLE 1. Pan American Health Organization/World Health Organization: Strategic Fund 2021 List of Medicines**

Medicine	Composition	Pharmaceutical form
Amlodipine	5 mg, 10 mg (maleate, mesylate or besylate)	Tablet
Chlorthalidone	12.5 mg 25 mg	Tablet
Hydrochlorothiazide	12.5 mg 25 mg	Tablet
Lisinopril	20 mg 40 mg	Tablet
Losartan	25 mg 50 mg 100 mg	Tablet
Lisinopril/Amlodipine	10 mg + 5 mg 20 mg + 5 mg 20 mg + 10 mg	Tablet
Lisinopril/ Hydrochlorothiazide	10 mg + 12.5 mg 20 mg + 12.5 mg 20 mg + 25 mg	Tablet
Telmisartan	40 mg 80 mg	Tablet
Telmisartan/amlodipine	40 mg + 5 mg 80 mg + 5 mg 80 mg + 10 mg	Tablet
Telmisartan/ Hydrochlorothiazide	40 mg + 12.5 mg 80 mg + 12.5 mg 80 mg + 25 mg	Tablet

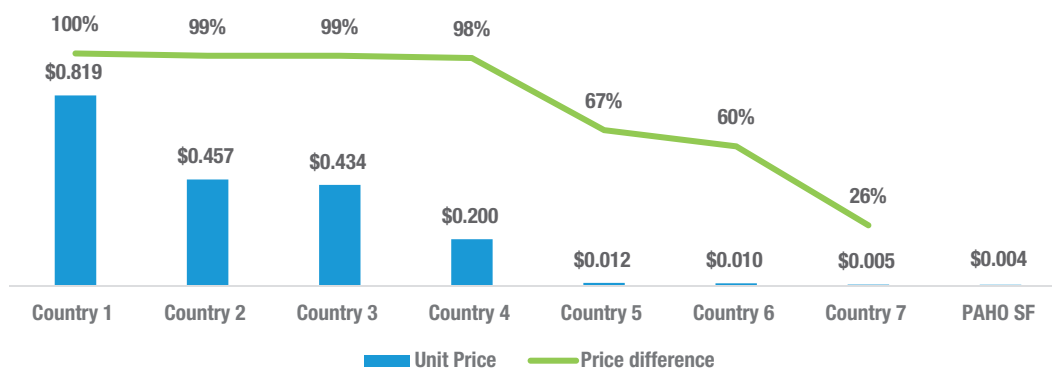
Source: the authors.

demand and joint purchasing, and often result in comparatively higher prices. Additionally, the gradual processes of updating treatment protocols, reviewing national therapeutic formularies, and incorporating new formulations of antihypertensive medicines, especially FDC, are challenges that countries must address to improve availability.

Regarding market structure, nationally-differentiated prices were identified for the recommended list of antihypertensive medicines, and savings opportunities were estimated in the procurement of generic medicines from multiple sources in markets with the assured competition. In the price analysis of amlodipine 5 mg (tablet)—one of the medicines preferred by the countries—it was shown that the price available through the PAHO Strategic Fund represented an opportunity for affordable procurement in different countries of the Region, enabling a significant increase in access to treatment. (see Figure 1)

The comparison presented in Figure 1 is from the subregions of South America, Central America, and the Caribbean. It suggests the importance of ongoing evaluations in each country that participates in the initiative, and of improving price transparency, institutional dialogue with countries, and technical cooperation to strengthen national health and supply systems. Other antihypertensive medicines recommended by WHO and by the HEARTS Initiative standardized treatment protocols were also evaluated (Figure 2). The analysis detected countries purchasing brand-name products that were up to 200 times more expensive than the quality-assured generic version available through the Strategic Fund. These price differences suggest potential savings of millions of dollars, which would make it possible to maintain the programs' current budgets while providing thousands of patients access to treatment.

<sup>1</sup> Market research and documentary analysis focused on procurement aspects, especially the regulatory framework. This was validated by additional information from national experts.

**FIGURE 1. Price comparison of amlodipine 5 mg tablets between seven countries of the Region of the Americas and the PAHO/WHO Strategic Fund, 2020–2021**

Source: the authors, based on 2020–2021 public procurement data sources.

For country A (Figure 2A), variations in the prices of the HEARTS-recommended medicines available through the Strategic Fund ranged from 42% to 91%. In the vast majority of countries of the Region, there are no current patents for telmisartan and its combinations (8), thus guaranteeing the entry of generics to the market. Even so, it is possible to continue to ensure a reduction in the price of fixed-dose combinations. As can be seen in Figure 2, a price reduction of 69% can be obtained for telmisartan 40 mg/amlodipine 5 mg (tablet), and of 83% for telmisartan 80 mg/amlodipine 5 mg (tablet), compared to the currently established price in the SF for the generic formulations of these medicines. In country B (Figure 2B), the price difference for three antihypertensive medicines was found to range from 58% to 95% compared to the prices of generic medicines available in the SF. This would also mean that four times as many patients could be treated and controlled while maintaining the same budget.

Some of the barriers to access to new products involve restrictions due to patents. Specifically, fixed-dose combinations of telmisartan currently have patent protection in two countries in the Region, and market restriction in a third country in which the patent was denied (although the decision was appealed). Recently, some related patents have expired in certain countries (8). The monopoly and high prices of the reference product impacted the inclusion of these medicines as medicines of choice in treatment protocols.

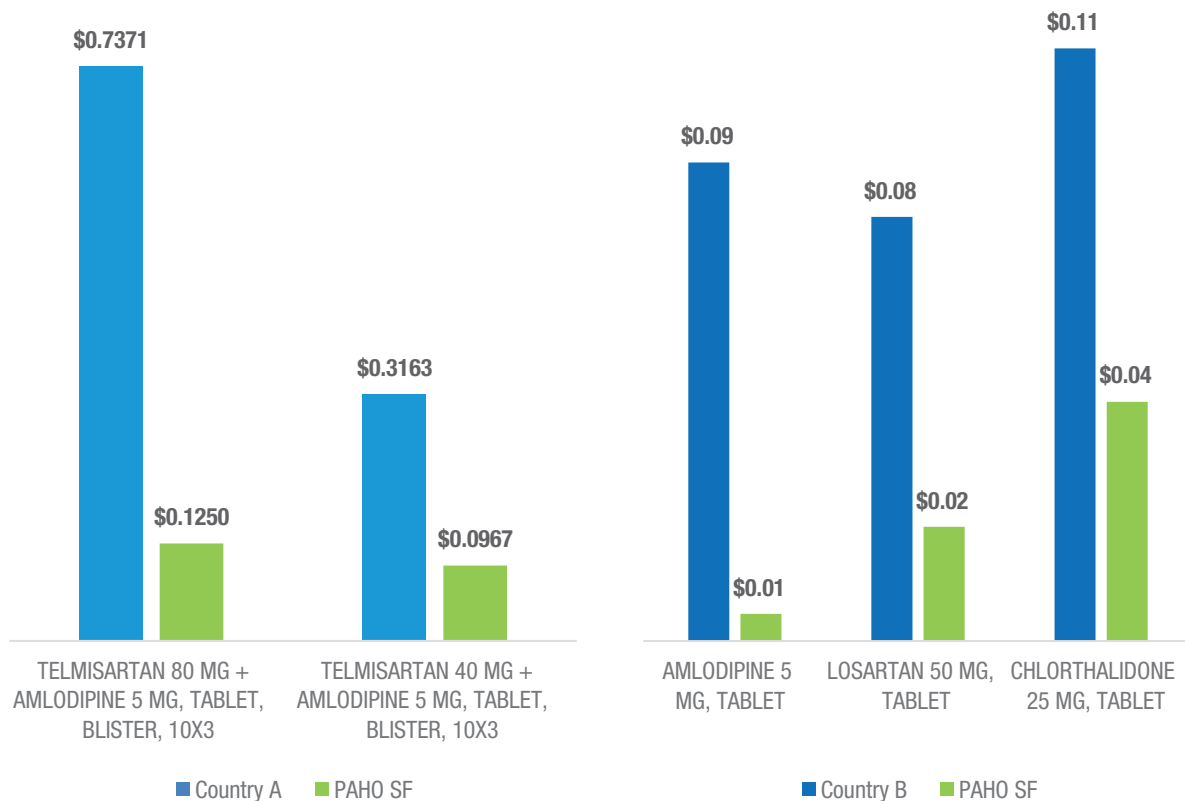
Additionally, one of the strategic pillars of the HEARTS initiative is blood pressure measurement, (9) and a key point of this pillar is promoting and guaranteeing the use of automated blood pressure measuring devices (BPMD). In the Region, manual blood pressure monitors have gradually been replaced by automated blood pressure monitors due to environmental problems arising from the use of mercury, lack of calibration, incorrect measurements from aneroid devices in clinical practice, and the consistently better accuracy offered by automated devices. The Strategic Fund, with the aim of improving access to these health technologies, has developed technical specifications and requirements for the procurement of validated BPMDs, according to WHO recommendations and consistent with the proposed regulatory framework to ensure compliance with quality standards and clinical validation (10).

Digital devices have cost-opportunity benefits, increasing detection capability while decreasing the need for training on their use. However, the analysis carried out by the SF, in coordination with other areas of PAHO, established that these devices are purchased in a decentralized manner and are generally analog devices. Lack of access to accurate, validated, and affordable blood pressure devices is a barrier to proper care, especially in low-resource countries.

The Strategic Fund continues to support the countries of the Region of the Americas in their transition toward using clinically-validated automated devices by promoting pooled, centralized procurement for the joint benefit of the countries of the Region. At the same time, interprogrammatic and intersectoral work will continue in order to improve access to medicines and other health technologies in the implementation of the HEARTS Initiative. The work will focus on reviewing and updating protocols, including new fixed-dose combination antihypertensive medicines in national therapeutic formularies, making quality-assured generic medicines available, consolidating national and regional demand, and promoting joint purchasing to secure competitive prices for antihypertensive medicines and BPMDs.

One key takeaway is that, in some countries of the Region, the decentralization and fragmentation of public sector procurement is the greatest challenge when purchasing antihypertensive medicines and BPMDs. This limits the consolidation of demand and the possibility of better prices. Additionally, prices were found to vary widely, not only regionally but also nationally, presenting an opportunity for savings if these countries were to access the products through the Strategic Fund. In that regard, it was shown that the prices obtained by the SF for amlodipine 5 mg and 10 mg are significantly lower than in most of the seven countries analyzed, with a difference ranging from 20% to 99%. Considering that this is a low-cost medicine, the number of patients and the limited budgets of the Member States offer the opportunity to optimize public resources.

As final recommendations, the countries of the Region should: a) carry out a cost analysis of antihypertensive medicines, including other logistical components (freight, insurance, storage, etc.), to guide decision-making prior to procurement; b) review national regulations to consolidate

**FIGURE 2. Price comparison of five antihypertensive medicines between two countries of the Region of the Americas and the PAHO/WHO Strategic Fund, 2020–2021**

Source: the authors, based on 2020–2021 public procurement data sources.

demand and implement joint procurement between public sector institutions; and c) use regional joint procurement mechanisms to ensure savings opportunities with quality-assured products.

**Author contributions.** All the authors developed the study; JV and KH reviewed public procurement databases, performed data analysis and interpretation; NG, JV, and CL contributed to the manuscript design and provided background information on the progress of the Strategic Fund. All authors

contributed to the manuscript and reviewed and approved the final version.

**Conflicts of Interest.** All the authors declare that they are staff members of the Pan American Health Organization and are part of the Strategic Fund for Public Health Supplies team.

**Declaration.** The authors hold sole responsibility for the views expressed in this manuscript, which may not necessarily reflect the opinion or policy of the RPSP/PAJPH or WHO.

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Manuscript received on 22 March 2022. Revised version accepted for publication on 6 July 2022.

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## Avanzando para mejorar el acceso a los medicamentos y tecnologías sanitarias para las enfermedades cardiovasculares

### RESUMEN

Los objetivos del presente artículo son describir las intervenciones realizadas por el Fondo Estratégico de Organización Panamericana de la Salud, para facilitar el acceso y disponibilidad de medicamentos antihipertensivos y dispositivos para la medición de la presión arterial a los países de la Región de las Américas en apoyo a la implementación de la Iniciativa HEARTS; y presentar los resultados preliminares de los análisis de los precios de los medicamentos antihipertensivos. La metodología del estudio incluyó la revisión de informes realizados por el Fondo Estratégico durante los años 2019-2020, la evaluación de las modalidades de adquisición y revisión de las bases de datos de compras públicas para 5 medicamentos antihipertensivos, y el análisis comparativo con el precio obtenido por el Fondo Estratégico. Se identificaron diferencias que oscilaron entre 20% y 99%, lo que evidencia oportunidades de ahorro significativas. Asimismo, se presentan las acciones interprogramáticas desarrolladas en apoyo a la Iniciativa HEARTS, entre las que se destacan la inclusión de medicamentos antihipertensivos recomendados por la Organización Mundial de la Salud; la consolidación de la demanda regional y el establecimiento de precios competitivos con acuerdos a largo plazo para gestionar la adquisición de productos genéricos de calidad; y la definición de especificaciones técnicas y requisitos regulatorios para apoyar con la adquisición de dispositivos para la medición de la presión arterial. A través de este mecanismo, los Estados Miembros pueden disminuir sus costos significativamente, extendiendo cobertura del tratamiento y diagnóstico a más personas.

### Palabras clave

Acceso a medicamentos esenciales y tecnologías sanitarias; antihipertensivos; Fondo Estratégico; costos de medicamentos

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## Avançando para melhorar o acesso a medicamentos e tecnologias de saúde para as doenças cardiovasculares

### RESUMO

Os objetivos deste artigo são descrever as intervenções realizadas pelo Fundo Estratégico da Organização Pan-Americana da Saúde para facilitar o acesso e a disponibilidade de medicamentos anti-hipertensivos e aparelhos de medição de pressão arterial aos países da Região das Américas, em apoio à implementação da iniciativa HEARTS; e apresentar os resultados preliminares da análise dos preços dos medicamentos anti-hipertensivos. A metodologia do estudo incluiu a revisão de relatórios feitos pelo Fundo Estratégico durante os anos de 2019 e 2020, a avaliação das modalidades de aquisição e revisão dos dados de compras públicas de 5 medicamentos anti-hipertensivos e uma análise comparativa com o preço obtido pelo Fundo Estratégico. Foram identificadas diferenças que oscilaram entre 20% e 99%, o que evidencia oportunidades de economia significativas. Da mesma forma, são apresentadas as ações interprogramáticas desenvolvidas em apoio à iniciativa HEARTS, entre as quais se destacam a inclusão de medicamentos anti-hipertensivos recomendados pela Organização Mundial da Saúde; a consolidação da demanda regional e o estabelecimento de preços competitivos com acordos de longo prazo para gerenciar a aquisição de genéricos de qualidade; e a definição de especificações técnicas e requisitos regulatórios para subsidiar a aquisição de aparelhos de medição de pressão arterial. Por meio desse mecanismo, os Estados Membros podem reduzir seus custos significativamente, ampliando a cobertura de tratamento e diagnóstico para atingir mais pessoas.

### Palavras-chave

Acesso a medicamentos essenciais e tecnologias em Saúde; anti-hipertensivos; Fundo Estratégico; custos de medicamentos.

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