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WHAT IS THE OPPORTUNITY COST OF FINANCING BRANDED DRUGS?

The case of the Dominican Republic

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Catalina Gutiérrez • Natalia Jorgensen

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SUMMARY

» **We find ourselves in the fortunate position of having access to more beneficial technologies than we can finance.** However, this abundance, coupled with an aging population and epidemiological changes, is straining healthcare spending worldwide. For these increased expenses to translate into improved population health, it is crucial for them to be sustainable, not to displace other vital investments and to align with the goals of health systems. Because resources are inherently finite, allocating them to one technology necessarily implies not allocating them to others. In the Dominican Republic, public resources are allocated to finance higher-cost branded drugs, even when equally effective unbranded generic substitutes are available. This article quantifies these costs in terms of the health lost due to this resource allocation.

» **Generics have a 77 percent penetration in the Dominican Republic's retail market. However, unbranded generic drugs account for just 7 percent, with the remainder being comprised of branded generic and innovative drugs.** On average, unbranded generics are 3.5 times less costly than their equivalent innovators and branded generics. This implies that the contributive regime of the Dominican Republic could save annually US$13 to US$60 million by substituting them with unbranded generics. This article demonstrates that if these saved resources were directed toward expanding existing health services, Dominicans could gain annually between 4,000 to 18,000 life years in perfect health. On the other hand, if these resources were allocated to closing coverage gaps in highly cost-effective interventions, the benefits would be significantly greater. This article estimates the gains to be achieved by utilizing the potential savings to bridge the coverage gaps in cervical cancer screening and in the detection and management of diabetic patients. In the most conservative scenario, the savings would allow the country to close 100 percent of the gap in cervical cancer detection and 59 percent in diabetes detection and management. This translates to an annual gain of 12,000 life years in perfect health. In the less conservative scenarios, both gaps could be entirely closed with just 4 to 8 months of savings, resulting in a gain of 18,000 life years in perfect health, with resources remaining for other investments.

JEL codes: H10, H11, H21, H30, H51, H61, I1

Keywords: Health expenditure, Public health expenditure, Medications, Prices, Priority setting, Pharmaceutical policies, Pharmaceutical products, Procurement, Procurement policies, Efficiency, Expenditure, Prioritization, Resources, Health, Generic medications, Healthy living, Cost-effectiveness.

INTRODUCTION

» **Health spending is on the rise globally due to shifts in demographics and epidemiology, the introduction of new, and more expensive, medical technologies and increased demand for services driven by higher incomes.** Over the last two decades, health spending in Latin America and the Caribbean grew from 6.6 percent to 7.9 percent of GDP, with projections indicating a potential increase of up to 2 additional GDP points by 2030 [1]. Moreover, these figures do not encompass the new challenges countries face post-pandemic, such as the investment required to prepare for similar future events. This spending growth should be sustainable, not displace other vital investments and should yield favorable cost-benefit outcomes. While it is unrealistic to halt spending growth altogether, governments possess the ability to shape and enhance its efficiency to maximize its benefits, ultimately leading to better health outcomes.

» **Financing higher-cost branded drugs —including both branded generics and innovators— when equally effective, lower-priced unbranded generic substitutes are available, represents a potential spending inefficiency, yet it remains an area that has not been sufficiently studied in the region.** The objective of this article, therefore, is to estimate the potential savings that the Dominican Republic's health system could achieve by funding unbranded, lower-priced generic drugs of comparable effectiveness and safety instead of innovative drugs. For the purposes of this article, branded drugs include both innovative products and branded generics.

1. THE OUTPATIENT DRUG MARKET IN THE DOMINICAN REPUBLIC AND ITS FINANCIAL COVERAGE

The Dominican Republic allocates 6 percent of its GDP to healthcare, slightly below the Latin America and Caribbean average.

However, the share of the health spending not covered by insurance systems (that is, the out-of-pocket health spending, or OPHS) is 44.7 percent. Notably, the Dominican Republic ranks fourth highest in OPHS in the region[1]. Of this expenditure, drug spending is the primary component, representing over 46 percent (Azael Lorenzo and Penson, 2018).

The country's social security system is structured around two regimes: contributive and subsidized, providing coverage through the Seguro Familiar de Salud (SFS, Family Health Insurance). As of 2019, the SFS covered 78.1 percent of the Dominican Republic population (Azael Lorenzo and Penson, 2018). Benefits are provided through the Plan Básico de Salud (Basic Health Plan), which covers outpatient drugs for a given list of active ingredients. The plan fully covers the subsidized population and covers 70 percent (with an annual maximum of DOM$8,000) for those in the contributive regime (Rathe and Moliné, 2011).

This article focuses on prescription outpatient drugs acquired at private pharmacies. According to IQVIA data, this market had sales of US$662 million in 2019[2], comprising US$147 million in innovator drugs, US$466 in branded generics and US$49 million in unbranded generics (see Table 1).

TABLE 1 Drug market in retail pharmacies in the Dominican Republic, 2019, in millions of dollars

	All	With substitute	
		All	Sample
Innovative	147	48	41
Branded generic	466	207	189
Unbranded generic	49	46	42
Total	662	300	272

Source: authors' elaboration based on IQVIA.

2. DATA

For this article, we used price and quantity aggregates from IQVIA, which provides monthly price and sales data for individual products.

IQVIA:DR collects information from chain pharmacies, distributors and laboratories, offering representative data for most of the country from 72 percent of the country's pharmacies[3].

To estimate the opportunity cost of using branded drugs, we employed two methodologies, which we further discuss in the following section. The first methodology utilizes the cost-effectiveness threshold estimated for the Dominican Republic (Riascos *et al.*, 2023). The second methodology estimates the opportunity cost by considering the resources saved by substituting with unbranded generics, which could then be allocated to closing coverage gaps in essential services related to two priority interventions: cervical cancer detection and the diagnosis and management of diabetic patients.

For the coverage gaps methodology, we relied on price information provided by the Superintendencia de Salud y Riesgos Laborales (SISALRIL, Health and Labor Risks Superintendency). To define the health service baskets and usage frequencies for the selected interventions, we utilized data from a 2020 pilot study aimed at updating the benefit package, adjusting prices to 2022 levels. Prevalence data from the Global Burden of Disease study (GBD, 2019) were used to estimate coverage gaps in essential services. The effective coverage was based on expert opinion. The cost-effectiveness data for the essential services interventions were obtained from a review of scientific literature.

Finally, we obtained price index and exchange rate information from the World Bank's development indicators and the Banco de la República de República Dominicana, respectively. Given the unavailability of World Bank data for 2022, we utilized inflation and exchange rate data reported by the Banco de la República de República Dominicana, ensuring consistency across the data sources.

3. METHODOLOGY

ESTIMATING THE POTENTIAL SAVINGS FROM A SUBSTITUTION WITH UNBRANDED GENERICS

Consider an individual, denoted as *i* who consumes a quantity q_{ijm} of a drug *j* in market *m*. Here, the sub-index *j* represents the type of drug, which can be either generic *(j=G)* or branded *(j=B)*, including both branded generics and innovators. Market *m* is defined such that two drugs belong to the same market if an individual can substitute between them. In this article we assume that the market is defined by the combination of active ingredient, presentation, administration route and pharmaceutical liberation[4].

The respective unit prices are denoted as p_{Bm} and p_{Gm}, with the difference indicated as $\Delta_m \equiv p_{Bm} - p_{Gm}$. Additionally, we assume that the individual must pay out-of-pocket a fraction α_{ij} of the drug's price.

Therefore, an individual i's potential savings from substituting the branded version with the generic version of drug *j* in market *m* are:

$$A_{im} = \alpha_{ij} \cdot \Delta_m \cdot q_{iBm}$$

That is, the potential A_{im} equal the quantity of the branded drug consumed multiplied by the difference in out-of-pocket expenditures between both drugs.

There are three important observations regarding the definition of A_{im}.

1. It only applies when generic alternatives to branded products are available in the market. Where no generic alternatives are available, the potential savings are null by definition.

2. It quantifies the savings in case there is no variation in total consumed quantities due to the substitution. That is, it answers the question of how much smaller the expense would have been if the person had substituted all their consumption of the branded drug with the same consumption of generic drugs.

3. It quantifies the savings given the current price differences. However, policies that promote the substitution toward generic drugs are expected to produce changes in the relative prices between branded and generic drugs. Specifically, inducing more competition between segments could narrow the price gaps between them, and could even result in price increases for some generic drugs.

We can also define the potential savings within a specific market as:

$$A_m = \sum_i A_{im}$$

Assuming an average coverage in α_m, we can re-write A_m as:

$$A_m = \alpha_m \cdot \Delta_m \cdot Q_{Bm}$$

where $Q_{Bm} \equiv \sum_i q_{iBm}$ is the total quantity consumed of the branded drug in market *m*.

This equation is the cornerstone to estimating the potential savings within a market *m*. To that end, we use the IQVIA database, from which we obtain the price differences and quantities consumed of the branded drug.

Alternative Expression

Another way to express the previous equation allows us to represent the potential savings using variables that can be more easily compared across markets. To do this, we introduce the concept of "propensity to consume branded drugs" in market m, which is the market share of branded drugs within market *m*:

$$\beta_m \equiv \frac{Q_{Bm}}{Q_{Bm} + Q_{Gm}}.$$

We also define the "total value of market *m*", R_m, as the average price of generics multiplied by the total amount of sales in the market:

$$R_m \equiv p_{Gm} \cdot Q_m$$

Thus, we can re-write the equation for the potential savings in the market as:

$$A_m = \alpha_m \cdot \left(\frac{p_{Bm}}{p_{Gm}} - 1\right) \cdot \beta_m \cdot R_m$$

This way of expressing the potential savings shows that they will be higher in markets where the relative price is higher, the market share of branded drugs is higher and the total market value is higher.

- **Sample selection:** To conduct this analysis, we filtered the database removing data for food, vitamins and other natural products.

- **Coverage:** We assumed a financial coverage of 70 percent, equal to the coverage under the contributive regime for outpatient drugs for annual expenditures under the maximum of DOM$8,000. This coverage is an upper bound, assuming that members do not reach the DOM$8,000 maximum.

ESTIMATING THE OPPORTUNITY COST OF CONSUMING INNOVATIVE AND BRANDED GENERIC DRUGS INSTEAD OF UNBRANDED GENERICS

Net Health Benefit Using the Cost-Effectiveness Threshold Method

A resource allocation is considered efficient when no alternative allocation can produce greater benefits. In healthcare, these benefits are typically measured in terms of clinical outcomes, such as improved glucose control or fewer asthma episodes per month, as well as in life years gained, reduced disabilities or enhanced quality of life. In this article, we utilize the concept of quality-adjusted life years (QALY), where one QALY represents one life year in perfect health.

The opportunity cost of an investment refers to the health gained or lost by not allocating the resources to alternative interventions, typically the best lower-cost alternative available within the health system. To quantify the amount of health lost or gained we use the concept of net health benefit (NHB). NHB compares the incremental QALY generated by one technology with the QALY that those same resources would provide if invested in the overall health system.

The NHB is calculated as:

$$(1) \quad NHB = (QALY_x - QALY_a) - \frac{(C_x - C_a)}{CET}$$

The first term represents the difference in healthy life years provided by technology *x* compared to technology *a*. As the use of innovative or branded generic drugs does not offer additional therapeutic benefit beyond unbranded generics, and there are no gains in terms of QALY, the first term of the equation equals zero[5].

C represents the total cost of the technology, and C_x - C_a is the savings generated by financing technology *x* instead of technology *a*. The second term quantifies how much health (QALY) could be obtained if the saved resources were allocated within the health system, and it is calculated using a measure known as the cost-effectiveness threshold (CET). The CET is a measure of how much it costs a given health system to produce, on average, the equivalent of one life year in perfect health.

In the case of branded drugs, since the first term of the equation is zero and unbranded generics are usually cheaper, the net health benefit is simply the number of QALY gained if the resources saved by substituting with unbranded generics were allocated to the health system:

$$(2) \qquad NHB = \frac{Resources\ saved\ by\ substituting\ for\ unbranded\ generics}{CET}$$

To estimate the NHB, we used the cost-effectiveness threshold estimated by Riascos *et al.* [7] for the Dominican Republic, which equals 39 percent of its per capita GDP. For 2019, the threshold is US$3,190, meaning the Dominican health system produces one life year in perfect health at a cost of US$3,190.

Net Health Benefit in Terms of Bridging Gaps in Essential Services

In countries where essential services have gaps in coverage, as in most low- and medium-income countries, the most evident opportunity cost arises from the health lost by not directing potential savings toward closing those gaps. Essential services are generally highly cost-effective, meaning that through them the system produces one QALY at a very low cost, often below the average cost needed to produce a QALY. In such instances, the opportunity cost of financing branded drugs instead of addressing these services would far exceed that calculated with Equation 2. Bearing this in mind, we conducted an additional analysis to gauge the benefits that could be realized by reallocating the resources saved from substituting with unbranded generics to closing the gaps in two preventive services: cervical cancer screening and diabetes diagnosis and management.

To calculate the health gains from closing these gaps, we relied on Jorgensen *et al.* (2023), which estimates the value of the services required and the coverage gaps in the Dominican Republic. It also provides information on the QALY provided by each intervention and their incremental cost-effectiveness ratio relative to scenarios where no action is taken.

To estimate the health gains from closing the coverage gaps in these services, we used the incremental cost-effectiveness ratio (ICER) and the unit cost for each service within the selected interventions, as estimated by Jorgensen *et al.* (2023). The ICER represents the ratio between the QALY obtained by covering one person compared to taking no action and the cost of covering one person (as opposed to taking no action).

The opportunity cost for the Dominican Republic, which is equivalent to the net health benefit of closing the gaps, is calculated as:

$$(3) \qquad NHB_i = \frac{Resources\ saved\ by\ substitution}{ICER_i}$$

Here, the sub-index *i* denotes the specific service (i.e., cervical cancer detection, diabetes detection and management). NHBi indicates how many life years in perfect health (QALY) could be obtained if the resources saved by the substitution were directed toward addressing gap *i*.

4. RESULTS

POTENTIAL SAVINGS FROM SUBSTITUTING WITH UNBRANDED GENERICS

As we previously discussed, potential savings are feasible in markets offering both generic and branded options (which include innovators and branded generics). The total sales across markets with potential savings amount to US$300 million, with the majority (69 percent) corresponding to sales of branded generics (refer to Table 1). After the sample selection mentioned earlier (which involved excluding vitamins, medical devices, food and problematic data), the total sales of markets with potential sales amount to US$272 million (as indicated in Table 1). This segment encompasses 258 markets and 191 active ingredients.

We observe significant price differences between generic and branded products; in the average market, the price of branded products is 3.5 times higher than the price of generics. Figure 1 illustrates the distribution of relative prices, denoted by $\mathrm{p_{Bm}/p_{Gm}} - 1$. There is a considerable dispersion of relative prices (standard deviation of 4.6); some markets exhibit price ratios exceeding 35 times. Additionally, there are negative differentials (indicating generics being pricier than branded drugs on average) in 14 percent of all markets.

Despite these price differences, branded drugs maintain a relatively high market share. The market share of branded drugs in the average market is 68 percent. Figure 2 illustrates the distribution of the market share of branded drugs across each market (β_m). The distribution exhibits significant dispersion, with a standard deviation of 0.4.

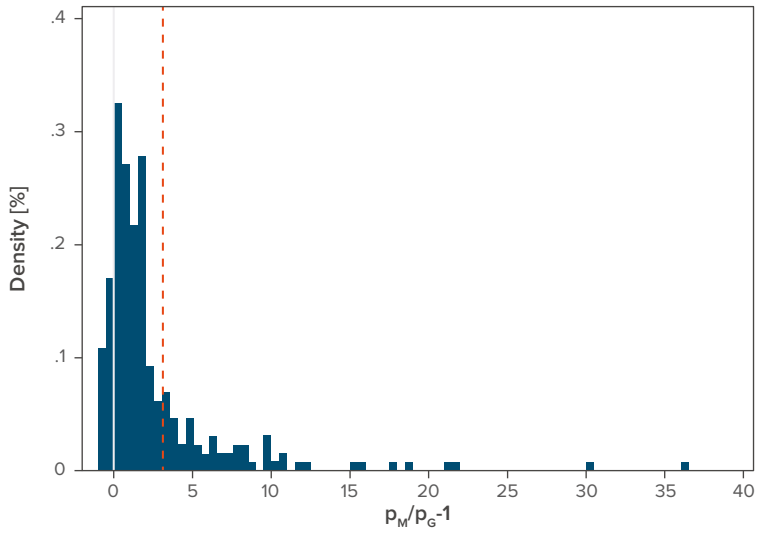
As previously mentioned, the potential savings increase with higher price differences, greater market share of branded drugs and higher total market value.

Figure 3a portrays the relationship among these three variables across various markets using a scatter plot. Each point on the graph represents a market, with the relative price of alternatives $(\mathrm{p_{Bm}/p_{Gm}} - 1)$ plotted on the horizontal axis and the market share of branded drugs (β_m) on the vertical axis. The size of the circle is proportional to the total market value (R_{Gm}). For enhanced clarity, Figure 3b presents the same for markets where $\frac{p_{Bm}}{p_{Gm}}$ - 1 ≤ 10 along with the linear fit estimated by ordinary least squares.

Several noteworthy patterns emerge. Firstly, higher relative prices of branded drugs tend to correspond with lower market shares. This aligns with expectations, as higher prices of branded drugs relative to generic alternatives lead to increased usage of generics. Secondly, larger markets generally exhibit lower relative prices compared to smaller markets. These correlations suggest that, to a certain extent, the various factors contributing to potential savings within a specific market are balanced across markets.

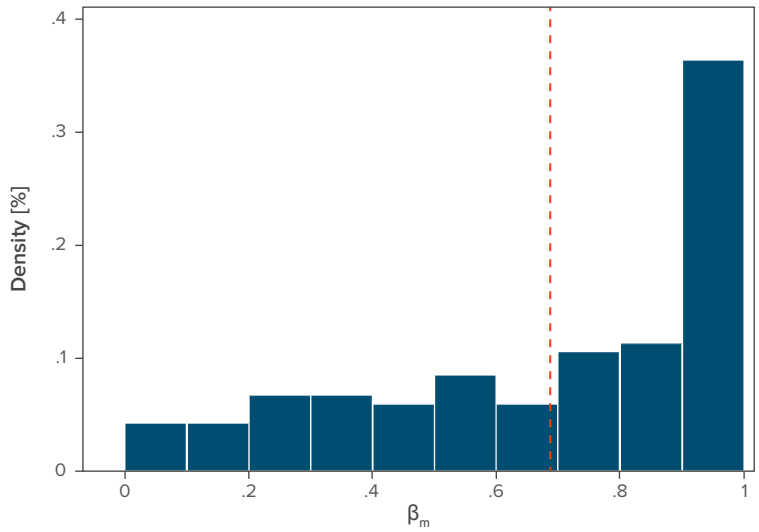
Applying the methodology described earlier, we find that the aggregate total potential savings across all markets amount to US$122 million, representing 18 percent of total drug sales in the retail channel.

FIGURE 1 Distribution of relative prices between branded and generic drugs



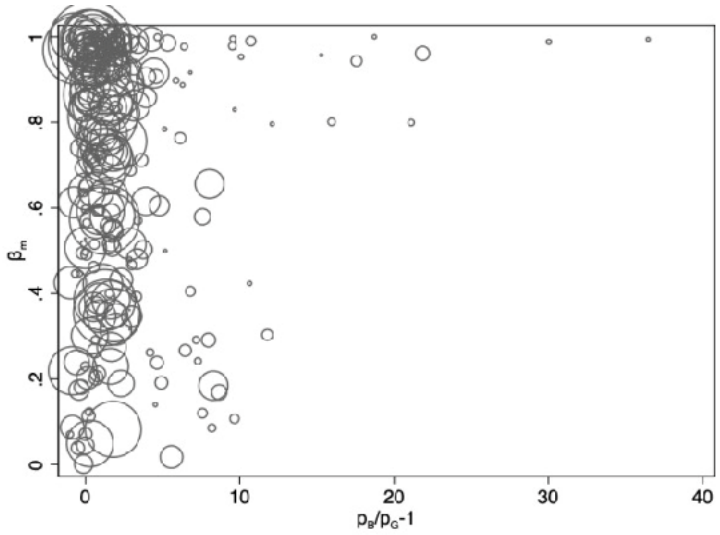
Source: authors' elaboration based on IQVIA.

FIGURE 2 Distribution of the market share of branded drugs



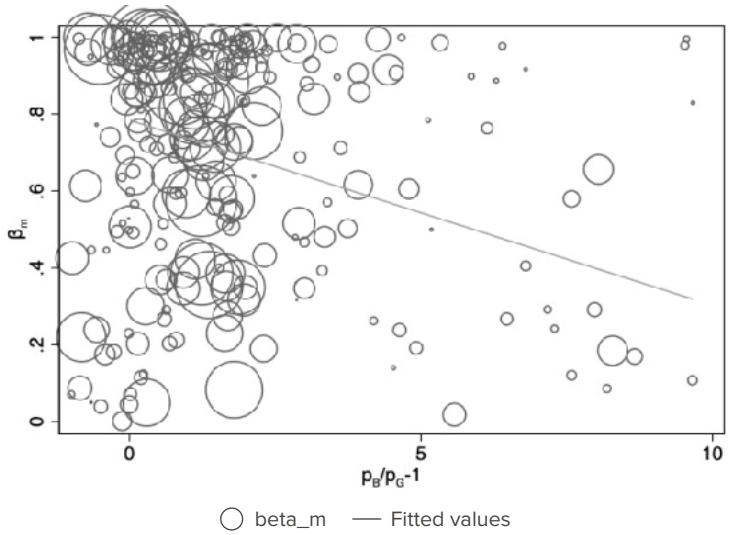
Source: authors' elaboration based on IQVIA.

FIGURE 3a Relationship between relative prices, market share of branded drugs and market size



Source: authors' elaboration based on IQVIA.

FIGURE 3b Relationship between relative prices, market share of branded drugs and market size, sample $p_{Bm}/p_{Gm} - 1 <= 10$



Source: authors' elaboration based on IQVIA.

5. PUBLIC SECTOR SAVINGS

The potential savings of US$122 million encompasses both the portion covered by social insurance and the out-of-pocket expenses borne by households. Unfortunately, we lack the necessary information to disaggregate purchases between those covered by SFS and those paid out-of-pocket. We employed three methods to estimate the proportion of the total savings applicable to the contributive regime.

Not all molecules available on the retail market are covered by the SFS. We determined that total sales for the SFS-covered molecules amounted to US$295 million, of which US$196 million had potential substitutes. The potential savings within these markets amount to US$86 million. Table 2 outlines the potential savings for both the total market and the subset of molecules covered by the SFS.

Assuming an average coverage rate of 70 percent for the SFS-covered molecules, the potential savings for these molecules would divide into US$60 million for the insurance system and US$26 million in reduced out-of-pocket spending (note that 70 percent is an upper bound of the actual coverage). Additionally, households would benefit from savings derived from molecules not covered by the SFS, totaling US$36 million (equivalent to US$64 million in 2022 dollars).

The previous estimation assumes that all sales of SFS-covered molecules at retail pharmacies are conducted through the SFS, making it an upper bound of the potential savings. However, it is possible that a portion of the sales of SFS-covered molecules are paid for directly by households (out-of-pocket) rather than through the SFS. We provide a second estimation based on information collected by SISALRIL on pharmacy retail purchases made by members of the contributive regime. For 2019, SISALRIL reports payments to pharmacies totaling US$95 million (DOM$4.878 billion). Table 2 shows that

TABLE 2 **Potential savings for the total market and for the sub-sample of molecules covered by the SFS**

	Outpatient market total (million dollars, 2019)	Sub-sample with SFS coverage (million dollars, 2019)
Total value of market sales	662	295
With a substitute	271	196
Potential savings	122	86
Potential savings as a share of sales	18%	29%

Source: authors' elaboration based on IQVIA and SISALRIL.

the potential savings amount to 29 percent of total sales for SFS-covered molecules. Applying this fraction to the sales reported for SISALRIL yields a potential savings of US$27.5 million (US$31 million in 2022 dollars).

A third estimation utilizes available data on out-of-pocket spending by households. In 2018, the Oficina Nacional de Estadística (National Statistics Office) conducted a study on out-of-pocket health spending (Oficina Nacional de Estadística, 2020). Utilizing this information and the expenditure reported by SISALRIL for the same year, we deduce that 11 percent of outpatient drug spending is covered by health insurance resources[6]. Assuming that the estimated savings are distributed proportionally to spending, the savings accrued to the insurer would total US$13 million (equivalent to US$14.4 million in 2022 dollars).

Table 3 presents the three scenarios we have just detailed.

Overall, we estimate that the Dominican contributive regime could save a minimum of US$13 million and up to US$60 million annually, with an intermediate scenario yielding annual savings of US$27.5 million.

TABLE 3 **Alternative scenarios for the distribution of the potential savings between the public sector and households, 2019, in millions of dollars**

	Contributive regime savings	Households' savings	Total retail market savings
Upper bound	60	62[7]	122
Intermediate bound	27.5	94.5	122
Lower bound	13	109	122

Source: authors' elaboration based on IQVIA and SISALRIL.

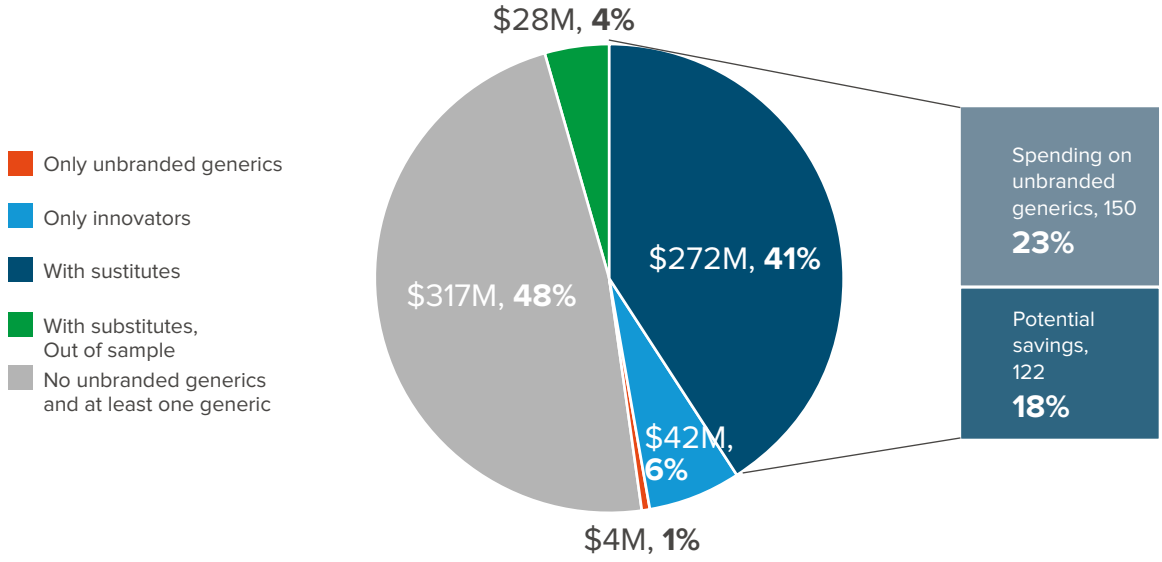
6. EXPLORING THE LACK OF GENERIC ALTERNATIVES

Table 1 reveals that approximately 55 percent (in terms of value) of sales in the Dominican Republic's pharmacy retail channel occur in markets where substitution between unbranded and branded drugs (including both innovators and branded generics) is not possible. In other words, the potential savings from substituting purchases of branded products toward unbranded generics are severely restricted due to the absence of generic alternatives. To gain a deeper understanding and put the potential savings into perspective, **Figure 4 categorizes the total market under study (with total sales amounting to US$662 million) into the following groups:**

- Markets where substitution is not possible because only innovators are available.
- Markets where substitution is not possible because only unbranded generics are available.
- Markets where substitution is not possible because no unbranded generics are available, although at least one branded generic is present.
- Markets where substitution is possible.

Most of the markets where substitution with unbranded generics is not possible belong to the group where at least one branded generic is available Indeed, these markets represent 48 percent of the total market (US$317 million). The presence of a generic indicates that the innovative drug is off-patent, allowing for the potential entry of more generics into the market. Additionally, the group of markets where no substitution is possible because only innovators are available accounts for 6 percent of the total. Unfortunately, we cannot discern which of these markets are on-patent and which are off-patent due to data limitations. However, since some may be off-patent,

FIGURE 4 **Value distribution by market structure, in millions of dollars**



Source: authors' elaboration based on IQVIA.

the 6 percent represents an upper bound of the on-patent market where generics (both branded and unbranded) cannot enter. Lastly, the smallest share pertains to markets where only generics are available (<1 percent, US$4 million).

THE OPPORTUNITY COST OF FINANCING BRANDED DRUGS IN TERMS OF QALY

In 2019, the potential savings from substituting with unbranded drugs amounted to US$122 million. Out of that sum, the social security system could save US$60 million (an upper bound estimate). Using equation 2, this translates to an opportunity cost for the Dominican social security system of $\frac{US\$60\ million}{US\$3{,}190} = 18{,}808$ QALY. Essentially, diverting resources from the health system to purchase branded drugs instead of their generic substitutes implies a loss equivalent to more than 18,000 life years in perfect health per year. In a more conservative approach, the public sector savings totaling US$13 million would equate to 4,000 annual QALY. These findings are presented in Table 4.

As we mentioned earlier, when a country faces gaps in the coverage of essential health services, it might be more beneficial to measure the opportunity cost in terms of the health gains that could be achieved by using the available resources to bridge those gaps instead of financing branded drugs.

With 2022 data, Jorgensen *et al.* (2023) estimates the coverage gaps in two essential services and the cost of bridging them. It finds that in 2022, the gap in the timely detection of cervical cancer in the Dominican Republic was 54 percent; and the gap in the timely detection and comprehensive non-pharmacological management of diabetic patients was 61 percent.

Table 5 presents the life years that could be gained by reallocating the resources saved by substituting with unbranded generics to close these gaps. The estimated annual cost of closing the coverage gaps in these two interventions is US$21.8 million, whereas the savings from substituting with unbranded generics, in the most conservative scenario, amounted to US$13 million for 2019, equivalent to US$14.4 million in 2022. Therefore, with the resources saved in one year, the system could entirely bridge the gap in cervical cancer detection and cover nearly 60 percent of the gap in the diagnosis and management of diabetic patients. This would result in a gain of 12,000 QALY. In less conservative scenarios, both gaps could be completely bridged with the resources saved in 4 to 8 months, resulting in a gain of 18,000 life years in perfect health, with resources remaining for other investments[8]. Furthermore, since the coverage gaps in these services are generally larger in vulnerable populations, reallocating resources would also lead to equity gains.

TABLE 4 QALY gained by reallocating the potential resources saved by substituting with unbranded generics to other health system services

Threshold value	Savings (million dollars, 2019)			QALY gained		
	Upper bound	Intermediate bound	Lower bound	Upper bound	Intermediate bound	Lower bound
3,190	60	27.7	13.0	18,808	8,697	4,075

Source: authors' elaboration.

TABLE 5 Potential QALY gained by reallocating saved resources to close coverage gaps, 2022 dollars

Intervention	Annual cost per case	Estimated gap (people equiring coverage)	Annual financial cost of bridging the gap	ICER (cost of each QALY)	Resources allocated to bridgin the gap	Percentage of the gap covered in the conservative savings scenario	Annual QALY gained using the lower bound of potential savings	Annual QALY gained by complete coverage of the gap
Timely detection of cervical cancer through visual detection or tests such as Papanicolaou	9.53	392,504	3,740,563	910	3,740,563	100%	4,109	4,109
Detection and management of diabetes among at-risk adults, including glucose control, arterial pressure and lipid management and constant feet care.	49.36	366,455	18,088,219	1,288	10,675,720	59%	8,286	14,040
Totales			**21,828,781.92**		**14,416,282.78**		**12,395**	**18,149**

Source: authors' elaboration based on Jorgensen et al. (2023).

7. SUMMARY AND POLICY RECOMMENDATIONS

A policy promoting the use of generic drugs in the Dominican Republic can enhance healthcare access, reduce drug spending and annually provide 12,000 to 18,000 additional life years in perfect health.

This article estimates the potential savings from substituting branded products with unbranded generics to be US$122 million, equivalent to 45 percent of spending in markets where substitution is possible. The magnitude of these potential savings is derived from the significant price differentials and the high market share of branded drugs. Up to 18,000 life years in perfect health could be gained if the saved resources were redirected to provide other services currently covered by the health system.

Alternatively, the potentially saved resources from a substitution with unbranded generics could be allocated to bridge gaps in screening for cervical cancer and in the diagnosis and management of diabetic patients. In this scenario, the Dominican Republic could gain 12,000 life years in perfect health in the most conservative estimate; in the least conservative scenarios, both gaps could be completely bridged, gaining 18,000 life years in perfect health, with resources remaining for other health investments, thereby resulting in more QALY gained
.

It is noteworthy that approximately 55 percent of sales occur in markets where substitution is not possible, mainly due to the absence of unbranded generic alternatives. Specifically, 48 percent of sales occur in markets where branded generics are available but unbranded ones are not, and 6 percent in markets where only innovators are available. Further analysis in these markets could offer valuable insights to devise policies that may enhance the penetration of unbranded generics in the market, leading to additional savings that could be reallocated for improving population health.

This article underscores that the use of branded drugs carries a clear opportunity cost in terms of lost years and quality of life. A better understanding of why consumers and prescribers prefer branded drugs over their generic counterparts is crucial for devising policies to mitigate this cost. Economic literature points to a lack of consumer information regarding the suitability of different products for treating specific conditions. Additionally, there is a lack of trust in the quality of unbranded generics among both the population and prescribers.

Some of the policymakers interviewed for this article view the absence of bioequivalence requirements for generic drugs in the Dominican Republic as a significant obstacle to substituting with generics. **Quality regulations in the pharmaceutical market are generally regarded as a necessary condition to increase the penetration of generics and unbranded generics (WHO, 2000).** Without them, progress in strategies promoting substitution is hindered.

ANNEX

TABLE A1 Cost-effectiveness threshold for the Dominican Republic; cost per QALY, in current currency (2016-2022)

	Per capita GDP (1)	Minimum CET as a % of GDP (2)	Maximum CET as a % of GDP (2)	Minimum CET DOM$	Maximum CET DOM$	Exchange rate (3)	Minimum CET US$	Maximum CET US$	Intermediate CET as a % of GDP (2)	Intermediate CET DOM$	Intermediate CET US$
2016	331,253	32.7%	41.8%	108,349	138,307	46.03	2,354	33,005	39%	129,189	2,806
2017	357,149	32.7%	41.8%	116,820	149,119	47.49	2,460	3,140	39%	139,288	2,933
2018	393,464	32.7%	41.8%	128,698	164,282	49.47	2,601	3,321	39%	153,451	3,102
2019	419,251	32.7%	41.8%	137,132	175,048	51.25	2,676	3,415	39%	163,508	3,190
2020	405,163	32.7%	41.8%	132,524	169,166	56.52	2,345	2,993	39%	158,014	2,796
2021	485,049	32.7%	41.8%	158,654	202,521	57.07	2,780	3,549	39%	189,169	3,315
2022*	578,534	32.7%	41.8%	189,232	241,553	54.93	3,445	4,398	39%	225,628	4,108

Source: (1) Per capita GDP: World Bank, available at https://data.worldbank.org/indicator/NY.GDP.PCAP.CN?locations=DO. For 2022, we calculate per capita GDP based on 2021 per capita GDP and growth based on the Boletín Informativo del Banco de la República de República Dominicana, available at https://www.bancentral.gov.do/a/d/5568-bcrd-informa-que-la-economia-dominicana-crecio-49--en-el-ano-2022#:~:text=Asimismo%2C%20dicha%20cifra%20permite%20alcanzar,séptima%20econom%C3%ADa%20de%20América%20Latina.
(2) Minimum, intermediate and maximum threshold: Riascos et al. (2023).
(3) Exchange rate: Banco de la República de República Dominicana, available at https://www.bancentral.gov.do/SectorExterno/HistoricoTasas.

TABLE A2 Provision basket for cervical cancer detection

Intervention	Description (clinical guide /dosage)	Source for description	Level of care	Service type	Note on assigned provision
Timely detection of cervical cancer through visual inspection or tests such as the Papanicolaou	Guidance and information exchange	Control Integral de Cáncer Cervicouterino, Guía de Prácticas Esenciales, PAHO/WHO, 2016	Primary level of care	Guidance	General medical consultation
	Cytology (Papanicolaou frotis) Screening of all women 30-49 years old or liquid base cytology (LBC)		Primary level of care	Pathologic anatomy	Basic stain study in vaginal cytology, tumoral and/or functional
	HPV tests Screening of all women 30-49 years old		Primary level of care	Laboratory	HPV tests
	Screening of all women 30-49 years old or liquid-based cytology (LBC)		Primary level of care	Pharmaceutical (active ingredient)	Acetic acid

TABLE A3
(1 of 2)

Provision basket for diagnosis and management of type 2 diabetes

Intervention	Description (clinical guide /dosage)	Source for description	Level of care	Service type	Note on assigned provision
Detection and management of diabetes among at-risk adults, including glucose control, arterial pressure and lipid management and constant feet care	General consultation	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	Primary and secondary level	Consultation	General medicine consultation
	Endocrinology consultation	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	Secondary and tertiary level	Consultation	Specialized medicine consultation
	Glucose level	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	Primary and secondary level	Laboratory	Glucose, O'Sullivan test +
	Oral glucose tolerance test	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	Secondary and tertiary level	Laboratory	Glucose, tolerance curve +
	Calcium	Expert opinion	All three levels	Laboratory	Calcium by colorimetry *+
	Chlorine	Expert opinion	All three levels	Laboratory	All three levels
	Magnesium	Expert opinion	All three levels	Laboratory	Magnesium+
	Phosphorous	Expert opinion	All three levels	Laboratory	Inorganic phosphorous [phosphates]
	Potassium	Expert opinion	All three levels	Laboratory	Potassium +
	Sodium	Expert opinion	All three levels	Laboratory	Sodium+
	Serum creatinine	Expert opinion	All three levels	Laboratory	Creatinine in serum, urine or other

TABLE A3
(2 of 2)

Provision basket for diagnosis and management of type 2 diabetes

Intervention	Description (clinical guide /dosage)	Source for description	Level of care	Service type	Note on assigned provision
Detection and management of diabetes among at-risk adults, including glucose control, arterial pressure and lipid management and constant feet care	Microalbuminuria	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	All three levels	Laboratory	Albumin
	Glycated hemoglobin test HBA1c	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	All three levels	Laboratory	Glycated hemoglobin by monoclonal antibodies
	VDRL	Expert opinion	All three levels	Laboratory	Serology [non treponemic test] VDRL in serum or CSF & * +
	HDL	Expert opinion	All three levels	Laboratory	High-density cholesterol [HDL]
	LDL	Expert opinion	All three levels	Laboratory	Enzymatic low-level cholesterol [LDL]
	Total cholesterol	Expert opinion	All three levels	Laboratory	Total cholesterol
	Triglycerides	Expert opinion	All three levels	Laboratory	Triglycerides +
	Non-mydriatic eye fundus	Guía AIAD sobre diagnóstico, control y tratamiento de diabetes tipo 2 en Medicina Basada en la Evidencia, 2019	Secondary and tertiary level	Procedure	Non-mydriatic eye fundus
	Electrocardiogram	Expert opinion	All three levels	Procedure	High-resolution electrocardiogram [late potentials study] +

NOTES

[1] Source: WHO. See https://apps.who.int/gho/data/node.main.GHEDOOPSCHESHA2011?lang=en.

[2] We used 2019 data to estimate the savings because that is the year of the last version of IQVIA before the COVID-19 pandemic.

[3] The IQVIA database collects data from 72 percent of retail pharmacies. Those who supply the information suggest expanding using 1/0.72 as the expansion factor. However, since pharmacies that do not report or are excluded from the sample are possibly the smallest ones, the number of pharmacies is not necessarily a good expansion factor for sales volume. Information on the percentage of sales captured by the database is not available. Consequently, we did not use the suggested expansion factor for this article. Additionally, we were not able to clarify if the price reported in the database includes the pharmacy's profit margin or not. We assumed that the value reported in the database as "*list price*" is the same as the "*ex-manufacturer price*", which is the price for the public and includes the pharmacy's profit margin. These adjustments imply that this article's estimates are a conservative (or a lower bound) estimate of total sales.

[4] This implies the assumption that individuals can substitute drugs with different dosages. The goal of this exercise is to quantify the potential savings in the case in which this type of substitution is possible.

[5] This assumes that unbranded generics have passed the necessary quality standards and are bioequivalent to innovators and/or interchangeable with branded generics. Health agencies must guarantee these bioequivalences and interchangeability.

[6] We use what the study reports as direct out-of-pocket spending. The study calculates out-of-pocket outpatient drug spending for 2018 at DOM$33.5 million. Adding that to what SISALRIL reports as payment to retail pharmacies for the same year (DOM$4 million), the result is that public purchases represent 11 percent of total purchases on the retail market.

[7] US$25 million for molecules covered by the SFS and US$36.5 million for those not covered.

[8] The estimated savings for the highest scenarios (US$60 million and US$27.5 million) are equal to US$64 million and US$31 million in 2022, values which largely exceed the cost of covering the two gaps we analyzed. As we mentioned, to bring 2019 savings to 2022 dollars we used the inflation reported for the Dominican Republic available in the World Bank's database and the exchange rate reported by the Banco de la República de República Dominicana.

BIBLIOGRAPHY

1. Azael Lorenzo, G. and Penson, E. (2018). "Análisis del gasto de bolsillo en salud de los hogares en República Dominicana a partir de datos de la ENGIH-2018". Technical report, Oficina Nacional de Estadística, Gobierno de República Dominicana.

2. Atal, J. P., Cuesta, J. I. and Sæthre, M. (2019). "Quality Regulation and Competition: Evidence from Pharmaceutical Markets". Mimeo.

3. Rathe, M. and Moliné, A. (2011). "Sistema de salud de República Dominicana". *Salud Pública de México*, 53.

4. Riascos, A. (2023). "Metodología para la estimación del umbral de costo-efectividad: el caso de República Dominicana". Washington D.C.: Inter-American Development Bank.

5. Jamison, D. T., Gelband, H., Horton, S., Jha, P., Laxminarayan, R., Mock, C. N. and Nugent, R., editors (2018). *Disease Control Priorities: Improving Health and Reducing Poverty.* Volume 9, *Disease Control Priorities* (third edition). Washington, DC: World Bank.

6. Jorgensen, N., Betatti, L., Gutiérrez, C., Giedion, U. and Ollendorf, D. (2023). "¿Cuál es el costo de oportunidad de financiar medicamentos de alto costo? El caso de República Dominicana". Washington D.C.: Inter-American Development Bank.

7. Oficina Nacional de Estadística (2020). "Análisis del gasto de bolsillo en salud de los hogares en República Dominicana. A partir de datos de la ENGIH-2018". República Dominicana: Oficina Nacional de Estadística.

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