Ministry of Health’s spending on drugs: program trends from 2002 to 2007

ABSTRACT

OBJECTIVE: To analyze the evolution of the Ministry of Health’s spending on drugs.

METHODS: The Ministry of Health’s total (aggregate) spending on drugs and its programs’ (not aggregate) were analyzed between 2002 and 2007. Actions that financed drug acquisition were obtained from the Siga Brasil system and classified according to pharmaceutical service programs. Settled values were identified for each program. For 2006 and 2007, antiretroviral drug acquisitions were analyzed. As regards drugs from the Programa de Dispensação em Caráter Excepcional (Exceptional Circumstance Drug Distribution Program), budget action data were compared to those available in the Sistema Único de Saúde (Unified Health System). Values obtained were deflated by applying the Índice de Preços ao Consumidor Amplo (Broad Consumer Price Index). Exploratory data analysis was subsequently performed.

RESULTS: Spending in 2007 was 3.2 times higher than 2002 and drug spending participation in total spending rose from 5.4% in 2002 to 10.7% in 2007. Primary care drug spending increased by 75%, and strategic program spending by 124%. In the case of antiretroviral drugs, the increase was about 6%, but with an increase by 77% from 2005 to 2006, followed by a reduction by 29% from 2006 to 2007. The most significant increase in spending was observed with exceptional circumstance distribution drugs, 252% between 2003 and 2007.

CONCLUSIONS: There was significant increase in drug spending between 2002 and 2007, with greater participation of antiretroviral and exceptional circumstance distribution drugs, which are comprised by a large number of patent-protected pharmaceuticals.


INTRODUCTION

In Brazil, the publication of the Política Nacional de Medicamentos (National Drug Policy) in 1998\(^1\) encouraged the creation of programs aimed at guaranteeing the population’s access to drugs.

Offer of essential drugs, included in the Programa de Medicamentos de Dispensação em Caráter Excepcional (Exceptional Circumstance Distribution Drug Program), with an unusual high cost per unit known as Alto Custo (High Cost), has increased.\(^4\)

If, on the one hand, drug access is fundamental to guarantee the constitutional right to health, on the other, it has become a reason for concern about the evolution of spending. A study performed in 2007 showed irregular growth in spending on health and drugs at the federal level. For the Ministry of Health, while total spending on health increased by 9.6%, those on drugs increased by 123.9%, between 2002 and 2006.\(^b\)

Similar situation has occurred in other countries. In the United Kingdom, spending on drugs in primary care grew 10% between 2001 and 2002 and caused a financial crisis.\(^3\) In Canada, growth in spending was estimated at 6% in 2006, totaling US$ 25 billion, of which US$ 21.1 billion were on prescription drugs.\(^3\)

In the case of Brazil, even though there is a good estimate of the total value allocated by the Ministry of Health for drugs in recent years (2002 a 2006);\(^c\) little is known about the evolution of spending among the different programs that comprise total spending.

Ministerial Decree GM/MS nº 204, from January 29th 2007;\(^c\) organized and categorized drug acquisition resources in the Bloco de Financiamento da Assistência Farmacêutica (Pharmaceutical Service Funds):

- Pharmaceutical Service Basic Component – aimed at pharmaceutical service materials and drug acquisition in primary health care and those associated with specific health programs and problems.
- Pharmaceutical Service Strategic Component – funds pharmaceutical service actions for the following strategic health programs: a) control of endemic diseases, such as tuberculosis, leprosy, malaria, leishmaniasis, Chagas’s disease and other endemic diseases with a national or local scope; b) AIDS/STD program’s ARV drugs; c) blood and blood derivatives; and d) immune-biological vaccines and serums.
- Exceptional Circumstance Distribution Drug Component – aimed at acquisition and distribution of this type of drugs, in accordance with criteria established by the Protocolos Clínicos e Diretrizes Terapêuticas (Therapeutic Directives and Clinical Protocols).

In this context, the present study aimed to analyze the Ministry of Health’s evolution of spending on drug programs.

**METHODS**

Analysis was performed from total (added) spending and its (not added) programs, between 2002 and 2007.

Survey of Federal Budget actions that funded drug acquisition was performed using the Siga Brasil system.\(^4\) As research universe, the item “Despesa execução” (settled expense) of each year was selected from its corresponding Lei Orçamentária Anual (LOA – Annual Budget Law), such as LOA 2007 – Despesa execução. The universe name, program as code and description, action as code and description, and values settled were defined as research “result objects”. The “consultation filter” was the “Fundo Nacional de Saúde” (FNS – National Health Fund) budget unit.

Settled values that were constant on the spreadsheet were added to obtain the total value settled by the FNS for each year. In the case of values settled for drug acquisition, all budget actions were identified on each spreadsheet as code and description, whose name is associated with or suggests the offer of treatment to patients, regardless of the category of resource use (whether direct use or transfer to other federal units, foreign locations or private non-profit institutions).

Coherence among the product defined in the LOA\(^c\) for each action, the objective of the program to which it belongs, and the indicators proposed for each program was observed to confirm whether budget actions actually funded drug acquisition.

The important and unexpected reduction in the value settled for the budget action of acquisition of HIV/AIDS drugs, between 2006 and 2007, led to the ARV drug acquisition survey, made during these two years, to compare data according to sources. This search was conducted on the Portal de Compras do Governo Federal website,\(^f\) according to the following path:


Each year’s contract records were consulted and those related to ARV drug acquisition were copied. These records include data on the contractor, contractual object, value, amount and effective date of contract term. As regards the Exceptional Circumstance Distribution Program drugs, budget action data were compared to those available on the web page of the Departamento de Informática do Sistema Único de Saúde – Datasus (Unified Health System Department of Information Technology), according to the following path: informações de saúde > assistência à saúde > produção ambulatorial > Brasil por região e unidade da federação > tabnet (linha: procedimento após 10/99; coluna: ano de competência; conteúdo: valor aprovado > procedimento após 10/99: seleção apenas dos medicamentos). Data refer to values approved to be transferred to the State Departments of Health as payment for Autorizações de Procedimento de Alta Complexidade (Apac – High Complexity Procedure Authorizations).

All data were input on an electronic spreadsheet and the values obtained were deflated by applying the Índice de Preços ao Consumidor Amplo (IPCA – Broad Consumer Price Index), thus enabling them to be compared with 2007 values.

**RESULTS**

Actual growth in drug spending was observed between 2002 and 2007 (Figure 1). Spending in 2007 was 3.2 times higher than in 2002 and participation of drug spending in the Ministry of Health’s total spending rose from 5.4% in 2002 to 10.7% in 2007.

Distribution of total spending on drugs in pharmaceutical service programs or actions defined in the federal budget is shown on Table 1. On this Table, spending on drugs for exclusive hospital use is not included, as they are funded with resources from the Autorizações de Internação Hospitalar (AIH – Hospital Admission Authorizations), nor are those aimed at offering antineoplastic chemotherapeutic drugs, funded with resources from the Autorizações de Procedimentos de Alta Complexidade em Oncologia (Apac-Onco – High-Complexity Oncology Procedure Authorizations).

In the period analyzed, spending on primary care drugs increased by 75%, and that on strategic program drugs, by 124%. In the case of STD/AIDS drugs, the increase was about 6%. However, the situation of spending on such drugs was peculiar: an increase of 77% between 2005 and 2006, and a subsequent decrease of 29% between 2006 and 2007.

The most substantial increase in spending was observed with exceptional circumstance distribution drugs. In this case, based on the federal budget, it was not possible to distinguish this from the remaining expenses in 2002. By analyzing the series from 2003 to 2007, the rise in spending was 252%.

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**Figure 1.** Percentage of value settled for acquisition of drugs of the National Health Fund. Brazil, 2002-2007.

**Figure 2.** Value with HIV/AIDS drug acquisition settled by the federal government per patient. Brazil, 2002-2007.
The increase in the federal budget value settled for the action that funds acquisition of drugs for people with STD/AIDS was 44% between 2002 and 2007, and 3.7% between 2006 and 2007. To analyze the reduction occurred in these two last years, spending on the STD/AIDS Program treatment per patient was estimated, assuming these drugs were used in the same year they were acquired. The number of patients in treatment was obtained from the Programa Nacional de DST/AIDS (National STD/AIDS Program). The result of this estimate is shown on Figure 2. Relevant reduction (33%) in the patient’s mean spending was observed between 2002 and 2003, reaching a plateau that continued until 2005, when there was an increase of 67% between 2005 and 2006, with a subsequent reduction of about 32% in 2007. During this period, average annual spending on treatment per patient was R$ 4,302.00 (2007 reais or constant reais). In addition, as regards STD/AIDS treatment drugs, data on ARV drug acquisition by contract were collected on the Portal de Compras do Governo Federal website (ComprasNet), between 2006 and 2007. Values collected do not include acquisition of drugs from the agreement category, which is performed when the government acquires drugs from public pharmaceutical laboratories, for example. In 2006, R$ 745.8 million (2007 reais) were spent, and in 2007, R$ 452.2 million. There was a reduction of 39% in the value spent on ARV acquisition by contract (R$ 293.6 million).

The following drugs were purchased in 2006, rather than 2007, totaling about R$ 317.5 million (2007 reais) in spending, in that year, thus representing 43% of total spending on ARV drugs acquired by contract: amprenavir 150 mg capsule, atazanavir 150 mg capsule, didanosine 400 mg capsule, efavirenz 200 mg capsule, efavirenz 600 mg pill, and ritonavir 80 mg/ml oral solution.

On the other hand, in 2007, R$ 30.3 million were spent on the following drugs that had not been acquired in 2006 (about 7% of total spending on ARV drug acquisition by contract): darunavir 300 mg pill, fosamprenavir 700 mg pill and lopinavir/ritonavir 80/20 mg/ml oral solution.

As regards drugs acquired by contract in 2006 and 2007, R$ 428.4 million (2007 reais) and R$ 421.9 million were spent, respectively. Table 2 shows the share of spending on each antiretroviral drug in each year’s total spending on this group of drugs.

Moreover, Table 2 shows that the majority of these drugs (79%, or 11 of the 14 ARV drugs) had their prices substantially reduced between 2006 and 2007. There was also reduction in the amount acquired for 50% of them.
In terms of exceptional circumstance distribution drugs, for which a significant increase in budget spending was found between 2003 and 2007 (252%), comparison with the values approved by the Ministry of Health for procedures paid to the State Departments of Health revealed differences between the two sources (federal budget and Datasus), as shown on Table 3.

From 2003 to 2005, Datasus values were higher than those settled in the specific budget action that funds acquisition of these drugs, subsequently reversing in 2006 and 2007.

Table 3. Resources executed with the Exceptional Circumstance Distribution Drug Program, according to data on outpatient service production of the Unified Health System and federal budget. Brazil, 2002 to 2007.

<table>
<thead>
<tr>
<th>Year</th>
<th>Values approved for procedures (2007 R$)</th>
<th>Values settled (2007 R$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>520,654,575.72</td>
<td>-</td>
</tr>
<tr>
<td>2003</td>
<td>673,146,214.84</td>
<td>555,196,908.00</td>
</tr>
<tr>
<td>2004</td>
<td>1,011,364,355.62</td>
<td>872,574,884.09</td>
</tr>
<tr>
<td>2005</td>
<td>1,237,295,810.90</td>
<td>1,183,519,039.70</td>
</tr>
<tr>
<td>2006</td>
<td>1,361,730,578.98</td>
<td>1,449,180,509.87</td>
</tr>
<tr>
<td>2007</td>
<td>1,410,181,600.74</td>
<td>1,956,332,705.60</td>
</tr>
</tbody>
</table>


DISCUSSION

There is a relationship between federal budget actions and specific pharmaceutical service programs, aimed at guaranteeing the population’s successful access to drugs, enabling the estimation of spending on drugs for specific programs. Traditional pharmaceutical service programs are present in each component of the Pharmaceutical Service Funds. Budget actions were developed based on these programs.

The Ministry of Health’s significant increase (222%) in total spending on drugs, between 2002 and 2007,
The share of spending on drugs in the Ministry of Health’s total spending shows the importance that this expense component has assumed throughout the years analyzed. The small reduction observed in 2006 and 2007 is justified by the fact that total resources allocated by the Ministry of Health increased more than the growth in drug spending in 2007, when compared to the previous year.

Even though the share in total spending has decreased, increase in drug spending is a world trend and some factors have already been pointed out to explain this pattern.1

Table 1 shows that the major contribution to the increase in total spending on drugs in the period analyzed resulted from exceptional circumstance distribution drugs (an increase of 252% between 2003 and 2007). In addition, data confirm the discrepancy between resources allocated for primary health care drugs and those allocated for medium- and high-complexity health care drugs. In 2007, for example, R$ 319.9 million were allocated in transfers for states and cities to acquire primary care drugs and R$ 2.7 billion in STD/AIDS drugs and those of exceptional circumstance distribution. Even if the Ministry of Health’s strategic program drugs (tuberculosis, leprosy, and human insulin) were included in the amount for primary care, the ratio between spending on STD/AIDS and exceptional circumstance distribution drugs and spending on pharmaceutical services in strategic and primary care would be 2.6 reais to 1 real.

However, the scope of these programs needs to be considered. STD/AIDS and exceptional circumstance distribution drugs serve specific groups of patients (those with HIV/AIDS and those with chronic and usually rare diseases), while pharmaceutical service drugs in strategic and primary care are aimed at more important diseases from an epidemiological point of view and, consequently, the population as a whole. Major differences between drugs used in these two subgroups of programs make it difficult to compare and make conclusions about a possible emphasis on medium- and high-complexity care, to the detriment of primary care. One of them is that an important portion of STD/AIDS and exceptional circumstance distribution drugs are protected by patents, thus causing the cost of these products to be higher.

Studies on factors in the recent trend in ARV drug cost in Brazil showed that those which had been patented (11 of the 18 drugs included in the treatment consensus in 2007, for example) contributed to 60% to 70% of the total cost with ARV drugs between 2001 and 2003, and 80% between 2004 and 2005.6 In the present study, values settled for the budget action of ARV drug acquisition showed a reduction in spending between 2002 and 2005, with a subsequent increase of 77% between 2005 and 2006. Nunn et al6 found that the annual cost per patient decreased between 2001 and 2003, whereas it more than doubled in 2005. For the present study, this spending decreased between 2002 and 2005, and only in 2006 was there an increase of 67% (Figure 2). The divergence between these two studies could be explained by the year of curve inflexion, resulting from different data sources. The authors6 previously mentioned used data on ARV drug spending from the Programa Nacional de DST/Aids (National STD/AIDS Program) until 2005 (which could have some inaccuracy), while the present study used data from the federal budget, which agree with data on ARV drug spending, updated on the Program’s web page.

Even though it was not possible to identify all the Ministry of Health’s ARV drug acquisitions, their greater amount in terms of resources (performed by contract with private companies) was dealt with. Acquisitions made by public pharmaceutical laboratories, producers of generic ARV drugs, were not included, because consultation of the Ministry of Health’s agreement database has not been available for open access until now.

Based on this analysis, as there was greater reduction (39%) in the total value of contracts to purchase ARV drugs than in the total value settled for budget actions (29%), between 2006 and 2007, drugs acquired by contract began to contribute less to the program’s total spending in 2007.

Reduction observed in the value allocated in these acquisitions could be almost completely explained by performing stock control in 2006, as only one (didanosine 400mg) of the ARV drugs, which had not been purchased in 2007, is manufactured domestically.6

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The remaining drugs are protected by patents, even though efavirenz, which became subject to compulsory licensing in May 2007, is one of them, thus enabling acquisition of this generic drug internationally. In addition, there was no change in therapeutic consensus in this year and, as a result, none of these drugs stopped being/ began to be less used.

Reduction in prices of ARV drugs acquired both in 2006 and 2007 was observed, according to Table 2, even though such reduction was not enough to justify the magnitude of global reduction in spending. If the following are considered – difference in spending on ARV drugs between 2006 and 2007 of R$ 293.6 million (2007 reais); value of drugs purchased in 2006, rather than in 2007, of R$ 317.5 million; and spending on drugs, which had not been purchased in 2006, of R$ 30.3 million in 2007 – then, the difference between “spending not performed” (317.5 million) in 2007 and “added spending” (30.3 million) in the same year equalled R$ 287.2 million and, consequently, only R$ 6.4 million of the R$ 293.6 million difference observed can be attributed to changes in prices and amounts of ARV drugs acquired in two years. Thus, performing stock control in 2006 for use in 2007 is an important factor to explain this situation.

As regards exceptional circumstance distribution drugs, the fact that budget values settled between 2003 and 2005 were lower than the values in procedures approved reveals that resources from other budget actions, especially those for drug acquisition, were used to perform payments to State Departments of Health, which was fully achieved in 2002, when there was no specific budget action to fund the program (Table 3). In 2006 and 2007, this relationship reversed and this can be justified by the acquisition of the following drugs by the Ministry of Health, in a centralized manner: imiglucerase 200 UI, epoetin alfa 2,000 and 4,000 UI, human immune-globulin 5 g, interferon alfa-2b 3,000,000, 5,000,000 and 10,000,000 UI. In this way, it is possible to observe that these four pharmaceuticals were responsible for 28% of the program’s total spending.

Differences observed on Table 3, especially between 2003 and 2005, despite their not compromising the general spending analysis, show the limitation of working with budget data. There is always the possibility that resources from other actions, in addition to the main program funding source, may have been used. However, this situation does not invalidate the data and analysis presented, once this is the best way to approach the Ministry of Health’s drug spending, based on open access data sources.

The present study does not intend to defend indiscriminate restriction on drug spending. Even though there are no data on the number of people with drug access, values allocated indicate an important increase in the last years, which is relevant for primary care, as long as the resources are adequately used. Information on spending is an essential measure for efficient management of pharmaceutical services and SUS resources. Grangeiro et al predicted investment in other areas would be compromised, if current rates of ARV drug spending and gross domestic product growth were maintained.

In conclusion, despite the government’s having saved about half of the spending on ARV drug acquisition by negotiation, its role is as important as those of prescribers and patients. The increase in drug spending may be more associated with the number of drugs prescribed for certain age groups/sex and drug type in different therapeutic classes than with the population’s demographic changes. This emphasizes the importance of efficient management of pharmaceutical services and, consequently, of information about drug spending as a process component.

REFERENCES


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