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Exceptional circumstance drug dispensing: history and expenditures of the Brazilian Ministry of Health

ABSTRACT

OBJECTIVE: To describe the technical aspects of the Exceptional Circumstance Drug Dispensing Program of the Brazilian Ministry of Health, especially with respect to the cost of dispensed medication.

METHODS: Technical information was obtained from the ordinances that regulate the Program. Expenditure from 2000 to 2007 was obtained from the Sistema Único de Saúde's (Unified Healthcare System) Outpatient Information System. All drugs dispensed between 1993 and 2009 and the amount and cost of each procedure were evaluated, based on information from the high-complexity procedure authorization of each of the country's states.

RESULTS: The Program changed with the increase in the number of pharmacological agents and presentations distributed by, and the number of diseases contemplated in the program. In 1993, the program distributed 15 pharmacological agents in 31 distinct presentations. This number increased to 109 agents in 243 presentations in 2009. Total Ministry of Health expenditure with medications was R\$1,410,181,600.74 in 2007, almost twice the amount spent in 2000, R\$684,975,404.43. Diseases whose expenditure increased in the period included chronic renal insufficiency, transplantation, and hepatitis C.

CONCLUSIONS: The Exceptional Circumstance Drug Dispensing Program is in constant transformation, aimed at building instruments and strategies that can ensure and expand access to medication among the population. Alternatives should be sought to decrease the financial impact of the Program to a level that does not impact other sectors of the health care system, given the high cost associated with novel interventions.

DESCRIPTORS: Exceptional Drugs. Ordinances. Health Expenditures. National Drug Policy.

INTRODUCTION

Pharmaceutical care is part of health care and is critical to the resolution of most diseases. It involves the distribution of a large volume of public resources.^a For this reason, increasing access to drugs by the population is one of the great challenges of public policy.¹

In a number of countries, the proportion of total health expenditures related to drug purchases has risen substantially in recent years. In the United Kingdom,

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^a Conselho Nacional de Secretários de Saúde. Assistência Farmacêutica no SUS. Brasília(DF); 2007.

the amount of money spent on primary care medications increased by 10% between 2001 and 2002.³ In Canada, spending increased by 6% in 2006, reaching US\$ 25 billion.² The United States government estimated that drug-related spending would rise from US\$ 184 billion in 2003 to US\$ 519 billion in 2013.⁴

In Brazil, Ministry of Health (MoH) drug-related expenditures increased by 123.9% between 2002 and 2006, whereas the increase in total health care spending increased by only 9.6% in the same period.^b

Federal funding of drug purchases is currently regulated by GM ordinance n^o. 204, of 29 January 2007, which organized and categorized resources for purchasing these products in the Bloco de Financiamento da Assistência Farmacêutica (Pharmaceutical Care Fund). This fund was divided into three components: basic, strategic, and exceptional circumstance dispensation drugs,^c more recently renamed as the “specialized component of pharmaceutical care”.^d

The budget for this last component rose from R\$516 million in 2003 to R\$1.3 billion in 2006, corresponding to a real value increase of 159%. This program is therefore one of the major components of the increase in drug-related expenditures within the MoH.^{5,a}

In this context, the present article describes the technical aspects of the Exceptional Circumstance Drug Dispensing Program since its creation, in 1982, focusing primarily on the evolution of MoH expenditures on the program.

METHODS

The history of the Exceptional Circumstance Drug Dispensing Program is described based on an analysis of MoH ordinances issued since 1982. In parallel, we carried out a bibliographical survey of the literature on the subject.

Cost analysis began in 2000, the first year for which we were able to obtain complete data on the funds transferred from the MoH to the State Secretariats of Health specifically to cover the Program. This year also saw a substantial increase in the number of pharmacological agents and presentations provided free of charge by the MoH.

Expenditure analysis for the 2000-2007 period was based on data from the Sistema de Informações Ambulatoriais do Sistema Único de Saúde (SIA/SUS – Outpatient Information System of the Brazilian

Unified Health Care System), run by the MoH. We used outpatient data provided by the Brazilian states to the MoH, given as the “Approved value per year/competence according to procedure after 10/1999.” The “Approved value” item gives the amount of MoH funds allocated, according to the drug expenditures informed by the states through the Autorizações de Procedimento de Alta Complexidade (APAC – High-Complexity Procedure Authorization) registry.

Data for each State/Federation Unit were compiled in electronic spreadsheets for exploratory analysis and, to allow year-to-year comparisons, all values were converted into 2007 prices according to the General Price Index – “Internal availability” of the Fundação Getúlio Vargas.

Demographic data obtained from the DATASUS website were used for *per capita* expenditure analysis, comparing the population of each state and Region with the amount spent on medication through the Program.

MoH fund allocations were also analyzed to verify the price paid for each drug in the program, thus calculating the approximate expenditure on certain diseases covered by the Program as well as the fraction of total spending attributable to these conditions and the spatial distribution of these values. To this end, we added the amounts spent on all drugs used to treat a given disease based on SIA/SUS data. In parallel, we calculated the fraction of funds spent on this disease in comparison to the total expenditures of the Program.

RESULTS

The Exceptional Circumstance Drug Dispensing Program began to function in 1982, and provides drugs for the treatment of specific diseases that affect a limited number of patients. In most cases, these drugs are for long-term use.^e

Until 1993, the Program provided medication to transplant and chronic renal disease patients. In 1993, the current format of the Program began to be implemented, which included a list of 15 drugs in 31 formulations.^c

In 1996, SAS/MoH ordinance no. 204 established regulations aimed at increasing MoH control over expenditures. This ordinance created codes in the SIA/SUS table that allowed for computerization of the drug dispensing process, created a form for requesting exceptional circumstance drugs, and updated the list of drugs distributed free of charge by the Program.^a

^b Vieira FS, Mendes ACR. Evolução dos gastos do Ministério da Saúde com medicamentos. Brasília (DF): Ministério da Saúde; 2007.

^c Silva RCS. Medicamentos excepcionais no âmbito da assistência farmacêutica no Brasil. [Master's dissertation]. Rio de Janeiro: Escola Nacional de Saúde Pública Sérgio Arouca da Fiocruz; 2000.

^d Ministério da Saúde. Portaria 2.981, de 26 de novembro de 2009. Aprova o componente especializado da assistência farmacêutica. *Diário Oficial Uniao*. 30 nov 2009;Seção1:725.

In July 1999, Joint SE/SAS/MoH ordinance no. 14 regulated the financing and distribution of resources for drug purchasing within the Program, and one month later, SAS/MoH ordinance no. 409 implemented the APAC system for reimbursing the costs of Program drugs. Thus, in order to facilitate the implementation of drug dispensing control through APAC, the MoH established codes for each drug type, individualized user control through the Cadastro Nacional de Pessoa Física (CPF – National Natural Person Registry), mandated the use of the International Classification of Diseases (ICD), and defined the maximum amount of medication to be dispensed per request, among other measures.^a

Until this time, there were no specific norms regulating the inclusion or exclusion of drugs provided by the Program, nor was there an explicit set of technical criteria to be used. All drug inclusions were based on technical evaluations elaborated by consultants hired by the MoH. During this period, patient advocacy groups – perhaps due to their greater political conscience – mobilized themselves to support the inclusion and maintenance in the list of drugs of their interest. The selection of drugs into the Program was thus driven by pressure from these groups, which had the support of corporations and other social organizations.^c

In October 1999, GM/MoH ordinance no. 1,310 created the Pharmacological Assistance Committee, linked to the Secretaria de Assistência à Saúde (SAS – Department of Health Care). This committee included representatives from the SAS, from the Secretaria Executiva do Ministério da Saúde (MoH Executive Department), the Agência Nacional de Vigilância Sanitária (National Sanitary Surveillance Agency), the Conselho Nacional de Secretários de Saúde (National Council of Health Departments) and the Conselho Nacional de Secretarias Municipais de Saúde (National Council of Municipal Departments of Health). The goal of this committee was to establish technical criteria for the selection, inclusion, exclusion, and replacement of exceptional circumstance drugs from the SIA/SUS list.^a

Three years later, GM/MoH ordinance no. 1,318 included 64 pharmacological agents in 155 presentations, in a substantial alteration of the scope of the Program.^a

Completing this series of changes, the MoH published clinical protocols and therapeutic directives between 2001 and 2002 aiming to establish diagnostic criteria for each disease, criteria for the inclusion or exclusion of patients from treatment, the correct dosage of Program drugs, and mechanisms for patient control, follow-up, and evaluation. At this time, 30 different diseases were covered by the Program.^a

GM/MoH ordinance no. 2,577, of 27 October

2006, regulated the Exceptional Circumstance Drug Dispensing Program, defining, among others, the list of drugs dispensed, the diseases for which prescription of these drugs was authorized (based on ICD-10), and the norms regulating access to the Program. Another small alteration was the inclusion of new drugs and diseases under the Program, which occurred in September 2008, modifying the Appendix of Ordinance 2,577 through the publication of GM/MoH ordinance no. 1,869.

Another important milestone was GM/MoH ordinance no. 2,981^d of November 2009, which redefined the Program, changing its name to Componente Especializado da Assistência Farmacêutica (“Specialized Component of Pharmacological Care”). This ordinance defined the Program as a strategy for granting access to medication under the SUS, characterized as an effort to achieve the integrality of pharmacological treatment in the context of outpatient care. Patient care strategies in this Component were defined in clinical protocols and therapeutic directives published by the MoH.^d

This ordinance modified the access to and financing of medication, ensuring that distribution is now carried out based on agreement between the Federal, State/Federal District, and Municipal governments, each of which has distinct responsibilities. Thus, drugs in the Program are now divided into three groups according to source of financing: group 1 – financed by the Federal Government; group 2 – financed by State and Federal District governments; and 3 – financed by Municipal and Federal District governments. Drugs included in groups 1 and 2 continued to be dispensed by the State Departments of Health, whereas those in group 3 are now dispensed by the municipalities.^d

In addition, a number of medications and diseases were either included or excluded from the Program (Table 1), new forms were created for requesting the drugs distributed by the State Departments of Health, and several of the existing protocols were revised.

As a consequence of these modifications, many diseases previously not treatable through SUS were included in the Program throughout the years. Coverage thus increased from three major disease classes (transplants, chronic renal insufficiency, and hypophyseal dwarfism) to 288 chronic diseases, classified according to ICD-10.

Currently, the incorporation of new drugs into the Program is required to follow the principles of evidence-based medicine. Petitioners must now present studies demonstrating a drug’s efficacy and safety, as well as the advantages of this drug over the available therapeutic options (greater efficacy or safety or lower cost) or offer the opportunity for competition within a drug subgroup as a market regulatory strategy.^e

Table 1. Number of pharmacological agents and formulations included in the Exceptional Circumstance Drug Dispensing Program. Brazil, 1993-2008.

Year	Ordinance implementing the alteration	Number of pharmacological agents	Number of formulations
1993	SAS circular no. 418	15	31
1995	SAS/MS ordinance no. 102	22	33
1996	SAS/MS ordinance no. 204	32	53
1997	SAS/MS ordinance no. 17	34	56
2002	GM/MS ordinance no. 1,318	105	203
2006	GM/MS ordinance no. 2,577	102	208
2008	GM/MS ordinance no. 1,869	107	233
2009	GM/MS ordinance no. 2,981	109	243

Program Expenditures

Between 2000 and 2007, resources allocated to the Program were transferred to the States and Federal District by the MoH based on the mean sum approved for a given period according to APAC information.^e

Although state Secretariats of Health usually co-finance the Program,² the data below do not include funds provided by the States. Only the sums approved by the MoH for financing the Program are presented. Between 2000 and 2007, the MoH expenditure with Program drugs increased by 106% (Table 2; Figure 1).

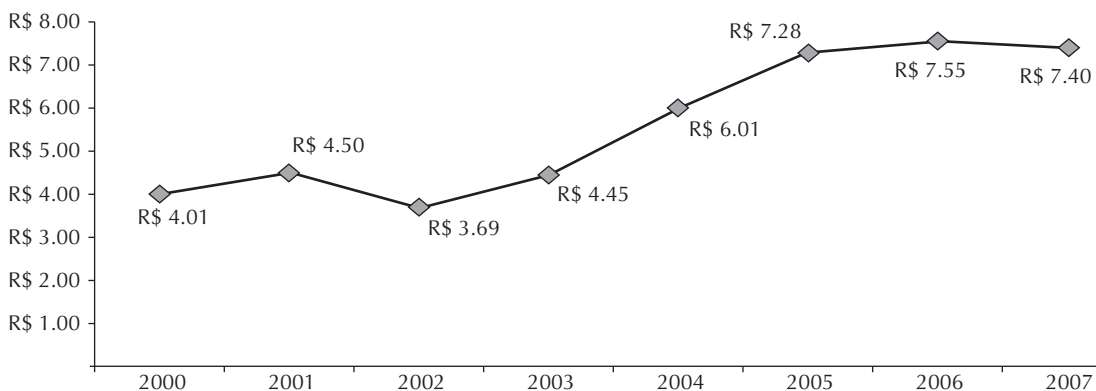
In all of the country's regions, the *per capita* increase was smaller than the increase in total annual drug-related spending. Analysis of annual *per capita* expenditure in each region shows that, during the studied period, expenditures were consistently higher in the Southeast Region, increasing from R\$ 5.69 in 2000 to R\$ 11.00 in 2007. During the same period, the North Region consistently showed the lowest *per capita* expenditure: R\$ 1.14 in 2000 to R\$ 1.80 in 2007. These same two regions (Southeast and North) also showed the largest and smallest total annual expenditure on medications in the Program, respectively.

Table 2. Annual Ministry of Health expenditures with drugs included in the Exceptional Circumstance Drug Dispensing Program. Brazil, 2000-2007.

Year	Annual expenditure (in Reais)
2000	684,975,404.43
2001	777,617,274.95
2002	651,842,605.65
2003	797,490,209.67
2004	1,084,660,016.68
2005	1,343,253,116.61
2006	1,406,436,999.30
2007	1,410,181,600.74

Note: Values deflated using the General Price Index – “Internal availability” of the Fundação Getúlio Vargas

Sao Paulo, Southeastern Brazil, has always been the state with the highest total drug-related expenditure in the Program, with R\$ 245.8 million in 2000 and R\$ 645.6 million in 2007. Up to 2004, the Brazilian state with lowest expenditures was Roraima, Northern, with R\$ 5.4 thousand spend in 2000 and R\$843.6 thousand in 2007. From 2005 to 2007, Amapá, also in Northern, became the state with the lowest expenditure, reaching



Note: Values deflated using the General Price Index – “Internal availability” of the Fundação Getúlio Vargas

Figure 1. Annual per capita expenditures, Ministry of Health Exceptional Circumstance Drug Dispensing Program. Brazil, 2000-2007.

R\$ 634.4 thousand in the final year studied. In spite of these numbers, Roraima displayed the highest relative increase in expenditure with Program drugs. Moreover, 15 federation units registered more than 100% increases in expenditures with Program drugs.

The state of Sao Paulo also had the highest *per capita* expenditure, which increased from R\$ 6.68 in 2000 to R\$ 15.50 in 2007. Roraima, Rondônia, and Amapá, all of which are located in the Northern Brazil, showed the lowest per capita expenditures, ranging from R\$ 0.02 (Roraima, 2000) to R\$ 1.00 (Amapá, 2007).

Per capita expenditures were heterogeneous also within Regions. *Per capita* expenditure in the State of Rio Grande do Sul was similar to that of the two other states in Brazil's South Region (R\$ 4.00); in the final year of the study, however, expenditure in Rio Grande do Sul was almost 50% lower than the mean of the other two states for that year (R \$8.65).

In the Southeast Region, *per capita* expenditure in the State of Rio de Janeiro (R\$ 3.82 in 2000 and R \$4.30 in 2007) was always lower than the average of the other three States in the Region (R\$ 5.15 and R\$ 9.30, respectively).

Similar scenarios were found in the state of Mato Grosso, Central-Western Brazil, which had a *per capita* expenditure of R\$ 4.90, whereas the mean expenditure in the region was R\$7.60, and in the State of Maranhão, with R\$1.70 *per capita* in contrast to a mean of R\$4.40 in the Northeastern region.

In spite of the increase in the number of covered diseases, the conditions originally included in the Program continued to represent the bulk of expenditures: in the first two years studied (2000 and 2001), chronic renal insufficiency (CRI) received the highest share of Program funds. From 2002 onwards, CRI drugs were overtaken by drugs aimed at preventing the rejection of transplants, which remained in first position until 2007. CRI and transplantation also accounted

for the highest fraction of expenditures throughout the studied period, with the exception of 2004, when Hepatitis C received the greatest share of resources (21.3%; Table 4).

DISCUSSION

The Exceptional Circumstance Drug Dispensing Program has undergone major changes, both technical and administrative in nature.

This Program, initially designed to cover a small and specific portion of the population afflicted by diseases regarded as "exceptional," had to come to terms with the brisk technical-scientific evolution of global health care throughout the years, ultimately becoming a gateway for the introduction of novel drugs developed for the treatment of diseases not yet covered by SUS. Such transformation becomes obvious when considering the number of pharmacological agents and formulations distributed by the program, which increased approximately 8-fold in nine years.

The transformation of the Program has been largely beneficial to the Brazilian population, granting free access to treatment of a number of life-threatening diseases. These changes were also beneficial to the Program's administrative structure, for they helped to create rules for the inclusion of drugs into the Program as well as for their subsequent distribution, providing both the MoH (the funding source) and the states (funding sources and distributors) with more complete and secure systems for information control.

However, as with any new technology, novel drugs arrive at the market with high price tags, and the inclusion of such drugs in the Program has had a large impact on MoH expenditure, as shown in the present study. Thus, an issue of fundamental importance to managers and the technical team is the definition of which drugs within a given therapeutic category should be provided by the Program for the treatment of a given disease.

Table 3. Annual Ministry of Health expenditures with drugs included in the Exceptional Circumstance Drug Dispensing Program according to Region. Brazil, 2000-2007.

Year	South	Southeast	Center-West	North	Northeast
2000	104,817,692.56	410,741,526.05	47,552,221.78	14,046,757.45	107,817,206.59
2001	120,528,803.29	457,251,347.51	54,956,538.57	17,011,299.85	127,869,285.73
2002	93,869,543.33	394,142,302.29	45,935,763.14	14,115,272.52	103,779,724.36
2003	111,273,242.24	479,256,021.31	59,860,324.08	25,267,937.59	121,832,684.46
2004	133,560,804.03	671,807,424.06	81,788,890.67	35,673,551.61	161,829,346.32
2005	179,506,051.30	843,959,392.99	99,479,041.48	32,028,264.33	188,280,366.51
2006	208,243,302.91	859,757,645.44	93,962,595.88	34,321,184.78	210,152,270.29
2007	188,087,361.95	891,405,156.62	94,663,474.38	27,606,463.81	208,419,143.98

Note: Values deflated using the General Price Index – "Internal availability" of the Fundação Getúlio Vargas

Table 4. Expenditures with selected diseases in the Exceptional Circumstance Drug Dispensing Program. Brazil, 2000-2007.

Diseases treated	2000		2007	
	Amount transferred (in reais)	Fraction of the annual total (%)	Amount transferred (in reais)	Fraction of the annual total (%)
Acne Conglobata	-	-	4,661,821.19	0.3
Acromegaly	4,996,036.85	0.7	26,897,638.90	1.9
Alzheimer's Disease	-	-	74,960,877.12	5.3
Chronic Pain	-	-	1,405,554.97	0.1
Chronic Renal Insufficiency	184,513,479.52	26.9	97,249,500.59	6.9
Congenital Adrenal Hyperplasia	-	-	62,302.90	0.01
Congenital Hypothyroidism	-	-	330,438.07	0.01
Cystic Fibrosis	14,708,955.77	2.1	24,852,171.17	1.8
Diabetes Insipidus	6,264,444.96	0.9	5,818,541.06	0.4
Dyslipidemia	-	-	74,247,392.77	5.3
Dystonia	16,160,850.22	2.3	24,000,514.87	1.7
Endometriosis/Myoma	44,758,859.39	6.5	27,711,790.96	2.0
Epilepsy	6,717,899.47	1.0	21,267,946.38	1.5
Growth Hormone Deficiency	29,648,667.15	4.3	33,471,824.36	2.4
Hepatitis B	-	-	545,361.91	0.01
Hepatitis C	25,532,094.56	3.7	55,496,753.35	3.9
Hyperprolactinemia	3,626,933.31	0.5	10,716,217.59	0.75
Immunodeficiencies	28,582,224.58	4.2	2,625,419.48	0.2
Lateral Amyotrophic Sclerosis	-	-	10,802,698.01	0.8
Multiple sclerosis	67,377,752.86	9.8	182,370,722.53	12.9
Osteoporosis	17,291,411.79	2.5	30,409,434.18	2.1
Parkinson's disease	-	-	39,262,719.46	2.8
Phenylketonuria	-	-	4,282,673.39	0.3
Psoriasis	4,641,481.34	0.7	5,392,881.63	0.4
Rectocolitis	1,383,586.20	0.2	21,003,793.44	1.5
Rheumatoid Arthritis	-	-	147,232,846.74	10.4
Schizophrenia	20,281,452.55	3.0	208,850,317.23	14.8
Severe Asthma	-	-	22,626,559.75	1.6
Sickle-Cell Disease	-	-	230,556.56	0.01
Transplants	142,374,722.07	20.8	241,077,396.83	17.1
Wilson's disease	347,105.88	0.1	892,726.26	0.05

Note: Values deflated using the General Price Index – "Internal availability" of the Fundação Getúlio Vargas

Considering the Public Health goal of ensuring the best possible care for the majority of the population, and given that resources for achieving this goal are finite, detailed evaluation becomes increasingly necessary. More cost-effective alternatives must be sought in order to promote more rational use of exceptional drugs. Properly choosing a few, effective drugs will open space for the inclusion of other drugs for diseases not yet covered by SUS.

The MoH has been able to rationalize the use of these novel technologies through the publication of the Clinical Protocols and Therapeutic Directives.

However, the current scenario is that system users, physicians, pharmaceutical companies, and the Judiciary pressure the MoH to include new drugs in the Program as soon as these appear on the market. Individuality is being placed above collectivity, hampering efforts to organize the service.

An analysis of the inclusion and exclusion of pharmacological agents showed that very few drugs were excluded from the program after their initial introduction. In the pharmaceutical field, as in many other health-related areas in Brazil, there is a lack of an infrastructure for monitoring the use of a new technology in

order to make a decision on continuing or abandoning its use. This is in spite of this stage being known to be as important as implementation, since it can prevent the unnecessary maintenance of an ineffective drug, creating space for the inclusion of others.

To evaluate the exclusion of an item from the list of medications provided by the Program does not necessarily mean to terminate the distribution of this item through SUS. Rather, such evaluation is aimed at assigning the distribution of a drug to the appropriate level of health care given the prevalence of the disease which it is meant to treat. Achieving this goal was the motivation behind MoH ordinance no. 2,981, which mandates that drugs aimed at treating diseases that currently affect a large portion of the population – such as dyslipidemia, hypothyroidism, and osteoporosis – now be distributed through the primary health care network.

This ordinance will also bring about changes in the profile of expenditures with this component of pharmaceutical care, since now the three spheres of government (Federal, state, and municipal) are responsible for financing specific groups of medications.

As to differences in terms of funding between the country's regions and states, it is important to point out that the MoH does not determine the sum to be allocated. Rather, funds are allocated according to what each State reports through APAC – that is, it is the demand of the population that determines the amount spent on Program drugs. Together with the data presented above, this suggests that, in spite of its growth throughout the country, there are still differences in knowledge of and access to the Program between the Brazilian Regions and between states within the same region.

In conclusion, we have shown that the Specialized Component of Pharmaceutical Care is a key part of Brazilian Public Health policy, allowing access to drugs for the treatment of highly complex diseases at the same time as it accounts for a substantial fraction of the budget of the different spheres of government. For this very reason, the Program should remain in constant transformation in order to increase access of the population to health care services and to find therapeutic alternatives capable of reducing the financial impact of drug purchases on other areas of Public Health.

REFERENCES

1. Araújo ALA, Pereira LRL, Ueta JM, Freitas O. Perfil da assistência farmacêutica na atenção primária do Sistema Único de Saúde. *Cienc Saude Coletiva*. 2008;13(Suppl):611-7. DOI:10.1590/S1413-81232008000700010
2. Kondro W. Drug spending tops \$25 billion. *CMAJ*. 2007;176(13):1816. DOI: 10.1503/cmaj.070680
3. Macdonald S. Increased drug spending is creating funding crisis, report says. *BMJ*. 2003; 326(7391):677. DOI:10.1136/bmj.326.7391.677
4. Moynihan R. Drug spending in North America rose by 11% in 2003. *BMJ*. 2004; 328(7442):727. DOI:10.1136/bmj.328.7442.727
5. Vieira FS. Gasto do Ministério da Saúde com medicamentos: tendência dos programas de 2002 a 2007. *Rev Saude Publica*. 2009;43(4):674-81. DOI: 10.1590/S0034-89102009005000041

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