Next-generation drugs inclusion to the South's HIV/AIDS programs: The Brazilian experience on third-line drugs

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Brazil, which has one of the largest patients cohort (315 000 people on TARV) and one of the oldest, is the first country in the south to confront the challenge of third-line treatments distribution. Currently, the National Program HIV/AIDS distributes six third-line ARV (Darunavir, enfuvirtide, étravirine, raltégravir, tipranavir and maraviroc) to the patients in virological treatment failure. Our research is interested in the evolution of the purchase price of each ARV and the impact of third-lines on the total budget devoted to acquisition of ARVs.

Key-words: third-line antiretrovirals; purchase price; acquisition of ARV.

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Introduction: Third-line antiretroviral drugs (ARV) are now indicated for the treatment of multi-resistant HIV/AIDS patients in virological treatment failure. Although being the last and highly effective line of defense, they are almost not present in the South, because of their prohibitive cost. Therefore, Brazil, where these drugs have been adopted since 2005, constitutes an ideal laboratory to study next generation drugs inclusion.

Materials and Methods: Study the Brazilian Program focusing on costs of this new treatment strategy. We monitored the purchases between 2007 and 2009 looking for unitary costs of drugs and the total costs for the Ministry of Health. This research was based on the review of official documents from the Ministry of Health and statistical work on National Health Bank (BPS) and Ministry of Health budget databases.

Results: The National Program HIV/AIDS now distributes five third-line ARV: Darunavir (introduced in 2007), enfuvirtide (2005), etravirine (2010), raltegravir (2008), tipranavir (2010), all patented and imported at very high prices. Over time, however, a lower purchase price is observable (see table1). Thus the price of darunavir (300mg tablet) decreased by 19.6% between 2007 and 2009; enfuvirtide (108mg vial) by 19.3% between 2007 and 2009; raltegravir (400mg tablet) by 12.8% between 2008 and 2009. As the data from BPS was incomplete from 2010, we were obligated to neglect etravirine and tipranavir because these two drugs were introduced only in 2010.

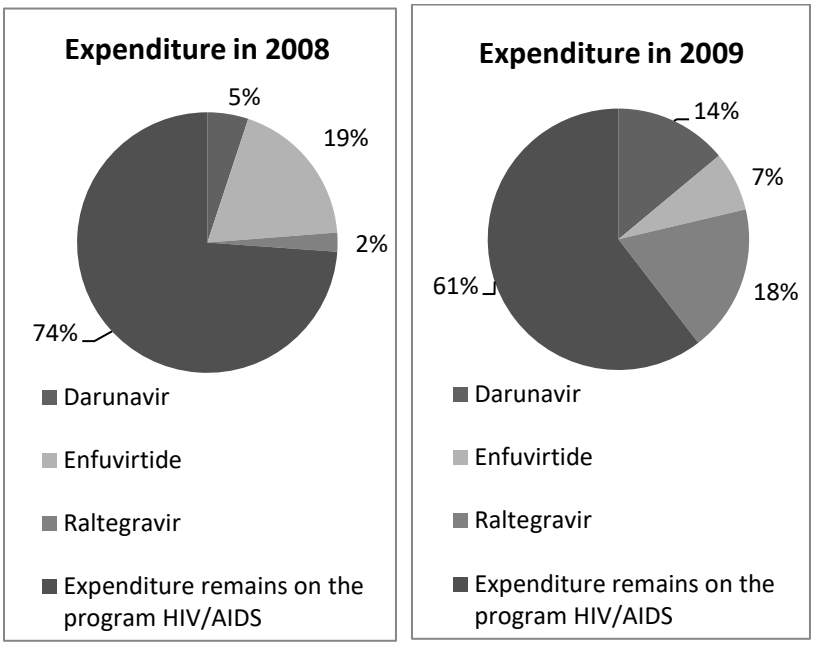
Table 1 – Informations for third-line ARV at Brazil

	Total Cost (dollar)	Average Annual Price	Daily Dose Price	Quantity Purchased
Darunavir 300mg tablet				
2007	$ 11 357 243,05	$ 4,95	$ 19,81	2 293 200
2008	$ 16 768 434,62	$ 4,98	$ 19,92	3 366 480
2009	$ 51 648 122,75	$ 3,98	$ 15,94	12 961 000
Enfuvirtide 108mg vial				
2007	$ 24 836 274,11	$ 25,87	$ 51,74	960 000
2008	$ 61 612 677,02	$ 24,65	$ 49,31	2 499 000
2009	$ 27 234 536,44	$ 20,87	$ 41,74	1 305 000
Raltegravir 400mg tablet				
2008	$ 7 771 986,41	$ 10,65	$ 21,30	729 600
2009	$ 67 394 879,46	$ 9,29	$ 18,58	7 254 160

Source: data from BPS (2011)

In 2008, only three third-line ARVs (darunavir, raltegravir and enfuvirtide) consumed together approximately 26% of the total budget for the acquisition and distribution of National HIV/AIDS Program (see graphic 1 below). In 2009, the situation becomes even more significant: almost 40% of the total budget for the acquisition and distribution of National HIV/AIDS Program were spent with these three ARVs (see graphic 2).

Graphic 1 and 2: Total budget of acquisition and distribution of the National HIV / AIDS Program (ARVs and other drugs).



Source: data from Brasil (2011b) and BPS (2011)

Discussion and Conclusion: Brazil is considered a middle-income country and therefore cannot be benefited with the low prices offered to low-income countries. However, as ARVs purchases are performed centrally, we expected a greater bargaining power by the Ministry of Health. In practice there are price reductions when increasing quantity purchases, but this does not seem sufficient to ensure financial sustainability of the rising third-line ARV Program. Today, third-line ARVs are distributed to 10,000 patients (from the universe of 190,000 patients that are currently receiving antiretroviral therapy) and consume 40% of the total ARV procurement. This scenario seems daunting given the strategies of ARV treatment, which already consumes 2% of the total ministerial budget. In fact, it is essential to continue negotiations with the pharmaceutical industry, furthermore we must not forget the investment in infrastructure and human resources for national production. In the future, Brazil can be benefited by voluntary licenses granted by the patent-pool strategies, but it is necessary to be able to absorb the new technologies involved in the production of third-line drugs.