

Technical Report: Assessment of the Availability of Antimalarial Medicines in the Public and Private Markets in Countries of the Amazon Basin

April 2010



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This report is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Acknowledgments

Adrian Barojas, a consultant with the United States Pharmacopeia, worked on the literature review and the first version of the protocol for this study. Information was gathered in the five AMI countries and analyzed by MSH/SPS consultants Henry Espinoza, Yenifer Hinestroza, Magdalena Jiménez, Andy Marsden, and Angélica Pérez. Edgar Barillas, MSH/SPS associate consultant, compiled the regional data and prepared this report.

Recommended Citation

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Management Sciences for Health/Strengthening Pharmaceutical Systems. 2010. *Technical Report: Assessment of the Availability of Antimalarial Medicines in the Public and Private Markets in Countries of the Amazon Basin*. Presented to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

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ACRONYMS AND ABBREVIATIONS

AMI	Amazon Malaria Initiative
FPP	finished pharmaceutical product
MoH	Ministry of Health
MSH	Management Sciences for Health
NMCP	National Malaria Control Program
PAHO	Pan American Health Organization
SF	Strategic Fund
SPS	Strengthening Pharmaceutical Systems
USAID	U.S. Agency for International Development

INTRODUCTION

In the countries sharing the Amazon basin, the various Ministries of Health (MoHs), through their respective National Malaria Control Programs (NMCPs), guarantee the availability of antimalarial medicines, free of charge, for all patients diagnosed with malaria at public institutions. Although the sale of antimalarials in private pharmacies is not explicitly prohibited by regulations currently in force in these countries, the free availability of such medicines in the public sector is expected to act as a disincentive to their sale in the private sector.

Nevertheless, scattered information provides evidence of the availability and unrestricted sale of antimalarial medicines to the general public in countries sharing the Amazon basin. One study conducted in Bolivia in 2005 revealed the unrestricted sale of antimalarial medicines in 61 percent of all pharmacies visited.¹ A second study carried out in Colombia in the same year provided evidence of the unrestricted prescription of antimalarial medicines by private pharmacies in Córdoba and Nariño.² A recent study conducted by the Management Sciences for Health Strengthening Pharmaceutical Systems (MSH/SPS) Program in Colombia³ also suggests that the private market for antimalarials may be significant, despite the presence of almost universal free medicine coverage for the entire population. The importance of this private sector market in the region, in terms of patients treated and pharmaceuticals sold, is unknown.

The private sale of antimalarial medicines creates a risk of treatment without appropriate diagnosis, a risk of incomplete or inadequate treatment, and the risk of the use of monotherapies (particularly artemisinin derivatives) that may generate resistance. Accordingly, the Amazon Malaria Initiative (AMI), with funding provided by the U.S. Agency for International Development (USAID), is seeking to determine the magnitude of this market in countries of the Amazon basin.

Study Objectives

To identify the antimalarial medicines registered in each country, those that are procured by public health institutions and those that are marketed in the private sector.

¹ Añez, Arleta, et al. 2005. *Disponibilidad y uso de medicamentos antimaláricos en Bolivia* [Availability and use of antimalarial medicines in Bolivia]. Study conducted for AMI/RAVREDA.

² Chaparro, Pablo, et al. 2005. *Estudio piloto de la disponibilidad y uso de los medicamentos antimaláricos para el tratamiento de la malaria no complicada en tres departamentos de alto riesgo en Colombia* [Pilot study of the availability and use of antimalarial medicines for treating uncomplicated malaria in three high-risk departments of Colombia]. Study conducted for AMI/RAVREDA.

³ MSH/COHAN. 2008. *Evaluación de las prácticas de prescripción, dispensación y adherencia a tratamiento antimalárico en Pizarro (Chocó) y Tumaco (Nariño) – Colombia* [Evaluation of prescribing and dispensing practices and adherence to antimalarial treatment in Pizarro (Chocó) and Tumaco (Nariño) – Colombia].

Methodology

Between January and March 2010, MSH/SPS consultants in AMI member countries visited medicine registration and control offices, NMCPs, and pharmaceutical-producing laboratories and private distributors in five countries: Bolivia, Colombia, Ecuador, Guyana, and Peru.

In medicine registration offices, consultants identified antimalarial finished pharmaceutical products (FPPs)⁴ for which medicine registration was current as of 2009. Excluded were numerous dosage forms of clindamycin and doxycycline, which are not used exclusively for treatment of malaria. FPPs procured by public institutions (MoH or Social Security) during the same period (2009) by means of a variety of mechanisms—donations, direct purchase through international agencies, and public tender—were recorded in a database. The consultants also identified and recorded those FPPs that were procured despite their lack of proof of up-to-date medicine registration. For each FPP, both purchase price and number of units procured were recorded. Using information obtained from health registries, consultants identified pharmaceutical-producing laboratories or distribution firms, and visits subsequently were made to each to gather information on volume of sales (units sold to both the public and private sectors) and distributor prices for 2009. Of the five countries studied, information on the private market was available for only Bolivia, Guyana, and Peru. In Peru, information was available from the Directorate General of Pharmaceuticals, Supplies and Medicines.

⁴ Active pharmaceutical ingredients (one or more), in all dosage forms, produced by the various pharmaceutical laboratories included in the study.

RESULTS

In Colombia, 13 antimalarial medicines were identified⁵ in 50 FPPs; for 48 of these FPPs, a currently valid health registration certificate had been issued. Only 4 were procured by the MoH in 2009 through local providers, and all 4 had proof of up-to-date medicine registration with the health registry.

In Ecuador, 11 antimalarial medicines were identified in 15 FPPs; 12 of these FPPs held a current medicine registration certificate. Three FPPs were procured by the MoH in 2009, 2 by direct purchase through the Pan American Health Organization's Strategic Fund (PAHO/SF) and 1 in the form of a donation from a subregional project of the Global Fund to Fight AIDS, Tuberculosis and Malaria. None of these FPPs held a currently valid medicine registration certificate.

In Colombia and Ecuador, information could not be obtained on volumes of antimalarials marketed in the private sector. No evidence is available on availability of antimalarial medicines in private facilities in Ecuador. In Colombia, in contrast, a study carried out by MSH/SPS in 2008⁶ revealed a shortage of medicines for treating *P. vivax* in some public facilities. Accordingly, patients were given a prescription to purchase antimalarials in private pharmacies, where these medicines were indeed available.

In both Colombia and Ecuador a significant number of FPPs identified as being registered with health authorities had not been procured by the public sector. However, no inferences should be made regarding private sector sales of antimalarial medicines based on medicine registration with pharmaceutical authorities. Registration of medicines despite a lack of intent to immediately market them in the private sector is a common business practice.

In Peru, 20 antimalarial medicines were identified in 64 FPPs; 62 of these FPPs showed evidence of active registration with health authorities as of February 2010. All medicines marketed in the public sector were in possession of a valid medicine registration certificate with the exception of 2 received as donations.⁷ The request for donated medicines is explained by the fact that Peru experienced problems in its efforts to procure medicines because of a lack of bidders participating in its public tenders. In 2009, only 5 medicines were procured from local providers.

In Guyana, 18 antimalarial medicines were identified in 21 FPPs. Only 6 medicines held an active medicine registration certificate at the time the study was conducted. The MoH procured 12 medicines in 2009: 11 through local producers or distributors and 1 (Coartem) as a direct purchase through PAHO/SF. Neither of these medicines had been registered with health registry

⁵ In this document, the term *medicine* is used to refer to active pharmaceutical ingredients in a variety of dosage forms (regardless of the laboratory producing that medicine).

⁶ MSH/COHAN. 2008. *Evaluación de las prácticas de prescripción, dispensación y adherencia a tratamiento antimalárico en Pizarro (Chocó) y Tumaco (Nariño) – Colombia.*

⁷ A donation of 58,960 tablets of primaquine 15 mg to Ecuador and a donation of 301,000 tablets of primaquine 15 mg and 200,000 tablets of chloroquine 250 mg to Colombia.

authorities. Registration with the health registry is required for all pharmaceutical products used in Guyana.⁸

In Bolivia, 7 antimalarial medicines were identified in 11 FPPs; only 2 had a currently active medicine registration certificate. The MoH procured 8 FPPs in 2009, 3 as donations and 5 by direct purchases made through the PAHO/SF. None of the medicines procured by the MoH held a current medicine registration certificate. In Bolivia, medicines used by the public sector do not require registration.

All products procured by the public sector in these countries were included in the therapeutic guidelines in place in their respective NMCPs.

Table 1. Selected Indicators of Procurement and Marketing of Antimalarials in the Public and Private Sectors of Amazon Basin Countries, 2009

Indicator	Peru	Guyana	Bolivia	Ecuador	Colombia
No. of antimalarial FPPs with and without a valid medicine registration certificate	64	21	11	15	50
No. of FPPs with a valid medicine registration certificate	62	6	2	12	48
No. of antimalarial medicines with and without a valid medicine registration certificate	20	18	7	11	13
No. of medicines included in the national medicine list	9	11	6	—	11
No. of medicines included in NMCP therapeutic guidelines	8	12	7	7	3
No. of medicines procured through donations	2	0	3	1	0
No. of medicines procured by means of direct purchases made through international agencies	0	1	5	2	0
No. of medicines procured from local producers/distributors	5	11	0	0	4
No. of medicines distributed in the private sector	3	6	2	—	—
Percentage of dosage forms procured by the public sector (by various means) that did not have a current medicine registration certificate	100	0	0	0	100

— = not available.

In 2009, three antimalarials were sold in private pharmacies in Peru (hydroxychloroquine sulfate, chloroquine, and mefloquine), one in private pharmacies in Bolivia (chloroquine), and six in private pharmacies in Guyana (four fixed-dose combinations of artemisinin, mefloquine, and proguanil). In Bolivia, almost 300,000 units of chloroquine 150 mg were introduced into the market. In Peru, 137,400 units of chloroquine 150 mg, 588,000 units of hydroxychloroquine 200 mg, and 100,200 units of mefloquine 250 mg were distributed. Because it is not possible in this study to determine whether chloroquine and hydroxychloroquine were used for autoimmune

⁸ Immediately after the results of this study were made known, the process of registering drugs used in the public sector was begun.

conditions, it can be established definitively only that the mefloquine distributed in Peru—in extremely small quantities—was the only antimalarial (used exclusively for that purpose) available in the private sector.

In Guyana, in contrast, the market for medicines used exclusively for treating malaria is more substantial. In 2009, 40,000 units of the combination artesunate sulfamethoxyprazine + pyrimethamine and 50,000 tablets of the combination dihydroartemisinin + piperazine + trimethoprim (figure 1) were distributed to private pharmacies. During the same period, the public sector procured only 20,000 units of artemisinin-based combination therapies (Coartem in a variety of dosage forms).

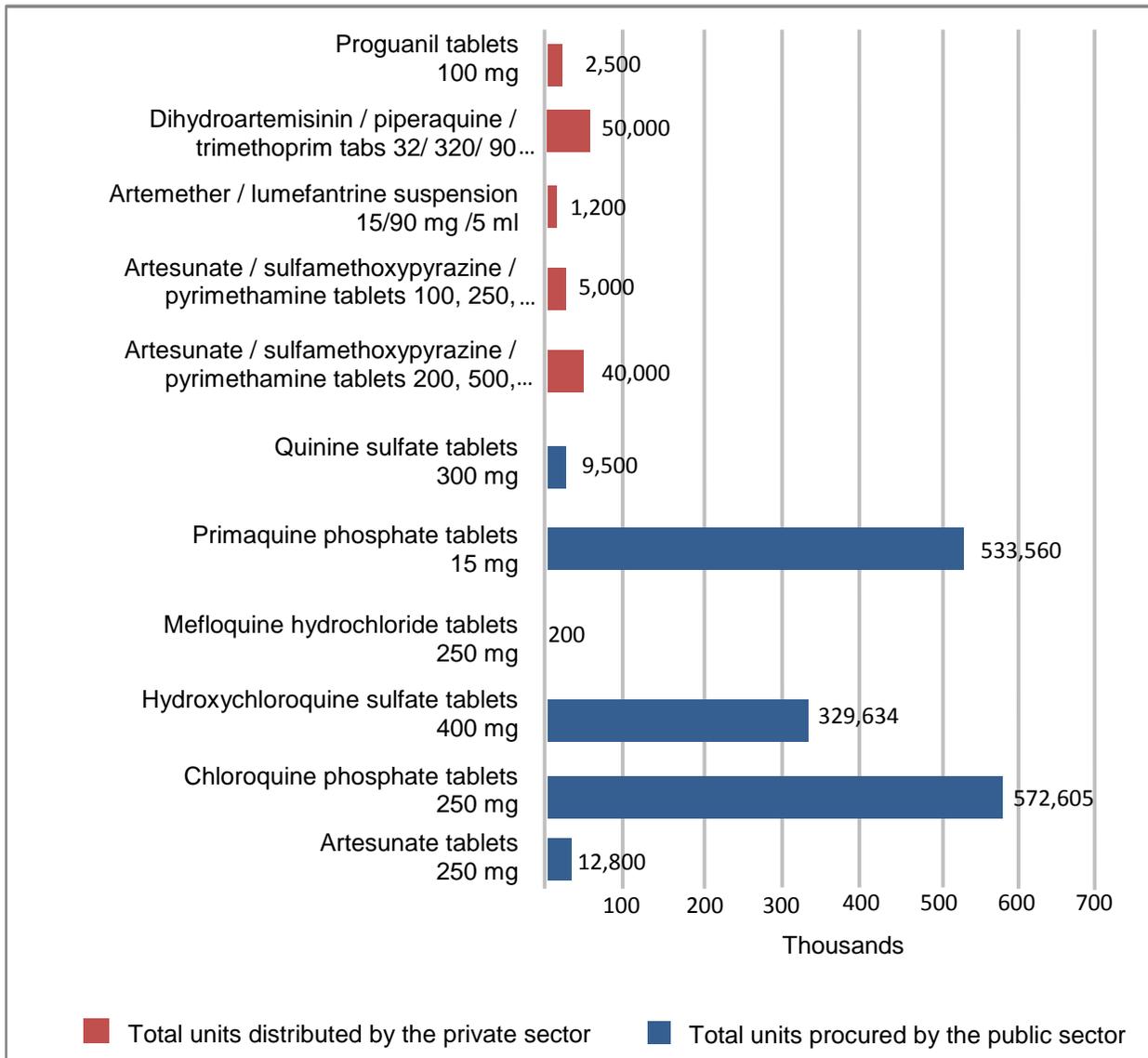


Figure 1. Units of antimalarials procured by the public sector and distributed in the private sector of Guyana, 2009

ANALYSIS AND DISCUSSION OF RESULTS

Procurements of antimalarial medicines in the public sector in 2009 do not accurately reflect consumption because some countries either had on hand significant amounts of stock from prior years or had experienced problems with national tender initiatives. Nevertheless, data on public sector consumption can be obtained from medicine distribution records and reports of cases treated.

The most significant information that this study sought to provide involved the availability of antimalarial medicines in the private sector. Because surveys of a representative sample of private pharmacies using techniques such as the “simulated patient” are lengthy, costly, and provide no information on total sales volume, a decision was made to gather data from government medicine registration offices and from individual pharmaceutical production laboratories or marketing outlets. The obvious difficulty with this methodology is the zeal with which private firms safeguard this type of information, which they consider to be not only strategic in nature but also politically sensitive. Even given these difficulties, however, information was obtained from the private sectors of Bolivia, Guyana, and Peru.

The information gathered provides evidence of the private sale of antimalarials in all three countries. In Bolivia and Peru, sales account for relatively substantial volumes but include medicines that are possibly being used for the treatment of autoimmune conditions and insignificant volumes in the case of medicines used exclusively to treat malaria. Because no restrictions prohibit the sale of such products, the data suggest that the availability in the public sector of diagnosis and treatment without charge acts as a disincentive to private market sales of these medicines.

In Guyana, in contrast, volumes of private sales are significant. In the case of artemisinin-based combination therapies, the volume of units sold suggests that the number of patients to whom medicines are dispensed in the private sector may be greater than those receiving these medicines in the public sector. Although this study did not focus on the causes of these findings, the well-known lack of public health services—particularly in the mining areas bordering Brazil—may explain the substantial private marketing of antimalarials (some of which are not recommended by the World Health Organization) in Guyana.

Although it was not a central objective of this study, the data gathered documented the failure to secure proper registration with health authorities of a number of medicines procured by NMCPs. Pharmaceutical registration is an important tool for certifying medicine quality, and it is therefore essential that the necessary steps be taken to correct this problem.

